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Filed pursuant to Rule 424(b)(4)
Registration No. 333-257505

Prospectus

14,000,000 shares

cerevel

Common stock

We are offering 14,000,000 shares of our common stock.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CERE." The last reported sale price of our common stock on the Nasdaq Capital Market on July 1, 2021 was $26.85.

We are an "emerging growth company" and a "smaller reporting company" under the federal securities laws and are subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

	Per share	Total
Public offering price	$ 25.00	$350,000,000
Underwriting discounts(1)	$ 1.50	$ 21,000,000
Proceeds to Cerevel Therapeutics Holdings, Inc. before expenses	$ 23.50	$329,000,000

(1) See "Underwriting" for additional disclosure regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 2,100,000 shares of common stock from us at the public offering price, less underwriting discounts and commissions.

Investing in our securities involves a high degree of risk. See the "Risk Factors" section beginning on page 16 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities to be issued under this prospectus or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares against payment on or about July 7, 2021.

J.P. Morgan **Goldman Sachs & Co. LLC** **Jefferies** **Stifel**

Co-Managers

Loop Capital Markets **Siebert Williams Shank**

July 1, 2021.

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You should rely only on the information contained in this prospectus, any amendment or supplement to this prospectus, and any related free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor any of the underwriters have authorized anyone to provide you with information that is different from, or in addition to, that contained in this prospectus, any amendment or supplement to this prospectus and any related free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United

States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus applicable to that jurisdiction.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under "*Where You Can Find More Information*."

This prospectus contains references to trademarks, trade names and service marks belonging to other entities. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Prospectus summary

This summary highlights selected information from this prospectus and does not contain all of the information that is important to you in making an investment decision. This summary is qualified in its entirety by the more detailed information included elsewhere in this prospectus. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus, including the information set forth under the sections titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus, as well as the consolidated financial statements and related notes included elsewhere in this prospectus.

Overview

We are a clinical-stage biopharmaceutical company pursuing a targeted approach to neuroscience that combines a deep understanding of disease-related biology and neurocircuitry of the brain with advanced chemistry and central nervous system, or CNS, target receptor selective pharmacology to discover and design new therapies. We seek to transform the lives of patients through the development of new therapies for neuroscience diseases, including schizophrenia, epilepsy and Parkinson's disease. Our "ready-made" pipeline of 11 small molecule programs, which includes five clinical-stage product candidates, was developed through over a decade of research and investment by Pfizer Inc., or Pfizer, and was supported by an initial capital commitment from an affiliate of Bain Capital and a keystone equity position from Pfizer. We are advancing our broad and diverse pipeline with six clinical trials underway or expected to start by the end of 2021 and up to seven clinical data readouts expected by the end of 2023. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with the proven expertise of large pharmaceutical company experience and capabilities in drug discovery and development.

Our portfolio of product candidates is based on a differentiated understanding of the neurocircuitry of CNS diseases, as well as the key pillars of our targeted approach to neuroscience: (i) receptor-drug interactions at the atomic level to achieve targeted receptor subtype selectivity, (ii) orthosteric and allosteric chemistry to achieve ideal receptor pharmacology and (iii) robust packages of preclinical and clinical data that elucidate the key points of differentiation for our compounds. Our rational design approach uses measured and calculated structural and surface charge information from the target protein combined with high-resolution crystallography data, computational homology models, screening of single-residue mutant proteins, indirect solution-phase imaging techniques and other biophysical measurements to glean key molecular-level information about the interaction between a target protein and our product candidates. These insights then drive structure-informed design of subsequent molecules. Due to our understanding of the specificity and dynamic range of neural networks and how to modulate them, we believe that our product candidates have the potential to achieve optimal therapeutic activity while minimizing unintended side effects of currently available therapies. Below are our five clinical-stage product candidates:

1. CVL-231 is a positive allosteric modulator, or PAM, that selectively targets the muscarinic acetylcholine 4 receptor subtype, or M4. We conducted a Phase 1b trial of CVL-231 in patients with schizophrenia, consisting of Part A, a multiple ascending dose, or MAD, study and Part B, a pharmacodynamic, or PD, assessment. In June 2021, we announced topline results for the Phase 1b trial. Both doses of CVL-231 demonstrated a clinically meaningful and statistically significant improvement in Positive and Negative Syndrome Scale, or PANSS, total score at 6 weeks

and were overall well-tolerated compared with placebo. See "—Recent Developments" for more information. The results of this trial and emerging data from two position emission tomography, or PET, receptor occupancy trials will inform dose selection and design for a Phase 2 program in schizophrenia.

2. Darigabat (formerly known as CVL-865) is a PAM that selectively targets the alpha-2/3/5 subunits of the $GABA_A$ receptor. In the second half of 2020, we initiated a Phase 2 proof-of-concept trial, known as REALIZE, in patients with drug-resistant focal onset seizures in epilepsy, or focal epilepsy, and a Phase 1 proof-of-principle trial in acute anxiety. Data is expected in the fourth quarter of 2021 for the Phase 1 anxiety trial and in the second half of 2022 for the Phase 2 focal epilepsy trial.

3. Tavapadon is a selective dopamine D1/D5 partial agonist that we are developing for the treatment of early- and late-stage Parkinson's disease. We initiated a registration-directed Phase 3 program for tavapadon beginning in January 2020, which includes two trials in early-stage Parkinson's, known as TEMPO-1 and TEMPO-2, one trial in late-stage Parkinson's, known as TEMPO-3, and an open-label safety extension trial, known as TEMPO-4. We expect initial data from our Phase 3 program to be available beginning in the first half of 2023.

4. CVL-871 is a selective dopamine D1/D5 partial agonist specifically designed to achieve a modest level of partial agonism, which we believe may be useful in modulating the complex neural networks that govern cognition, motivation and apathy behaviors in neurodegenerative diseases. In June 2021, the U.S. Food and Drug Administration, or FDA, granted Fast Track Designation for CVL-871 for the treatment of dementia-related apathy. We began screening patients in an exploratory Phase 2a trial for dementia-related apathy in the second quarter of 2021 with data expected in the second half of 2022.

5. CVL-936 is a selective dopamine D3-preferring antagonist that we are developing for the treatment of substance use disorder, or SUD. We have received a notice of award for cooperative grant funding from the National Institute on Drug Abuse, or NIDA, to support the development of this compound in opioid use disorder, or OUD. We initiated a Phase 1 single ascending dose, or SAD, trial in January 2020. We concluded dosing of Cohort 1 of the Phase 1 SAD trial after receiving sufficient clinical data for the intended purposes for this trial. We intend to conduct a multiple dose canine electroencephalogram, or EEG, study prior to additional Phase 1 SAD and MAD evaluations.

We believe that all five of our clinical-stage product candidates have target product profiles that may enable them to become backbone therapies in their respective lead indications, either replacing standards of care as monotherapies or enhancing treatment regimens as adjunct to existing therapies. Results from the clinical trials mentioned above will guide the potential development of our product candidates in additional indications with similar neurocircuitry deficits.

In addition to our clinical-stage pipeline, we plan to advance the development of our preclinical portfolio across multiple neuroscience indications. This preclinical portfolio includes CVL-354, our selective kappa opioid receptor antagonist, which we refer to as KORA, which we are developing in major depressive disorder, or MDD, and SUD, and for which we submitted an Investigational New Drug, or IND, in the second quarter of 2021. In addition, we are developing CVL-047, our selective PDE4 inhibitor (PDE4D-sparing), for the treatment of MDD and schizophrenia, and we plan to submit an IND in the fourth quarter of 2021. We are deploying the latest technologies, such as artificial intelligence and DNA-encoded chemical libraries, to efficiently identify new therapeutic molecules, including those with disease-modifying potential. We believe that our targeted approach to neuroscience will enable us to create a leading drug discovery and development platform to transform the lives of patients living with neuroscience diseases.

Behind our portfolio stands a team with a multi-decade track record of drug approvals and commercial success. This track record has been driven by their extensive experience with empirically-driven clinical trial design and implementation, a history of successful interactions with regulatory agencies and relationships with global key opinion leaders. We believe that the distinctive combination of our management team and our existing pipeline has the potential to bring to patients the next generation of transformative neuroscience therapies.

Our pipeline

The following table summarizes our current portfolio of product candidates. This table does not include two additional preclinical programs with disease-modifying potential that have not yet been disclosed.

Recent developments

Phase 1b Multiple Ascending Dose Trial

In June 2021, we completed a two-part, Phase 1b MAD trial to evaluate the safety, tolerability, pharmacokinetic, or PK, and preliminary PD of repeated daily doses of CVL-231 in patients with a primary diagnosis of schizophrenia per the Diagnostic and Statistical Manual of Mental Disorders, or DSM-V.

The objectives of Part A of the trial were to characterize physiological effects, identify any dose-limiting tolerability effects, and identify the maximum tolerated dose of CVL-231 in patients with schizophrenia.

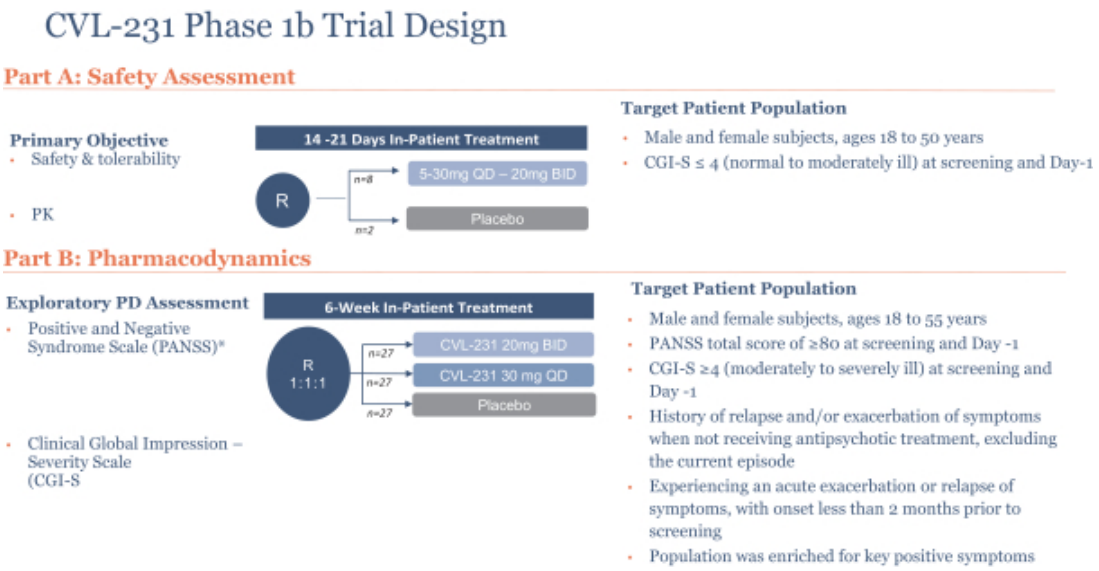
The measures used for this evaluation included treatment-emergent adverse events, or AEs, electrocardiogram, or ECG, results, vital signs measurement, clinical laboratory tests, physical and neurologic exams, suicidality as assessed by the Columbia-Suicide Severity Rating Scale, or C-SSRS, and extrapyramidal symptoms based on the Simpson-Angus Scale, or the SAS, the Abnormal Involuntary Movement Scale, or the AIMS, and the Barnes Akathisia Rating Scale, or the BARS, assessments.

Once a dosing regimen was identified in Part A of the trial, further safety, PK and preliminary PD were examined in Part B. The measures used for this evaluation included change from baseline in PANSS total score and subscales (negative, positive and general psychopathology), the Clinical Global Impression of Severity, or CGI-S, and the Brief Assessment of Cognition in Schizophrenia, or BACS, symbol coding test. PANSS is a widely used and validated measure of the severity of the core positive and negative symptoms associated with schizophrenia, as defined by the DSM-V. CGI-S is included as a supplementary scale to provide a global assessment of clinical status. The symbol coding test of the BACS is a highly sensitive measure of cognitive defects in patients with schizophrenia and is included as an exploratory measure to evaluate cognition.

In Part A, the key inclusion criteria included men and women 18 to 50 years of age with a CGI-S £ 4 at screening and at Day -1 and a PANSS total score £ 80 at the time of screening and at Day -1. Daily doses of 5 mg to 40 mg (administered as 20 mg twice daily, or BID) were explored with up to 21 days of administration at target dosage. The Part A MAD safety and tolerability data were supportive of proceeding to 6 weeks of dosing in the subsequent Part B portion of the trial.

In Part B, the key inclusion criteria included (i) men and women 18 to 55 years of age, (ii) a CGI-S ³ 4 at screening and at Day -1, (iii) a PANSS total score ³ 80 at the time of screening and at Day -1, (iv) a history of relapse and/or exacerbation of symptoms when not receiving treatment, excluding the current episode, and (v) experiencing an acute exacerbation or relapse of symptoms, with onset less than two months prior to screening.

The diagram below summarizes the design of the trial:



* Trial not designed to demonstrate statistical significance

In Part B, 81 patients having the following demographics and baseline characteristics were randomized into one of two doses of CVL-231 or placebo.

Phase 1b Part B: Demographics & Baseline Characteristics

	PBO N= 27	CVL-231 30 mg QD N= 27	CVL-231 20 mg BID N= 27	All CVL-231 N= 54	Total N= 81
Demographics					
Age (years) at Screening: Mean (SD)	41 (9.7)	41(8.1)	38 (9.8)	40 (9.0)	40 (9.2)
% Male: N (%)	19 (70%)	23(85%)	21 (78%)	44 (81%)	63 (78%)
Race: N (%)					
Black or African American	17 (63%)	20 (74%)	19 (70%)	39 (72%)	56 (69%)
White	9 (33%)	7 (26%)	7 (26%)	14 (26%)	23 (28%)
Other	1 (4%)	0	1 (4%)	1 (2%)	2 (2%)
Weight (kg) Prior to Dosing: Mean (SD)	90.0 (16.0)	85.4 (13.3)	85.4 (15.4)	85.4 (14.3)	86.9 (14.9)
Disease Characteristics at Baseline: Mean (SD)					
PANSS Total Score	93 (8.8)	93 (7.3)	97 (7.9)	95 (7.7)	95 (8.1)
PANSS Positive Score	24 (2.7)	25 (3.0)	26 (2.6)	26 (2.8)	25 (2.8)
PANSS Negative Score	23 (3.3)	22 (3.7)	24 (3.8)	23 (3.8)	23 (3.6)
CGI-S Score	5 (0.6)	5 (0.5)	5 (0.7)	5 (0.6)	5 (0.6)

The endpoint used to measure the antipsychotic effect was the PANSS total score. The trial was 59% powered to detect a 7 point difference from placebo on the PANSS total score. Additional endpoints that we evaluated included the PANSS positive and PANSS negative subscales as well as the CGI-S. The primary pharmacodynamic results from the trial are as follows:

Pharmacodynamic Results Summary*

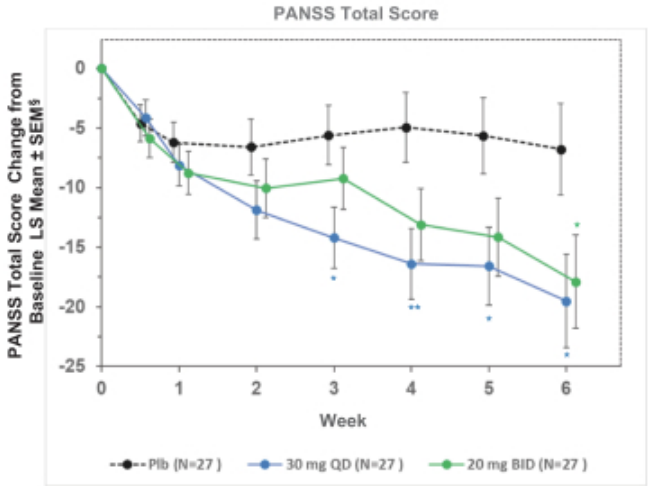
Week 6 (Day 42)	Placebo N=27	CVL-231 30 mg QD N= 27	CVL-231 20 mg BID N= 27	Combined CVL-231 N=54
PANSS Total Score				
LS Mean Change from Baseline	-6.8	-19.5	-17.9	-18.7
Difference vs Placebo (p-value)†		-12.7†	-11.1†	-11.9†
		p = 0.023	p = 0.047	p = 0.014
PANSS Positive Score				
LS Mean Change from Baseline	-2.5	-6.8	-4.9	-5.8
Difference vs Placebo (p-value)		-4.3	-2.4	-3.3
		p = 0.016	p = 0.166	p = 0.028
PANSS Negative Score at Baseline				
LS Mean Change from Baseline	0.1	-3.0	-3.6	-3.3
Difference vs Placebo (p-value)		-3.1	-3.7	-3.4
		p = 0.009	p = 0.002	p = 0.001

* Trial originally designed to be 59% powered to detect 7 point difference in PANSS total score vs. placebo

† Corresponds to Cohen's D effect sizes at Week 6 of -0.68 for CVL-231 30 mg QD, -0.59 for CVL-231 20 mg BID, and -0.64 for the two doses combined

Both doses of CVL-231 demonstrated clinically meaningful and statistically significant antipsychotic effects, with no meaningful differences in gastrointestinal side effects, extrapyramidal symptoms or weight gain compared with placebo. The 30 mg once-daily group demonstrated an improvement of 19.5 while the 20 mg twice daily cohort showed an improvement of 17.9 from baseline on the PANSS Total score after six weeks of treatment. Both treatment groups had statistically significant reductions relative to placebo of 12.7 and 11.1 respectively, with p-values less than 0.05. These results were further supported by statistically significant and clinically meaningful improvements in the PANSS-negative subscale for both doses – the 30 mg once daily group resulted in a point improvement of 3.1 over placebo with a p-value of 0.009 and the 20 mg twice daily group showed a 3.7 improvement over placebo with a p-value of 0.002. We also observed clinically meaningful improvements on the PANSS positive subscale for both doses, with the 30 mg once-daily group demonstrating a statistically significant reduction of 4.3 points versus placebo.

Key Pharmacodynamic Endpoint – PANSS Total Score



- 30 mg QD: 12.7 Point improvement versus placebo at Week 6 (19.5 of 30 mg QD vs 6.8 placebo) with P=0.023
- 20 mg BID: 11.1 Point improvement versus placebo at Week 6 (17.9 of 20 mg BID vs 6.8 placebo) with P=0.047
- Combined CVL 231: 11.9 Point improvement versus placebo at Week 6 (18.7 of CVL231 vs 6.8 placebo) with P=0.014

* P<0.05 vs Placebo ** P<0.01 vs Placebo

§ Derived from a mixed model for repeated measures (MMRM) with treatment group, visit, treatment group-by-visit interaction as fixed effect, baseline value as a covariate and the measurements within subject as repeated measures. An unstructured covariance matrix was used.

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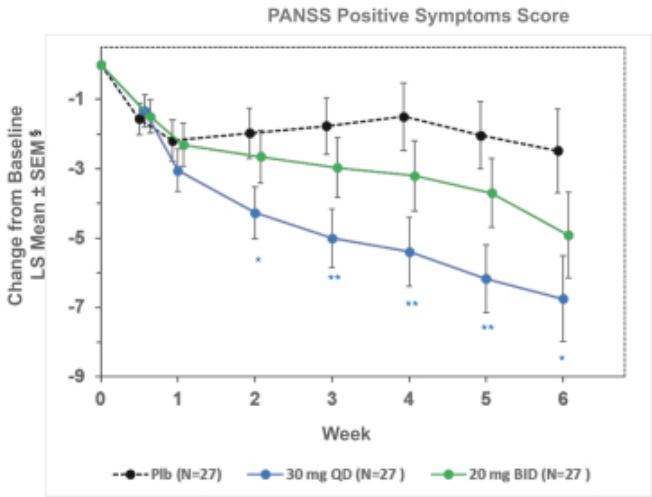
Statistical separation from placebo was achieved in the 30 mg once-daily group beginning at week 3 of the trial. These robust results were also observed when we evaluated the PANSS positive and PANSS negative subscales:

PANSS Positive Symptoms Score

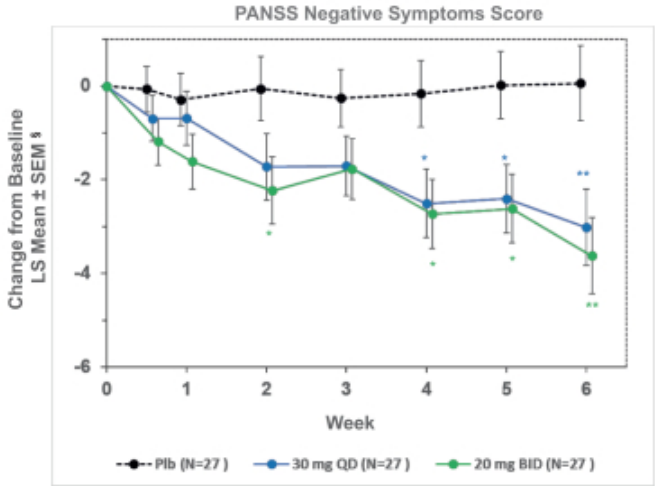


- 30 mg QD: 4.3 Point improvement versus placebo at Week 6 (6.8 of 30 mg QD vs 2.5 placebo) with P=0.016
- 20 mg BID: 2.4 Point improvement versus placebo at Week 6 (4.9 of 20 mg BID vs 2.5 placebo) with P=0.166
- Combined CVL 231: 3.3 Point improvement versus placebo at Week 6 (5.8 of CVL231 vs 2.5 placebo) with P=0.028

* P<0.05 vs Placebo ** P<0.01 vs Placebo

§ Derived from a mixed model for repeated measures (MMRM) with treatment group, visit, treatment group-by-visit interaction as fixed effect, baseline value as a covariate and the measurements within subject as repeated measures. An unstructured covariance matrix was used.

PANSS Negative Symptoms Score



- 30 mg QD: 3.1 Point improvement versus placebo at Week 6 (3.0 of 30 mg QD vs -0.1 placebo) with P=0.009
- 20 mg BID: 3.7 Point improvement versus placebo at Week 6 (3.6 of 20 mg BID vs -0.1 placebo) with P=0.002
- Combined CVL 231: 3.4 Point improvement versus placebo at Week 6 (3.3 of CVL231 vs -0.1 placebo) with P=0.001

* P<0.05 vs Placebo ** P<0.01 vs Placebo

§ Derived from a mixed model for repeated measures (MMRM) with treatment group, visit, treatment group-by-visit interaction as fixed effect, baseline value as a covariate and the measurements within subject as repeated measures. An unstructured covariance matrix was used.

CVL-231 was generally well-tolerated in the clinical trial. The incidence of treatment emergent adverse events for both dose cohorts were similar to placebo, including heart rate and blood pressure increases. The AE of headache had the highest incidence of reporting across all treatment groups, with placebo at 26%, 30 mg once-daily at 30%, and 26% for the 20 mg twice-daily cohort. Additionally, the rate of nausea was similar between CVL-231 and placebo (4% for placebo and 7% for both 30 mg once-daily and 20 mg twice-daily groups) and rates of other gastrointestinal AEs were very low and similar to placebo. CVL-231 was not associated with a greater incidence of weight gain than placebo and no adverse events related to extrapyramidal symptoms were reported. Serious adverse events reported in the study included COVID-19, accidental overdose, and exacerbation of schizophrenia (one instance of each).

Safety & Tolerability – Adverse Events

	PBO N= 27	CVL-231 30 mg QD N= 27	CVL-231 20 mg BID N= 27	All CVL-231 N= 54
Days on IMP				
Mean (SD)	37 (9.6)	36 (12.8)	35 (13.6)	36 (13.1)
Range	8, 42	4, 42	2, 42	2, 42
Number (%) Subjects with TEAE	14 (52%)	14 (52%)	15 (56%)	29 (54%)
Number (%) Subjects with TEAE Related to IMP	10 (37%)	7 (26%)	12 (44%)	19 (35%)
Number (%) Subjects with Serious TEAE	0	2 (7%)	1 (4%)	3 (6%)
Number (%) Subjects with AE of Special Interest (AESI)	3 (11%)	2 (7%)	4 (15%)	6 (11%)
Number (%) Subjects with TEAE Leading to Discontinuation of IMP	0	2 (7%)	1 (4%)	3 (6%)

The results of this trial support the advancement of CVL-231 to Phase 2 in schizophrenia.

Tavapadon financing

On April 12, 2021, or the Effective Date, Cerevel Therapeutics, Inc., or Cerevel Inc., our wholly-owned subsidiary, entered into a funding agreement, or the NovaQuest Funding Agreement, with NovaQuest Co-Investment Fund XVI, L.P., or NovaQuest, and a funding agreement, or the Bain Funding Agreement, with BC Pinnacle Holdings, LP, or Bain, pursuant to which NovaQuest and Bain will provide funding to Cerevel Inc. to support its development of tavapadon for the treatment of Parkinson's disease.

Pursuant to the NovaQuest Funding Agreement and the Bain Funding Agreement, or collectively, the Funding Agreements, Cerevel Inc. will receive up to $62.5 million in funding from each of NovaQuest and Bain, for a combined total of up to $125 million in funding, or the Total Funding Commitment, of which approximately $31.3 million (25% of the Total Funding Commitment) was received within 10 business days of the Effective Date, and $37.5 million (30% of the Total Funding Commitment), approximately $31.3 million (25% of the Total Funding Commitment) and $25.0 million (20% of the Total Funding Commitment) will be received on the first, second and third anniversaries of the Effective Date, respectively, subject to certain customary funding conditions.

In return, Cerevel Inc. agreed to pay to NovaQuest and Bain (i) upon approval of tavapadon by the FDA, a combined $187.5 million (1.5x of the Total Funding Commitment), or the Approval Milestone Payment, with 50% of the Approval Milestone Payment due within 30 days of FDA approval and 12.5% of the Approval Milestone

Payment due on each of the first four anniversaries of FDA approval, (ii) upon first reaching certain cumulative U.S. net sales thresholds, certain sales milestone payments and (iii) combined tiered, mid-single digit to low-double digit royalties on annual net sales of tavapadon in the United States.

At the time that NovaQuest and Bain collectively receive an aggregate of approximately $531.3 million (4.25x of the Total Funding Commitment), Cerevel Inc.'s payment obligations under the Funding Agreements will be fully satisfied. Cerevel Inc. has the option to satisfy its payment obligations to NovaQuest and Bain upon the earlier of FDA approval or May 1, 2025 by paying an amount equal to the Total Funding Commitment multiplied by a certain factor (which will initially be 3.00x and will increase over time to a maximum of 4.25x), less amounts previously paid to NovaQuest and Bain.

During the term of the Funding Agreements, Cerevel Inc. will use commercially reasonable efforts to develop and commercialize tavapadon in the United States, except that, upon the occurrence of certain significant safety, efficacy and regulatory technical failures of the program, or each, a Technical Failure, Cerevel Inc. will have the right to terminate the development of tavapadon and, upon such termination, will not be obligated to make any payments to NovaQuest and Bain. If Cerevel Inc. suspends or terminates the development of tavapadon or fails to perform certain diligence obligations for any reason other than a Technical Failure, Cerevel Inc. will pay NovaQuest and Bain a combined amount equal to the total amount funded by NovaQuest and Bain up to the date of termination, plus 12% interest compounded annually.

Cerevel Inc. has granted NovaQuest and Bain a security interest in the assets material to the development and commercialization of tavapadon in the United States, provided that Cerevel Inc. will be permitted to incur certain indebtedness and NovaQuest and Bain will agree to customary subordination in connection therewith. The Funding Agreements also include customary representations and warranties and covenants.

Risks associated with our business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "*Risk Factors*" in this prospectus. These risks include, but are not limited to, the following:

- The successful development of pharmaceutical products is highly uncertain.
- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.
- Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.
- Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or

more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Business interruptions resulting from the COVID-19 outbreak or similar public health crises could cause a disruption of the development of our product candidates and adversely impact our business.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- We depend heavily on our executive officers, third-party consultants and others and our ability to compete in the biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of their services or our inability to hire and retain such personnel would materially harm our business.
- Bain Investor and Pfizer have significant influence over us.
- We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- We depend and expect in the future to continue to depend on in-licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose license rights, which would substantially harm our business.

The risks described above should be read together with the text of the full risk factors described in the section entitled "*Risk Factors*" and the other information set forth in this prospectus, including our consolidated financial statements and the related notes. The risks summarized above or described in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

Corporate information

The mailing address for our principal executive office is 222 Jacobs Street, Suite 200, Cambridge, MA 02141, and our telephone number is (844) 304-2048. Our website address is http://www.cerevel.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of being an emerging growth company and a smaller reporting company

We are an “emerging growth company” as defined in the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take, have taken, and intend to take, advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earliest of (i) December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter.

The offering

Shares of our common stock offered by us	14,000,000 shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 2,100,000 additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Shares of our common stock to be outstanding immediately after this offering	141,325,116 shares (or 143,425,116 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $328.3 million, or approximately $377.6 million if the underwriters exercise their option to purchase additional shares in full, based on the public offering price of $25.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, (i) to fund our clinical and preclinical research and development programs and (ii) for working capital and other general corporate purposes. See "*Use of Proceeds*."
The Nasdaq Capital Market symbol	"CERE"
Risk factors	An investment in our common stock involves a high degree of risk. You should read this prospectus carefully, including the section entitled "*Risk Factors*" and our consolidated financial statements and related notes appearing elsewhere in this prospectus, before investing in our common stock.

The number of shares of our common stock to be outstanding after this offering is based on 127,325,116 shares of our common stock outstanding as of March 31, 2021, and excludes:

- 5,149,647 shares of common stock issuable upon the exercise of warrants to purchase shares of common stock outstanding as of March 31, 2021, with an exercise price of $11.50 per share;
- 16,084,192 shares of common stock issuable upon exercise of options outstanding as of March 31, 2021, with a weighted-average exercise price of $8.14 per share;
- 57,080 shares of common stock issuable upon the vesting of restricted stock units outstanding as of March 31, 2021;
- 12,793,203 shares of common stock available for future issuance as of March 31, 2021 under the Cerevel Therapeutics Holdings, Inc. 2020 Equity Incentive Plan, or the 2020 Plan; and

- 2,927,163 shares of common stock available for future issuance as of March 31, 2021 under the Cerevel Therapeutics Holdings, Inc. Employee Stock Purchase Plan, or the ESPP.

Except as otherwise noted, all information in this prospectus assumes:

- no exercise of the underwriters' option to purchase up to 2,100,000 additional shares of common stock in this offering; and
- no exercise of the outstanding warrants and options or vesting of the outstanding restricted stock units described above, in each case, after March 31, 2021.

Summary financial data

The following tables summarize our financial and operating data for the periods indicated. Our historical results are not necessarily indicative of the results that may be expected in the future for a full year or any interim period. The summary financial information below should be read in conjunction with the information contained in "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," our consolidated financial statements and notes related thereto, and other financial information included elsewhere in this prospectus. The statement of operations data for the three months ended March 31, 2021 and 2020 and the balance sheet data as of March 31, 2021 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The statement of operations data for the years ended December 31, 2020 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited financial statements include all adjustments, consisting of only normal and recurring adjustments, necessary for a fair presentation of such financial data.

(in thousands, except share amounts and per share data)	Year ended December 31,		Three months ended March 31,	
	2020	2019	2021	2020
			(unaudited)	
Statements of Operations Data:				
Operating expenses				
Research and development	$ 103,303	$ 50,294	$ 36,561	$ 26,959
General and administrative	45,813	33,169	14,010	10,743
Total operating expenses	149,116	83,463	50,571	37,702
Loss from operations	(149,116)	(83,463)	(50,571)	(37,702)
Interest income, net	224	1,552	15	204
Other income (expense), net	(3,274)	(46,433)	(425)	(15,710)
Loss before income taxes	(152,166)	(128,344)	(50,981)	(53,208)
Income tax benefit (provision), net	24	(45)	—	—
Net loss and comprehensive loss	$ (152,142)	$ (128,389)	$ (50,981)	$ (53,208)
Reconciliation of net loss attributable to common stockholders:				
Net loss	$ (152,142)	$ (128,389)	$ (50,981)	$ (53,208)
Benefit related to the redemption of Series A-1 redeemable convertible preferred stock at less than carrying value	3,871	—	—	—
Net loss attributable to common stockholders[1]	$ (148,271)	$ (128,389)	$ (50,981)	$ (53,208)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.01)	$ (2.90)	$ (0.40)	$ (0.87)
Weighted-average shares used in calculating net loss per share, basic and diluted	73,643,315	44,209,264	127,225,535	60,944,732

(1) See Note 13 to our audited consolidated financial statements and Note 9 to our unaudited condensed consolidated financial statements included in this prospectus for details on the calculation of basic and diluted net loss per share.

(in thousands)	As of March 31, 2021	
	Actual	As adjusted(2)
	(unaudited)	
Balance Sheet Data:		
Cash and cash equivalents	$343,287	$671,562
Working capital(1)	315,660	643,935
Total assets	408,104	736,379
Total liabilities	68,068	68,068
Total stockholders' equity	340,036	668,311

(1) We define working capital as current assets, less current liabilities. Refer to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

(2) As adjusted balance sheet data give effect to the sale of 14,000,000 shares of our common stock offered in this offering based on the public offering price of $25.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Risk factors

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with the other information in this prospectus, including our consolidated financial statements and the related notes included in this prospectus and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this prospectus to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Cautionary Note Regarding Forward-Looking Statements."

Risks related to our business

The successful development of pharmaceutical products is highly uncertain.

Successful development of pharmaceutical products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile);
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or New Drug Application, or NDA, preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country to the next and may be difficult to predict.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices, or cGMPs, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as AEs of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in July 2018 and our operations to date have been limited to non-commercial activities. All of our product candidates were initially developed by Pfizer, which we in-licensed pursuant to a license agreement, or the Pfizer License Agreement, entered into shortly after our formation. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization.

We have no products approved for commercial sale and have not generated any revenue from product sales to date, nor do we expect to generate any revenue from product sales for the next few years, if ever. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled $51.0 million and $152.1 million for the three months ended March 31, 2021 and the year ended December 31, 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $441.9 million and had not yet generated revenues. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance our clinical-stage product candidates CVL-231, darigabat, tavapadon, CVL-871 and CVL-936 through clinical development, including as we complete our registration-directed Phase 3 program for our most advanced product candidate, tavapadon;

- experience an increase in headcount and associated costs as we expand our research and development and establish a commercial infrastructure;
- advance our preclinical-stage product candidates into clinical development;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increase personnel to support our operations;
- meet the requirements and demands of being a public company;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Pfizer License Agreement and any future in-license or collaboration agreements;
- make milestone, royalty or other payments due under the Funding Agreements and any future financing or other arrangements with third parties;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

We have never generated revenue from product sales and may never be profitable.

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, the product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones,

including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have since our inception, investors may not receive any return on their investment and may lose their entire investment.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including our ongoing Phase 3 program for tavapadon and ongoing and planned clinical trials for darigabat, CVL-231, CVL-871 and CVL-936. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials. Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing approval for product candidates that we develop, we will require significant additional amounts of funding in order to launch and commercialize such product candidates and will also be required to make certain milestone and royalty payments under the Pfizer License Agreement and the Funding Agreements. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop, and we may need substantial additional funding to complete the development and commercialization of our product candidates.

Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments under the Pfizer License Agreement and the Funding Agreements;
- the royalty payments due under the Pfizer License Agreement and the Funding Agreements;

- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our receipt of additional funding from NovaQuest and Bain, or the Funding Investors, under the Funding Agreements;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or terminate our product development programs or plans for commercialization.

We believe that our existing cash and cash equivalents will enable us to fund our operating expense and capital expenditure requirements through at least the next twelve months. Our estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We currently have five clinical-stage product candidates as well as several other product candidates that are at various stages of preclinical development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical-stage product candidates, such as tavapadon and darigabat, and ensuring the development of additional potential product candidates.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for disorders of the brain and nervous system, our business, financial condition and results of operations could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, royalty-based financing, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, royalty-based financing or debt financing, if available, may result in our relinquishing rights to valuable future revenue streams or fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management team and may divert a disproportionate amount of our attention away from day-to-day activities, which may adversely affect our management team's ability to oversee the development of our product candidates.

If we raise additional capital through collaborations or marketing, distribution or licensing arrangements, or royalty-based financings with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, reduce or terminate our product discovery and development programs, commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Covenants in our Funding Agreements place restrictions on our operating and financial flexibility and if we do not effectively manage our covenants, our financial condition and results of operations could be adversely affected.

In April 2021, we entered into the Funding Agreements, pursuant to which the Funding Investors committed to provide funding to support our development of tavapadon for the treatment of Parkinson's disease. The Funding Agreements impose various diligence, milestone payment, royalty payment and other obligations on us. Pursuant to the Funding Agreements, we are required to comply with various covenants relating to the conduct of our business and the development and commercialization of tavapadon, including obligations to use commercially reasonable efforts to develop and commercialize tavapadon in the United States and certain limits on our ability to incur indebtedness, create or incur liens or dispose of assets. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our stockholders.

We are required to make payments to the Funding Investors upon the achievement of certain regulatory and sales milestones. In addition, if we suspend or terminate the development of tavapadon or fail to perform certain diligence obligations, under certain circumstances, we will pay the Funding Investors a combined amount equal to the total amount funded by the Funding Investors up to the date of termination, plus 12% interest compounded annually. We may not have sufficient capital to make the required payments to the Funding Investors on a timely basis or at all. In conjunction with the Funding Agreements, we also entered into

security agreements with the Funding Investors pursuant to which we granted the Funding Investors a security interest in the assets material to the development and commercialization of tavapadon in the United States to secure our obligations under the Funding Agreements. If we are unable to comply with such obligations, then the Funding Investors may be able to foreclose on the collateral that was pledged to the Funding Investors. Any of the foregoing events could significantly and adversely affect our financial condition and results of operations.

Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed any clinical trials or development of any product candidates. Our future success and ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. We have initiated our registration-directed Phase 3 program for our most advanced product candidate, tavapadon, which includes two trials in early-stage Parkinson's, one trial in late-stage Parkinson's and an open-label safety extension trial. All of our other product candidates are in earlier stages of development and will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an IND or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in our clinical trials;

- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for our most advanced product candidate, tavapadon, or any other product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The FDA, EMA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

The general approach for FDA approval of a new drug is dispositive data from two or more well-controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the

approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our registration-directed Phase 3 program for tavapadon after receiving input and feedback from the FDA, there can be no assurance that the design of our planned clinical trials will be satisfactory to the FDA or that the FDA will not require us to modify our trials or conduct additional testing, or that completing these trials will result in regulatory approval. See the section entitled "*Business—Our Solution–Tavapadon—Ongoing Clinical Trials—Phase 3 Fixed-Dose Early-Stage Parkinson's Trial*" in this prospectus for a description of our discussions with the FDA regarding the proposed primary endpoint of our Phase 3 trials of tavapadon in early-stage Parkinson's. Even if our Phase 3 clinical trials in early-stage Parkinson's achieve their primary endpoint, there can be no assurance that the FDA will find them sufficient to support approval if, for example, the FDA determines the contribution of the MDS-UPDRS Part II score to the primary endpoint results to be inadequate. Our Phase 2 early-stage Parkinson's trial of tavapadon did not use the MDS-UPDRS Part II score as a primary endpoint and was therefore not powered to show a statistically significant difference from placebo for this measure. In addition, based on our end-of-Phase 2 meeting with the FDA where we presented single-dose ECG, multiple-dose ECG and a model-based analysis of Phase 1 data, we plan to collect time-matched PK and ECG measures in a subset of patients as a sub-study in our planned Phase 3 fixed-dose early-stage Parkinson's trial. However, there can be no assurance that we will not be required to conduct additional testing on the safety and tolerability of tavapadon, including with respect to arrhythmia. Additionally, we are developing CVL-871 for the treatment of dementia-related apathy. There are no currently approved therapies for dementia-related apathy, and we may experience challenges in defining this indication. There are limited precedents for trial design, trial endpoints and regulatory pathway for this indication, which may make clinical development and regulatory approval of CVL-871 more challenging.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA, EMA or comparable foreign regulatory authorities may not file or accept our NDA or marketing application for substantive review;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Business interruptions resulting from the COVID-19 outbreak or similar public health crises could cause a disruption of the development of our product candidates and adversely impact our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the onset of the COVID-19 pandemic, we paused patient screening and enrollment of our Phase 3 trials of tavapadon for the treatment of Parkinson's in March 2020 (which we subsequently resumed in the second half of 2020) and concluded dosing of Cohort 1 of our Phase 1 SAD trial of CVL-936 after receiving sufficient clinical data for the intended purposes for this trial. The continued spread of COVID-19 or other global health matters, such as other pandemics, could further adversely impact our clinical trials or preclinical studies. We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business, including how it will impact our operations and the operations of our suppliers, vendors and business partners. We have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address this pandemic; however, the spread of COVID-19 has caused us to modify our business practices, including implementing a temporary work-from-home policy for all employees who are able to perform their duties remotely, temporarily restricting all non-essential travel and discouraging employee attendance at industry events and in-person work-related meetings. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of COVID-19.

In addition, the onset of the COVID-19 pandemic caused brief pauses in patient screening and enrollment in our Phase 3 trials of tavapadon for the treatment of Parkinson's (which we subsequently resumed in the second half of 2020), and we remain particularly vigilant about patient safety given the elderly nature of this population. While we have taken measures to revise clinical trial protocols to allow for remote visits, including home delivery of study medication, home health care visits to collect safety data and telemedicine visits to collect clinician-based trial assessments, such measures may not be sufficient to prevent missing data from impacting trial outcomes or delays in enrollment and trial completion caused by COVID-19. The primary endpoint in our early-stage Parkinson's trials is based, in part, on a physical assessment of motor symptoms performed by a clinician, which cannot be completed remotely, and, if a substantial number of subjects are unable to complete in-person assessments, the completeness and interpretability of the data that we are able to collect from these trials or our other clinical trials would be impacted, which may require changes to the statistical analysis plan, the enrollment of additional subjects or otherwise negatively affect our ability to use such data to obtain regulatory approval. Similarly, if patients are reluctant to participate in our trials due to fears of COVID-19 infection resulting from regular visits to a healthcare facility or unable to comply with clinical trial protocols due to quarantines or travel restrictions that impede patient movement or interrupt healthcare services, we may not be able to meet our current trial completion timelines.

In addition, COVID-19 may impact our ability to retain principal investigators and site staff for our clinical trials as healthcare providers may have heightened exposure to COVID-19 if an outbreak occurred in their geography or may be impacted due to prioritization of hospital resources toward the outbreak and restrictions on travel. Our clinical trial sites may be located in geographies that are disproportionately affected by the COVID-19 pandemic or actions taken by governmental and health authorities to address the pandemic. Furthermore, COVID-19 may also negatively affect the operations of third-party contract research organizations that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. Any negative impact COVID-19 has on patient

enrollment, site staffing or treatment or the timing and execution of our clinical trials could cause costly delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business and financial results. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

Three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could also lead to delays in our ongoing trials.

The extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, including vaccination campaigns, among others. In addition, recurrences or additional waves of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience prolonged business shutdowns or other disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operations and financial condition.

We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates.

We have in-licensed the rights to all of our current product candidates from Pfizer, for which they undertook prior research and development. We had no involvement with or control over the preclinical and clinical development of any of our product candidates prior to obtaining our in-license. In addition, we had no involvement in the development of third-party agents designed to be used in combination with our product candidates, such as L-dopa, which we intend to study in combination with tavapadon in our Phase 3 late-stage Parkinson's trial. Therefore, we are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or in-license in the future. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, while darigabat demonstrated anti-epileptic activity similar to lorazepam, a commonly prescribed benzodiazepine, or BZD, in a Phase 2 photoepilepsy trial, only seven patients were

treated with darigabat in that trial and we may not be able to replicate the observed results from that trial in our ongoing Phase 2 proof-of-concept trial in focal epilepsy. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. For instance, although they both activate muscarinic receptors, CVL-231 may not be able to replicate the anti-psychotic benefit observed in prior clinical trials of xanomeline.

In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials. For instance, in our Phase 3 clinical trials for tavapadon in early- and late-stage Parkinson's, we are using a slower titration method than was used in prior clinical trials. While we believe that the slower titration method may mitigate certain gastrointestinal and other adverse events, we cannot provide any assurances that it will provide the desired effects and it may result in unanticipated issues.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. For instance, prior clinical trials conducted by Pfizer with certain of our product candidates before we in-licensed them were terminated before conclusion of the trials. These trials included a Phase 2 trial of tavapadon in late-stage Parkinson's, a concurrent Phase 2 clinical trial of tavapadon in early-stage Parkinson's and two Phase 2 trials of darigabat. These clinical trials did not meet their primary endpoints and, even though we believe the data generated from these trials support our rationale for further clinical development of these product candidates, our belief is partially based on post-hoc analyses of such data.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which it may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. Delays in our development of tavapadon in the United States could also prevent us from, or delay us in, receiving additional payments under the Funding Agreements, as well as put us in potential breach of our development and commercialization obligations under the Funding Agreements. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product

candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. For example, in June 2021, we announced topline results from our Phase 1b MAD trial to evaluate the safety, PK and preliminary PD of repeated daily doses of CVL-231 in patients with a primary diagnosis of schizophrenia per the DSM-V.

Such topline results did not include results from the PK portion of the study. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

We may be subject to additional risks because we intend to evaluate our product candidates in combination with other compounds.

We intend to evaluate our product candidates in combination with other compounds. The use of our product candidates in combination with other compounds may subject us to risks that we would not face if our product candidates were being administered as a monotherapy. For instance, in our Phase 3 late-stage Parkinson’s trial, we are evaluating tavapadon in combination with L-dopa for the treatment of late-stage Parkinson’s, and L-dopa’s safety issues may be improperly attributed to tavapadon or the administration of tavapadon with

L-dopa may result in safety issues that such other therapies or tavapadon would not have when used alone. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside our control. If we experience efficacy or safety issues in our clinical trials in which our product candidates are being administered with other compounds, we may not receive regulatory approval for our product candidates, which could prevent us from ever generating revenue or achieving profitability.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

Patient enrollment is affected by many factors, including:

- the effects of COVID-19 on our ability to recruit and retain patients, including as a result of potential heightened exposure to COVID-19, prioritization of hospital resources toward the outbreak and unwillingness by patients to enroll or comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

Because certain of the prior clinical trials of our product candidates were terminated prior to the conclusion of the trial, we may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for such product candidates if we are unable to sufficiently demonstrate the potential of such product candidates to them. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of the company to decline and limit our ability to obtain additional financing if needed.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. In our planned and future clinical trials of our product candidates, we may observe a more unfavorable safety and tolerability profile than was observed in earlier-stage testing of these candidates.

Undesirable side effects have been observed in our product candidates to date. For example, in clinical trials of tavapadon, a dose-dependent increase in the frequency of nausea and headache was observed, with nausea, vomiting, dyskinesia, fall, fatigue, sleep disorder and tremors being the most common adverse events leading to discontinuation of tavapadon. In clinical trials of CVL-231, some moderate treatment-emergent increases in heart rate and blood pressure were observed following single doses of CVL-231 (>10 mg), which may be due to CVL-231's activity on the M4 receptor subtype and its subsequent reduction of striatal dopamine levels. These observed cardiovascular changes were asymptomatic and transient in nature, generally peaking within one to four hours following an oral dose before being generally resolved within 24 hours without intervention. We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any

or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

We have concentrated our research and development efforts on the treatment of disorders of the brain and nervous system, a field that faces certain challenges in drug development.

We have focused our research and development efforts on addressing disorders of the brain and nervous system. Efforts by pharmaceutical companies in this field have faced certain challenges in drug development. In particular, many neuroscience diseases such as anxiety, schizophrenia or dementia-related apathy rely on subjective patient-reported outcomes as key endpoints. This makes them more difficult to evaluate than indications with more objective endpoints. Furthermore, these indications are often subject to a placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidates. There can be no guarantee that we will successfully overcome these challenges with our product candidates or that we will not encounter other challenges in the development of our product candidates.

Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. For example, even if tavapadon ultimately receives regulatory approval, we may have difficulty in convincing the medical community that tavapadon's selective dopamine D1/D5 partial agonism has the potential to deliver promising therapeutic benefits. If any product candidate is approved but does not achieve an adequate level of

market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of our current product candidates are our initial focus, as part of our longer-term growth strategy, we plan to develop other product candidates. In addition to the product candidates in our clinical-stage pipeline, we have in-licensed additional assets that are in earlier stages of development. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates, and also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial and human

resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired.

The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our products may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected.

Our pipeline includes product candidates for a variety of neuroscience diseases. There is no precise method of establishing the actual number of patients with any of these disorders in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease or disorder. Our estimates as to prevalence may not be accurate, and the actual prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including our estimates as to the prevalence of Parkinson's, epilepsy and schizophrenia, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies which include estimates within the range that are lower than our estimates. The actual number of patients with these disease indications may, however, be significantly lower than we believe. Even if our prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or disorder or our products, if approved, may be indicated for or used by only a subset. Moreover, certain of our product candidates are being developed for indications that are novel. In the event the number of patients with the diseases and disorders we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. If any of our product candidates are approved and our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our revenues and our ability to achieve profitability or to meet our expectations with respect to revenues or profits.

Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The clinical and commercial landscapes for the treatment of neuroscience diseases are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We believe that a significant number of product candidates are currently under development for the same indications we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential

competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled "*Business—Competition*" in this prospectus for examples of the competition that our product candidates face.

In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates, including tavapadon, is approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than tavapadon, our other product candidates or any other product candidates that we may develop, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of tavapadon or any other product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize tavapadon or one or more of our other product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of tavapadon, our other product candidates and other future product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- our inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, along with our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants, utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing,

business email compromise attacks or other cyber-attacks. For example, in the first quarter of 2020, we discovered a business email compromise caused by phishing, which led to the misappropriation of a portion of our funds in late 2019. Even though we have implemented remedial measures promptly following this incident and do not believe that it had a material adverse effect on our business, we cannot guarantee that our implemented remedial measures will prevent additional related, as well as unrelated, incidents. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Our ability to use our net operating losses and research and development tax credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had U.S. federal net operating loss carryforwards totaling $213.9 million, all of which have an indefinite carryforward period. As of December 31, 2020, we had state net operating loss carryforwards totaling $206.2 million which begin to expire in 2038 and 2040. As of December 31, 2020, we also had U.S. federal and state research and development tax credit carryforwards of $5.7 million and $0.7 million, respectively, which expire at various dates through 2040 for federal purposes and 2035 for state purposes. The net operating losses which are limited in life and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with, or we undergo an ownership change following, this offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. If we determine that an ownership change has occurred and our ability to use our historical NOLs or credits is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. Section 382 and 383 of the Code would apply to all net operating loss and tax credit carryforwards, whether the carryforward period is indefinite or not.

Furthermore, our ability to utilize our historical NOLs or credits is conditioned upon us attaining profitability and generating U.S. federal and state taxable income. We are a clinical-stage biopharmaceutical company with

a limited operating history. We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our historical NOLs or credits.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing we conduct in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

For instance, in connection with the audit of our consolidated financial statements for the year ended December 31, 2019, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting related to our cash disbursement process. Specifically, our cash disbursement process was not adequately designed to identify unauthorized payment requests. In the first quarter of 2020, we discovered a business email compromise caused by phishing, which led to the misappropriation of a portion of our funds in late 2019. We do not believe that this breach had a material adverse effect on our business, but a deficiency in our internal controls resulted in the inability to prevent and timely detect the unauthorized disbursement requests. We have implemented measures designed to improve our internal control over financial reporting to remediate this material weakness, including continuing to evaluate cybersecurity risks, developing a priority list of critical information systems and designing and implementing control activities such as implementing additional security policies and processes, hiring and training additional personnel, strengthening supervisory reviews and further enhancing our processes and internal control documentation, and believe we have successfully remediated this material weakness as of December 31, 2020.

If we identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports or applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We also could become subject to investigations by the Nasdaq Stock Market, or Nasdaq, the Securities and Exchange Commission, or the SEC, or other regulatory authorities. We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Risks related to managing our business and operations

We are incurring, and will continue to incur, significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations.

As a public company, we are facing, and will continue to face, increased legal, accounting, administrative and other costs and expenses that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the Public Company Accounting Oversight Board and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements mandate us to carry out activities we have not done previously. In addition, additional expenses associated with SEC reporting requirements are being incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if our auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It will also be more expensive to obtain director and officer liability insurance as a public company. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on the board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

We qualify as an “emerging growth company” and a “smaller reporting company” within the meaning of the federal securities laws, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies and smaller reporting companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We qualify as an “emerging growth company” as defined in the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earliest of (i) December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. We have elected to take advantage of this exemption and will therefore, for so long as we are an emerging growth company, delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Therefore, we may not be subject to the same new or revised accounting standards as other public companies.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter.

Investors may find our common stock less attractive because we will rely on these exemptions, which may result in a less active trading market for our common stock and our stock price may be more volatile.

We depend heavily on our executive officers, third-party consultants and others and our ability to compete in the biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of their services or our inability to hire and retain such personnel would materially harm our business.

Our success depends, and will likely continue to depend, upon our ability to hire, and our ability to retain the services of our current executive officers, principal consultants and others, including N. Anthony Coles, M.D., our Chairperson and Chief Executive Officer, Scott Akamine, our Chief Legal Officer, Mark Bodenrader, our Chief Accounting Officer, Abraham Ceesay, our President, Kenneth DiPietro, our Chief Human Resources Officer, John Renger, Ph.D., our Chief Scientific Officer, Raymond Sanchez, M.D., our Chief Medical Officer, Kathleen Tregoning, our Chief Corporate Affairs Officer, and Kathy Yi, our Chief Financial Officer. Our executive officers may terminate their employment with us at any time. The loss of their services might impede the achievement of our research and development objectives.

Our ability to compete in the biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. In particular, we will need to retain and, in some cases, hire, qualified personnel with expertise in clinical development and operations, preclinical research and development, manufacturing, quality management, medical and regulatory affairs, finance and accounting and other areas in connection with the continued development of our product candidates. We currently rely, and for the foreseeable future will continue to rely, on third-party consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development objectives and activities as well as the development of our commercialization strategies.

Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

There can be no assurance that the services of third-party consultants and advisors will continue to be available to us on a timely basis when needed, that we will be able to manage our existing consultants and advisors or that we can find qualified replacements on economically reasonable terms, or at all. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified consultants and advisors, our ability to develop and commercialize our product candidates will be limited.

We only have a limited number of employees to manage and operate our business.

As of March 31, 2021, we had 122 full-time employees. Our focus on the development of multiple initial product candidates requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop our product candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. If we are not able to effectively expand our organization by hiring new employees, our clinical trials may be delayed or terminated, we may not be able to successfully execute the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our development and commercialization goals.

Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and CROs may engage in fraudulent conduct or other illegal activity. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities; and
- laws that require the reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in

regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of their attention to managing these growth activities. For instance, the transition to and build-out of our new headquarters may divert our management's time and attention. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Risks related to our organizational structure

Bain investor and pfizer have significant influence over us.

As of March 31, 2021, BC Perception Holdings, LP, or Bain Investor, and Pfizer own, collectively, approximately 69.1% of the outstanding shares of our common stock. Furthermore, as discussed in the section entitled "*Certain Relationships and Related Person Transactions*" so long as they own certain specified amounts of our equity securities, Bain Investor and Pfizer have certain rights to nominate our directors. As long as such persons each own or control a significant percentage of outstanding voting power, they will have the ability to strongly influence all corporate actions requiring stockholder approval, including the election and removal of directors and the size of our board of directors, any amendment of our certificate of incorporation or bylaws, or the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at other shareholders have purchased share or have held their shares for a longer period, they may be more interested in selling the company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders.

As a "controlled company" within the meaning of Nasdaq listing standards, we qualify for exemptions from certain corporate governance requirements. We have the opportunity to elect any of the exemptions afforded a controlled company.

Because Bain Investor and Pfizer, together, control more than a majority of the total voting power of our common stock, we are a "controlled company" within the meaning of Nasdaq listing standards. Under Nasdaq rules, a company of which more than 50% of the voting power is held by another person or group of persons acting together is a "controlled company" and may elect not to comply with the following Nasdaq rules regarding corporate governance:

- the requirement that a majority of our board of directors consist of independent directors;
- the requirement to have a nominating/corporate governance committee composed entirely of independent directors and a written charter addressing the committee's purpose and responsibilities;
- the requirement to have a compensation committee composed entirely of independent directors and a written charter addressing the committee's purpose and responsibilities; and
- the requirement of an annual performance evaluation of the nominating/corporate governance and compensation committees.

Currently, 10 of our 11 directors are independent directors, and we have an independent nominating and corporate governance committee and an independent compensation committee. However, for as long as the "controlled company" exemption is available, our board of directors in the future may not consist of a majority of independent directors and may not have an independent nominating and corporate governance committee or compensation committee. As a result, you may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq rules regarding corporate governance.

The Registration and Shareholder Rights Agreement provides that the doctrine of corporate opportunity does not apply with respect to certain of our stockholders, directors, non-voting observers or certain of their affiliates who are not our or our subsidiaries' full-time employees.

The doctrine of corporate opportunity generally provides that a corporate fiduciary may not develop an opportunity using corporate resources or information obtained in their corporate capacity for their personal advantage, acquire an interest adverse to that of the corporation or acquire property that is reasonably incident to the present or prospective business of the corporation or in which the corporation has a present or expectancy interest, unless that opportunity is first presented to the corporation and the corporation chooses not to pursue that opportunity. The doctrine of corporate opportunity is intended to preclude officers, directors or other fiduciaries from personally benefiting from opportunities that belong to the corporation.

Pursuant to the Amended and Restated Registration and Shareholder Rights Agreement, dated October 27, 2020, by and between us and the other parties thereto, or the Registration and Shareholder Rights Agreement, to the fullest extent permitted by law, the doctrine of corporate opportunity and any analogous doctrine does not apply to (i) Bain Investor, Pfizer, ARYA Sciences Holdings II, or Sponsor, and Perceptive Life Sciences Master Fund Ltd, or Perceptive PIPE Investor, (ii) any member of our board of directors, non-voting observer or any officer who is not our or our subsidiaries' full-time employee or (iii) any affiliate, partner, advisory board member, director, officer, manager, member or shareholder of Bain Investor, Pfizer, Sponsor or Perceptive PIPE Investor who is not our or our subsidiaries' full-time employee (any such person listed in (i), (ii) or (iii) being referred to herein as an External Party). Therefore, we renounced any interest or expectancy in, or being offered an opportunity to participate in, business opportunities that are from time to time presented to any External Party.

As a result, the External Parties are not prohibited from operating or investing in competing businesses. We therefore may find ourselves in competition with the External Parties, and we may not have knowledge of, or be able to pursue, transactions that could potentially be beneficial to us. Accordingly, we may lose a corporate opportunity or suffer competitive harm, which could negatively impact our business or prospects.

Delaware law and our certificate of incorporation and bylaws contain certain provisions, including anti-takeover provisions, that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our certificate of incorporation and bylaws, and the General Corporation Law of the State of Delaware, or the DGCL, contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our board of directors or depress the trading price of shares of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of our board of directors or taking other corporate actions, including effecting changes in our management. Among other things, our certificate of incorporation and bylaws include provisions:

- regarding the ability of our board of directors to issue shares of preferred stock, including “blank check” preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- that create a classified board of directors whose members serve staggered terms, with one class being elected each year by our stockholders;
- regarding the limitation of the liability of, and the indemnification of, our directors and officers;
- prohibiting stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of stockholders after such date and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors;
- requiring that a special meeting of stockholders may be called only by a majority of our board of directors, which could delay the ability of stockholders to force consideration of a proposal or to take action, including the removal of directors;
- controlling the procedures for the conduct and scheduling of our board of directors and stockholder meetings;
- regarding the ability of our board of directors to amend the bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the bylaws to facilitate an unsolicited takeover attempt; and
- regarding advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders’ meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of our board of directors.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our board of directors or management.

In addition, our certificate of incorporation includes a provision substantially similar to Section 203 of the DGCL, which may prohibit certain stockholders holding 15% or more of our outstanding capital stock from engaging in certain business combinations with us for a specified period of time.

Our bylaws designate specific courts as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, stockholders, employees or agents.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws or (v) any action asserting a claim against us governed by the internal affairs doctrine; provided, however, that the forgoing provisions will not apply to any claims arising under the Exchange Act or the Securities Act. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these forum provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

This choice of forum provisions in our bylaws may impose additional litigation costs on stockholders in pursuing such claims and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If our forum provisions are found to be unenforceable, we and our stockholders may incur additional costs associated with resolving such matters. The Court of Chancery of the State of Delaware and the U.S. District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks related to our dependence on third parties

We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and IRB approval, patient enrollment rates and compliance with GCPs. We have opened clinical trial sites and are enrolling patients in a number of countries where our experience is limited. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development

activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. The failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. Although we believe we have diversified our risk by engaging a number of CROs and other third- party organizations and there are a number of other CROs we could engage to continue these activities, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

In particular, we plan to rely on a hybrid functional service provider, or FSP, approach, where, rather than relying on a small number of third-party services providers for a full suite of services, we plan to use a wider

number of third-party service providers on an à la carte basis grouped by specific function. We may not be able to realize the cost savings typically associated with the hybrid FSP approach, or this approach may require us to incur increased startup or integration costs. Our hybrid FSP approach may also require us to manage and monitor an increased number of service providers and contractual relationships. Finally, this approach may require us to handle certain functions, such as collecting, transmitting and storing patient data in compliance with applicable data privacy laws, internally rather than outsourcing them to third parties. Handling these functions internally may require us to spend more time and capital hiring and training employees, and any failure to do so successfully may negatively impact our operations.

Under the Funding Agreements, the Funding Investors have the right to suspend payments to us or take other actions that may be adverse to our interests in certain circumstances.

Under the Funding Agreements, while the Funding Investors agreed to provide up to an additional $37.5 million, approximately $31.3 million and $25.0 million on the first, second and third anniversaries of the effective date of the Funding Agreements, respectively, such payments are subject to certain customary funding conditions, and, if those funding conditions are not satisfied or waived, we would not receive such payments. The Funding Investors may also suspend their obligation to make payments to us following the occurrence of enumerated events such as an uncured material breach, a material adverse effect (which includes certain adverse developments related to the development and regulatory approval of tavapadon) or a bankruptcy event. The Funding Investors' obligation to make development payments will resume upon their notice to us that the condition allowing them to suspend payments has been resolved or cured to their reasonable satisfaction. The Funding Investors may terminate their obligation to make any further development payments if such condition is not resolved or cured within 12 months. If the Funding Investors' payment obligations terminate in these circumstances, we will remain obligated to make the milestone and royalty payments contemplated in the Funding Agreements to the Funding Investors in the event we nonetheless receive FDA approval for tavapadon and commercialize tavapadon in the United States. Our ability to receive payments under the Funding Agreements also depends on the ability of the Funding Investors to meet their funding commitments. If we do not receive additional payments under the Funding Agreements, our business, results of operations, cash flows and financial condition could be adversely affected.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential

market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, APIs or drug products when needed or at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties.

We currently rely on and engage third-party manufacturers to provide all of the API and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. For instance, there are a limited number of suppliers who have spray-dried dispersion capabilities required to manufacture darigabat, and we can provide no assurance that we will be able to find an alternative manufacturer at an acceptable price. In addition, we typically order raw materials, API and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Many of the third-party manufacturers we rely on have only recently begun working with us and have limited or no experience manufacturing our API and final drug products. If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third- party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

Additionally, if any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third party owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture our product candidates.

If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Some of our manufacturers are located outside of the United States. There is currently significant uncertainty about the future relationship between the United States and certain countries, including China, with respect to trade policies, treaties, government regulations and tariffs. Increased tariffs could potentially disrupt our existing supply chains and impose additional costs on our business. Additionally, it is possible further tariffs may be imposed that could affect imports of APIs used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the United States or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs.

Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party

manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

We may need to maintain licenses for APIs from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.

Should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to these APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

Risks related to government regulation

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

In particular, the ultimate impact of Brexit is uncertain and cannot be predicted at this time. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU. For instance, in November 2017, European Union member states voted to move the EMA, the European Union’s regulatory body, from London to Amsterdam. Operations in Amsterdam

commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;

- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

While we may in the future seek designations for our product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for any of our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Breakthrough Therapy Designation for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

The FDA has granted Fast Track Designation for CVL-871 for the treatment of dementia-related apathy, and we may seek Fast Track Designation for some of our other product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. The receipt of Fast Track Designation for CVL-871 for the treatment of dementia-related apathy, and any future receipt of Fast Track Designation for other product candidates, does not guarantee a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

Some of our programs may be partially supported by government grant awards, which may not be available to us in the future or subject us to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry.

We have received a notice of award for cooperative grant funding from NIDA with respect to our product candidate CVL-936 to support the development of this compound in OUD. To fund a portion of our future research and development programs, we may apply for additional grant funding from NIDA or other governmental agencies. However, funding by these governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Therefore, we cannot assure you that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates.

Moreover, any intellectual property rights generated through the use of U.S. government funding are subject to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, which we refer to as march-in rights. The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

As a result of any funding from NIDA, or if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual

property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the civil False Claims Act, or the FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to

the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended, and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the U.S. Centers for Medicare & Medicaid Services, or the CMS, within the HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal consumer protection laws, which broadly regulative marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and FCA which may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector

General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pharmaceutical companies may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to closely scrutinize interactions between pharmaceutical companies and pharmaceutical providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States

with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company’s revenue generated from the sale of any approved products. Even if we do receive a favorable coverage determination for our products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product

pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If our product candidates are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our product candidates off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

Inadequate funding for the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA or other government agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be

subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to reward improper performance generally is governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the European Economic Area (comprising the EU Member States plus Norway, Iceland and Liechtenstein), or the EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

We are subject to evolving global data protection laws and regulation, which may require use to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. For example, the California Consumer Privacy Act, or CCPA, provides broad rights to California consumers with respect to the collection and use of their information by businesses. The California Consumer Privacy Rights Act, or CPRA, further expands the privacy and process enhancements and commitment of resources in support of compliance with California's regulatory requirements and may lead to similar laws in other U.S. states or at a national level.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, may seek to conduct clinical trials in EEA and may become subject to additional European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or the GDPR, became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10,000,000 or up to 2% of our total worldwide annual revenue for certain comparatively minor offenses, or up to €20,000,000 or up to 4% of our total worldwide annual revenue for more serious offenses. Given the limited enforcement of the GDPR to date, particularly in the pharmaceutical space, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

For any clinical trials we commence in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to

comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

As a result of our business combination with a special purpose acquisition company, regulatory obligations may impact us differently than other publicly traded companies.

On October 27, 2020, Cerevel Therapeutics, Inc., a private company and our predecessor, completed a business combination, or the Business Combination, with ARYA Sciences Acquisition Corp II, or ARYA, a special purpose acquisition company, or SPAC, pursuant to which we became a publicly traded company. As a result of this transaction, regulatory obligations have, and may continue, to impact us differently than other publicly traded companies. For instance, the SEC and other regulatory agencies may issue additional guidance or apply further regulatory scrutiny to companies like us that have completed a business combination with a SPAC. Managing this regulatory environment, which has and may continue to evolve, could divert management's attention from the operation of our business, negatively impact our ability to raise additional capital when needed or have an adverse effect on the price of our common stock.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws

may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Risks related to our intellectual property

We depend and expect in the future to continue to depend on in-licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose license rights, which would substantially harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We are and may in the future become a party to license agreements pursuant to which we in-license key intellectual property for our product candidates and their use. Soon after we began our operations in July 2018, we entered into the Pfizer License Agreement pursuant to which we in-licensed each of our current product candidates. The Pfizer License Agreement excludes the field of treatment of prevention, diagnosis, control and maintenance of inflammatory bowel diseases and disorders in humans by compounds or products exerting a therapeutic effect on Leucine-Rich Repeat Kinase 2, or the LRRK2 field, which is retained by Pfizer. The Pfizer License Agreement imposes various diligence, milestone payments, royalty, insurance and other obligations on us. For example, under the terms of the Pfizer License Agreement, we are obligated to use commercially reasonably efforts to develop and seek regulatory approval for each of the product candidates licensed to us in certain designated countries. If we fail to comply with any of these obligations, Pfizer may have the right to terminate the Pfizer License Agreement, in which event we would not be able to develop or market our product candidates covered by such licensed intellectual property. Upon Pfizer's termination of the Pfizer License Agreement for our material breach or either party's termination for bankruptcy, insolvency or other similar proceeding or force majeure, we would grant Pfizer an exclusive, sublicensable, royalty-free, worldwide, perpetual license under certain intellectual property we develop during the term of the Pfizer License Agreement. Any termination of our existing or future licenses could result in the loss of significant rights and would cause material adverse harm to our ability to commercialize our product candidates. See the section entitled "*Business—Pfizer License Agreement*" for additional information.

Additionally, Pfizer has an exclusive right of first negotiation in the event that we seek to enter into any significant transaction with a third party with respect to a product either globally or in certain designated countries. Significant transactions include exclusive licenses, assignments, sales, exclusive co-promotion arrangements, and other transfers of all commercial rights to a product globally or in the designated countries, as well as exclusive distribution agreements globally or in certain designated countries. This right of first negotiation may limit or delay our ability to enter into arrangements with other companies related to our product candidates and could discourage, delay or prevent a merger, acquisition or change of control of our company.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether we have used a sufficient level of effort to develop product candidates;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. The Pfizer License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payments, royalty, insurance and other obligations, and our failure to comply could give the applicable licensor a right to terminate the license, thereby impairing or preventing us from developing and marketing the product candidates covered by the applicable agreement.

Although we have the right to control the maintenance, prosecution and enforcement of rights in-licensed under the Pfizer License Agreement, we are required to conduct our activities in compliance with the terms of the Pfizer License Agreement, which imposes on us certain obligations and grants Pfizer certain rights with respect to these activities. Additionally, we may have limited control over the maintenance, prosecution or enforcement of other rights that we in-license, and we may also have limited control over activities previously or separately conducted by our licensors. For example, we cannot be certain that activities conducted by Pfizer or any other present or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may also have limited control over other intellectual property that is not licensed to us but that may be related to our in-licensed intellectual property. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could materially suffer.

Our success depends in part on our ability to protect our intellectual property, and patent terms may be inadequate to protect our competitive position. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection for our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is affected by the extent to which we have rights under valid and enforceable patents that cover these activities. If our patents expire, or we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the statutory expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. While various extensions such as patent term adjustments and/or extensions, may be available, the life of a patent, and the protection it affords, is limited. Our current composition of matter patents, and patents that may issue from our pending patent applications, covering new chemical entities, pharmaceutical compositions comprising those entities, and their use in methods of treating various diseases and/or disorders, which we licensed from Pfizer, in connection with the formation of our company, are expected to expire between 2033 and 2039, not including any patent term extensions or adjustments. Our earliest patents may expire before, or soon after, our product candidates achieve marketing approval in the United States or foreign jurisdictions. Once the patent life has expired, we may be open to competition from competitive products, including generics. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The expiration of the patents covering our lead product candidates, and our inability to secure additional patent protection, could also have a material adverse effect on our business, results of operations, financial condition and prospects.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license now or in the future may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, the patents covering our product candidates may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, there is no certainty that any of our patent applications related to a product candidate was the first to be filed. Furthermore, for United States applications in which at least one claim is entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of the application. We therefore cannot be certain that we were the first to invent any inventions covered by a pending patent application.

We may be required to disclaim part or all of the term of certain patents or certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents that we have had issued that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first-to-invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are now being felt in the prosecution of pending patent applications and the enforcement of issued patents. The applicability of the act, and new regulations on the specific applications and patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents;
- the APIs in our current product candidates may eventually become commercially available in generic drug products, and no patent protection may be available with regard to their formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regard to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or design around any of our or our licensors' technologies;
- it is possible that pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable because such omissions or inclusions are held to be done with deceptive intent;
- we may engage in scientific collaborations with one or more third parties, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all

confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived or completed by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may, for example, not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Thus, we may not be able to meaningfully protect our trade secrets.

If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. §271. If and when any of our product candidates are approved by the FDA, third-parties may then seek to enforce their U.S. patents by filing a patent infringement lawsuit against us. While we may believe that any claims of such patents that could otherwise materially adversely affect commercialization of our product candidates, if approved, and of which we are now aware, are not valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may also be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, or uses or formulations thereof, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be invalid or unenforceable. Such a license may not be available on commercially

reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and any patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees, consultants, collaborators or partners have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. This risk is similarly applicable with respect to claims by third parties against any current or future licensors.

We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license now or in the future.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we in-license or that we may own or in-license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignments may not be self-executing or may be breached. Our licensors may face similar obstacles. We or our licensors could be subject to ownership disputes arising, for example, from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

For example, we may develop products containing our compounds and pre-existing pharmaceutical compounds. Our product candidates may also require specific formulations to work effectively and efficiently and rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, formulations, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop or in-license such alternatives or replacement technology, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Additionally, we may from time to time collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter such infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If legal proceedings are initiated against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. In addition, a court may refuse to stop the other party from using the technology at issue on the grounds that the public interest favors the third party's continued use of our technology on a royalty basis. An adverse result in any litigation or defense proceedings could also put any related patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps

all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Third parties may choose to challenge the patentability of claims in our U.S. patents by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. Third parties may also choose to challenge our patents in patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices. The costs of these opposition or nullity proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent offices then our patents may be cancelled or narrowed in scope.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, and most patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by issued patents or any pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors also may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patents or any patent applications, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority or derivation of invention in the United States. If we or one of our licensors is a party to such proceedings involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during such litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent applications and patents. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result, if not cured, in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within

prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Changes in patent law in the United States and in ex-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing and proposing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents, particularly those directed to pharmaceutical and biopharmaceutical products and uses could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how these decisions or any future decisions by the U.S. Congress, the federal courts or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world is expensive. While many of our licensed patents, including the patents covering our lead product candidates, have been issued in major markets and other countries, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States where we have issued patents, or from selling or importing products made using our inventions in other jurisdictions. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we do not have patent protection or where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical and biopharmaceutical products, which could make it difficult for us or our licensors to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings for infringement by third parties or by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could also result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and any related patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We may not prevail in any lawsuits

that we initiate or are initiated against us and the damages or other remedies awarded in lawsuits that we initiate, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per eligible drug may be extended and only those claims covering the approved drug, an approved method for using it or a method for manufacturing it may be extended. Patent term extensions tied to marketing approval in foreign jurisdictions may also be available for our patents. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks related to our common stock and this offering

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry,
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of COVID-19;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;

- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

The price of our common stock may be volatile.

The price of our common stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us, our competitors or our industry;
- the public’s reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts’ projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and

- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism.

These market and industry factors may materially reduce the market price of share of our common stock regardless of our operating performance.

Because of potential volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $25.00 per share, purchasers of common stock in this offering will experience immediate dilution of $20.27 per share in net tangible book value of the common stock. In the past, we issued options and warrants to acquire common stock at prices significantly below the public offering price. To the extent these outstanding options and warrants are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See the section of this prospectus titled "*Dilution*" for a more detailed description of the dilution to new investors in the offering.

We will have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section of this prospectus titled "*Use of Proceeds*," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares may be sold into the market in the near future. This could cause the market price of shares of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. For instance, certain lock-up restrictions under the Registration and Shareholder Rights Agreement applicable to Sponsor, Perceptive PIPE Investor, Bain Investor and Pfizer recently expired in April 2021. In addition, the lock-up restrictions pertaining to this offering described in the section entitled "*Underwriting*" will expire 90 days from the date of this prospectus. Further,

shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Warrants will become exercisable for shares of our common stock, which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

Outstanding warrants to purchase an aggregate of 5,149,647 shares of our common stock became exercisable on June 9, 2021, in accordance with the terms of the warrant agreement governing those securities. The exercise price of these warrants is $11.50 per share. To the extent such warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of shares of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of our common stock.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have no current plans to pay cash dividends on our common stock. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant. We may not pay any dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Future offerings of debt or equity securities by us may adversely affect the market price of our common stock.

In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including commercial paper, medium-term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and/or cash from operations.

Issuing additional shares of our common stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing stockholders or reduce the market price of our

common stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our common stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings.

General risk factors

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

An active trading market for our common stock may not be sustained, which may make it difficult to sell the shares of our common stock you purchase.

An active trading market for our common stock may not be sustained, which would make it difficult for you to sell your shares of our common stock at an attractive price or at all. The market price of our common stock may decline below your purchase price, and you may not be able to sell your shares of our common stock at or above the price you paid for such shares or at all.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq’s listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our common stock;

- reduced liquidity for our common stock;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock.

Securities research analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. The price of our common stock may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, the price of our common stock could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, the price or the trading volume of our common stock could decline.

Cautionary note regarding forward-looking statements

Certain statements in this prospectus constitute “forward-looking statements” for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this prospectus may include, for example, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding our plans for clinical development of our product candidates, the initiation and completion of clinical trials and related preparatory work and the expected timing of the availability of results of clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the potential attributes and benefits of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete further development, approval and, if approved, commercialization of our product candidates;
- the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expense and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to identify, in-license or acquire additional product candidates;
- our ability to maintain the Pfizer License Agreement underlying our product candidates;
- our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we are pursuing for our product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection;
- our ability to contract with and rely on third parties to assist in conducting our clinical trials and manufacturing our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- the impact of laws, regulations, accounting standards, regulatory requirements, judicial decisions and guidance issued by authoritative bodies;

- our ability to attract and retain key scientific, medical, commercial or management personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the ability to recognize the anticipated benefits of the Business Combination and the tavapadon financing transaction;
- the effect of COVID-19 on the foregoing; and
- our use of the proceeds from this offering.

The forward-looking statements contained in this prospectus are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "*Risk Factors.*" Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

You should read this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements in this prospectus by these cautionary statements.

Market and industry data and forecasts

We obtained the industry and market data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, publicly available information and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry and market data included in this prospectus is reliable and based on reasonable assumptions, such data involve material risks and other uncertainties and are subject to change based on various factors, including those discussed in the section entitled "*Risk Factors*." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

Use of proceeds

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately $328.3 million, or approximately $377.6 million if the underwriters exercise their option to purchase additional shares in full, based on the public offering price of $25.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering as follows:

- approximately $200 million to $240 million to support the clinical development of CVL-231, our M4 PAM, in schizophrenia and the evaluation of additional indications, including dementia-related psychosis;
- approximately $40 million to $50 million to fund CVL-354, our selective KORA, and CVL-047, our selective PDE4 inhibitor, through initial clinical development;
- approximately $20 million to $30 million to fund early discovery initiatives, including potentially disease-modifying targets; and
- the remaining proceeds for working capital and other general corporate purposes, including to support organizational growth and infrastructure of the Company.

Based on our current plans, we believe our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next twelve months.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve.

We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development efforts, the status of and results from clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Dividend policy

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2021:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale and issuance by us of 14,000,000 shares of our common stock in this offering at the public offering price of $25.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information below in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this prospectus and the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in this prospectus.

	As of March 31, 2021	
(In thousands, except share and per share data)	**Actual**	**As adjusted**
Cash and cash equivalents	$ 343,287	$ 671,562
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value: 500,000,000 shares authorized; 127,325,116 shares issued and outstanding; 141,325,116 shares issued and outstanding, as adjusted	13	14
Additional paid-in capital	781,914	1,110,188
Accumulated deficit	(441,891)	(441,891)
Total stockholders' equity	340,036	668,311
Total capitalization	$ 340,036	$ 668,311

If the underwriters exercise their option to purchase additional shares in full, as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity, total capitalization and shares of common stock outstanding as of March 31, 2021 would be $720.9 million, $1,159.5 million, $717.7 million, $717.7 million and 143,425,116 shares, respectively.

The information set forth in the table above excludes each of the following:

- 5,149,647 shares of common stock issuable upon the exercise of warrants to purchase shares of common stock outstanding as of March 31, 2021, with an exercise price of $11.50 per share;
- 16,084,192 shares of common stock issuable upon exercise of options outstanding as of March 31, 2021, with a weighted-average exercise price of $8.14 per share;
- 57,080 shares of common stock issuable upon the vesting of restricted stock units outstanding as of March 31, 2021;
- 12,793,203 shares of common stock available for future issuance as of March 31, 2021 under the 2020 Plan; and
- 2,927,163 shares of common stock available for future issuance as of March 31, 2021 under the ESPP.

Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering. As of March 31, 2021, our historical net tangible book value was $340.0 million, or $2.67 per share. Our historical net tangible book value is the amount of our total tangible assets less our total liabilities. Historical net tangible book value per share represents historical net tangible book value divided by the 127,325,116 shares of our common stock outstanding as of March 31, 2021.

After giving effect to the sale of 14,000,000 shares of common stock in this offering at the public offering price of $25.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2021 would have been $668.3 million, or $4.73 per share. This represents a resulting increase in as adjusted net tangible book value of $2.06 per share to our existing stockholders and an immediate dilution of $20.27 per share to new investors in this offering.

The following table illustrates this dilution on a per share basis:

Public offering price per share		$25.00
Historical net tangible book value per share as of March 31, 2021	$2.67	
Increase in as adjusted net tangible book value per share attributable to this offering	2.06	
As adjusted net tangible book value per share after giving effect to this offering		4.73
Dilution in as adjusted net tangible book value per share to new investors in this offering		$20.27

If the underwriters exercise in full their option to purchase additional shares of our common stock, our as adjusted net tangible book value per share after this offering would be $5.00, representing an immediate aggregate increase in as adjusted net tangible book value per share of $2.33 to existing stockholders and immediate aggregate dilution in as adjusted net tangible book value per share of $20.00 to new investors in this offering, assuming a public offering price of $25.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The above table and discussion are based on 127,325,116 shares of our common stock outstanding as of March 31, 2021, and excludes:

- 5,149,647 shares of common stock issuable upon the exercise of warrants to purchase shares of common stock outstanding as of March 31, 2021, with an exercise price of $11.50 per share;
- 16,084,192 shares of common stock issuable upon exercise of options outstanding as of March 31, 2021, with a weighted-average exercise price of $8.14 per share;
- 57,080 shares of common stock issuable upon the vesting of restricted stock units outstanding as of March 31, 2021;
- 12,793,203 shares of common stock available for future issuance as of March 31, 2021 under the 2020 Plan; and
- 2,927,163 shares of common stock available for future issuance as of March 31, 2021 under the ESPP.

To the extent that outstanding options or warrants are exercised, new options or warrants are issued, or shares are issued under our equity incentive plans, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

Business

Overview

We are a clinical-stage biopharmaceutical company pursuing a targeted approach to neuroscience that combines a deep understanding of disease-related biology and neurocircuitry of the brain with advanced chemistry and central nervous system, or CNS, target receptor selective pharmacology to discover and design new therapies. We seek to transform the lives of patients through the development of new therapies for neuroscience diseases, including schizophrenia, epilepsy and Parkinson's disease. Our "ready-made" pipeline of 11 small molecule programs, which includes five clinical-stage product candidates, was developed through over a decade of research and investment by Pfizer and was supported by an initial capital commitment from an affiliate of Bain Capital and a keystone equity position from Pfizer. We are advancing our broad and diverse pipeline with six clinical trials underway or expected to start by the end of 2021 and up to seven clinical data readouts expected by the end of 2023. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with the proven expertise of large pharmaceutical company experience and capabilities in drug discovery and development.

Our portfolio of product candidates is based on a differentiated understanding of the neurocircuitry of CNS diseases, as well as the key pillars of our targeted approach to neuroscience: (i) receptor-drug interactions at the atomic level to achieve targeted receptor subtype selectivity, (ii) orthosteric and allosteric chemistry to achieve ideal receptor pharmacology and (iii) robust packages of preclinical and clinical data that elucidate the key points of differentiation for our compounds. Our rational design approach uses measured and calculated structural and surface charge information from the target protein combined with high-resolution crystallography data, computational homology models, screening of single-residue mutant proteins, indirect solution-phase imaging techniques and other biophysical measurements to glean key molecular-level information about the interaction between a target protein and our product candidates. These insights then drive structure-informed design of subsequent molecules. Due to our understanding of the specificity and dynamic range of neural networks and how to modulate them, we believe that our product candidates have the potential to achieve optimal therapeutic activity while minimizing unintended side effects of currently available therapies. Below are our five clinical-stage product candidates:

1. CVL-231 is a positive allosteric modulator, or PAM, that selectively targets the muscarinic acetylcholine 4 receptor subtype, or M4. We conducted a Phase 1b trial of CVL-231 in patients with schizophrenia, consisting of Part A, a multiple ascending dose, or MAD, study and Part B, a pharmacodynamic, or PD, assessment. In June 2021, we announced topline results for the Phase 1b trial. Both doses of CVL-231 demonstrated a clinically meaningful and statistically significant improvement in Positive and Negative Syndrome Scale, or PANSS, total score at 6 weeks and were overall well-tolerated compared with placebo. See "—Our Product Candidates—CVL-231—Phase 1b Multiple Ascending Dose Trial" for more information. The results of this trial and emerging data from two PET receptor occupancy trials will inform dose selection and design for a Phase 2 program in schizophrenia.

2. Darigabat (formerly known as CVL-865) is a PAM that selectively targets the alpha-2/3/5 subunits of the $GABA_A$ receptor. In the second half of 2020, we initiated a Phase 2 proof-of-concept trial, known as REALIZE, in patients with drug-resistant focal onset seizures in epilepsy, or focal epilepsy, and a Phase 1 proof-of-principle trial in acute anxiety. Data is expected in the fourth quarter of 2021 for the Phase 1 anxiety trial and in the second half of 2022 for the Phase 2 focal epilepsy trial.

3. Tavapadon is a selective dopamine D1/D5 partial agonist that we are developing for the treatment of early- and late-stage Parkinson's disease. We initiated a registration-directed Phase 3 program for tavapadon beginning in January 2020, which includes two trials in early-stage Parkinson's, known as TEMPO-1 and TEMPO-2, one trial in late-stage Parkinson's, known as TEMPO-3, and an open-label safety extension trial,

known as TEMPO-4. We expect initial data from our Phase 3 program to be available beginning in the first half of 2023.

4. CVL-871 is a selective dopamine D1/D5 partial agonist specifically designed to achieve a modest level of partial agonism, which we believe may be useful in modulating the complex neural networks that govern cognition, motivation and apathy behaviors in neurodegenerative diseases. In June 2021, the FDA granted Fast Track Designation for CVL-871 for the treatment of dementia-related apathy. We began screening patients in an exploratory Phase 2a trial for dementia-related apathy in the second quarter of 2021 with data expected in the second half of 2022.

5. CVL-936 is a selective dopamine D3-preferring antagonist that we are developing for the treatment of substance use disorder, or SUD. We have received a notice of award for cooperative grant funding from the National Institute on Drug Abuse, or NIDA, to support the development of this compound in opioid use disorder, or OUD. We initiated a Phase 1 single ascending dose, or SAD, trial in January 2020. We concluded dosing of Cohort 1 of the Phase 1 SAD trial after receiving sufficient clinical data for the intended purposes for this trial. We intend to conduct a multiple dose canine electroencephalogram, or EEG, study prior to additional Phase 1 SAD and MAD evaluations.

We believe that all five of our clinical-stage product candidates have target product profiles that may enable them to become backbone therapies in their respective lead indications, either replacing standards of care as monotherapies or enhancing treatment regimens as adjunct to existing therapies. Results from the clinical trials mentioned above will guide the potential development of our product candidates in additional indications with similar neurocircuitry deficits.

In addition to our clinical-stage pipeline, we plan to advance the development of our preclinical portfolio across multiple neuroscience indications. This preclinical portfolio includes CVL-354, our selective kappa opioid receptor antagonist, which we refer to as KORA, which we are developing in major depressive disorder, or MDD, and SUD, and for which we submitted an IND in the second quarter of 2021. In addition, we are developing CVL-047, our selective PDE4 inhibitor (PDE4D-sparing), for the treatment of MDD and schizophrenia, and we plan to submit an IND in the fourth quarter of 2021. We are deploying the latest technologies, such as artificial intelligence and DNA-encoded chemical libraries, to efficiently identify new therapeutic molecules, including those with disease-modifying potential. We believe that our targeted approach to neuroscience will enable us to create a leading drug discovery and development platform to transform the lives of patients living with neuroscience diseases.

Behind our portfolio stands a team with a multi-decade track record of drug approvals and commercial success. This track record has been driven by their extensive experience with empirically-driven clinical trial design and implementation, a history of successful interactions with regulatory agencies and relationships with global key opinion leaders. We believe that the distinctive combination of our management team and our existing pipeline has the potential to bring to patients the next generation of transformative neuroscience therapies.

Our approach

Fundamental to our targeted approach to neuroscience is understanding how deficits in neurocircuitry drive the development of symptoms in neuroscience diseases. Achieving optimal therapeutic benefit and minimizing unintended side effects in neuroscience diseases requires tuning the specificity and dynamic range of neural networks. Recent advancements in chemistry, genomics and proteomics have provided tools to enable targeted receptor selectivity with specificity to neural networks that underlie disease symptomatology. Fine-tuning the dynamic range of selective neurotransmitter neurocircuitry requires carefully designed receptor pharmacology, such as allosteric modulation or partial agonism, to normalize neural network function without over-activation or over-suppression.

Below are the key pillars of our targeted approach to neuroscience:

- ***Mechanism of action—targeted receptor selectivity:*** A single neurotransmitter can act on multiple receptor subtypes that are expressed differentially among neuron types and neural networks within the brain and nervous system. We believe the ability to selectively target neurotransmitter receptor subtypes may provide an important opportunity to achieve maximum activity within specific neural networks while minimizing unintended interactions in other areas of the nervous system that are targeted by non-selective compounds and result in unwanted side effects.
- ***Receptor pharmacology:*** Neural networks in the brain operate within a dynamic range, and our understanding of disease state mechanics allows us to design molecular attributes that are intended to normalize this range for each disease. For example, classical full receptor agonism or antagonism may fully activate or inactivate neural circuits and can compensate for disease but also may limit normal functional dynamic range. However, partial agonism or allosteric modulation can correct or fine-tune the range of network signaling without fully blocking or overexciting normal activity. Each disease state represents a unique abnormality in neural network activity requiring a nuanced pharmacological approach. In addition, molecules require specific physical and metabolic properties to become a viable commercial product. Incorporating all of these characteristics into a single molecule can be extremely challenging. The evidence to date for our product candidates suggests that they may balance targeted selectivity with optimal receptor pharmacology. We believe this underscores the differentiation and therapeutic potential of our pipeline.
- ***Robust clinical and preclinical evaluation*:** Our clinical-stage product candidates have undergone robust clinical and preclinical testing to provide support for continued advancement through the clinical development process. In these early clinical trials and preclinical studies, we have generally observed PK, bioavailability, brain penetration and reduced off-target activity, that demonstrate the potential for reducing tolerability issues. In addition, data from these trials support dose selection generally informed by PET receptor occupancy trials and clinical biomarkers. Based on extensive characterization and research, our product candidates were designed to reproduce validated biological activity while addressing the limitations of prior known compounds. We believe the wealth of clinical and preclinical data generated to date strongly positions our product candidates for clinical advancement.

Our pipeline

The following table summarizes our current portfolio of product candidates. This table does not include two additional preclinical programs with disease-modifying potential that have not yet been disclosed.

Our product candidates

CVL-231

We are developing CVL-231 for the treatment of schizophrenia. CVL-231 was rationally designed as a PAM that selectively targets the M4 receptor subtype to harness the anti-psychotic benefit believed to be associated with M4 while minimizing the cholinergic side effects typically associated with pan-muscarinic agonists. We believe CVL-231 has the potential to mark a significant medical advancement as the muscarinic acetylcholine pathway has long been associated with mediation of neurotransmitter imbalance underlying psychosis. To our knowledge, CVL-231 is the only M4-selective PAM currently active in clinical development.

CVL-231 demonstrated robust activity in multiple preclinical psychosis models, including potential benefit in improving cognitive endpoints. Our development plan for CVL-231 is informed by thorough *in vitro* and *in vivo* PK and PD characterization as well as data from competitive muscarinic compounds. CVL-231 has been evaluated in 17 healthy volunteers in a Phase 1 SAD trial which showed that it was generally well tolerated with no serious adverse events or treatment-related subject discontinuations.

We conducted a Phase 1b MAD trial to assess the safety, tolerability, PK and PD of CVL-231 in patients with schizophrenia. In June 2021, we announced topline results for the Phase 1b trial. Both doses of CVL-231 demonstrated a clinically meaningful and statistically significant improvement in Positive and Negative Syndrome Scale, or PANSS, total score at 6 weeks and were overall well-tolerated compared with placebo. See

"—Our Product Candidates—CVL-231—Phase 1b Multiple Ascending Dose Trial" for more information. The results of this trial support the advancement of CVL-231 into Phase 2 for schizophrenia. We also plan to conduct two positron emission tomography, or PET, trials in healthy volunteers to understand CVL-231 receptor occupancy and its impact on dopamine receptor PD, which will inform dose selection for our later-stage clinical trials.

Darigabat (formerly CVL-865)

We are developing darigabat for the treatment of both epilepsy and anxiety. Darigabat was rationally designed as an orally bioavailable, twice-daily PAM that selectively targets the alpha-2/3/5 subunits of the $GABA_A$ receptor. We believe that by having minimal receptor activation via the alpha-1 subunit-containing $GABA_A$ receptor, darigabat can minimize the negative side effects of sedation and potential for loss of efficacy with repeated use, or tolerance, and addiction seen with traditional non-selective $GABA_A$ receptor modulators, such as benzodiazepines, or BZDs. To our knowledge, darigabat is the only alpha-2/3/5 selective $GABA_A$ receptor PAM being evaluated in clinical trials for epilepsy.

Darigabat has been evaluated in 289 subjects across nine prior clinical trials. In a Phase 2, double-blind, crossover trial in photoepilepsy patients comparing darigabat to lorazepam, a commonly prescribed BZD, and to placebo, darigabat demonstrated anti-epileptic activity similar to lorazepam. In this trial, six out of seven photosensitive patients taking darigabat achieved complete suppression of epileptiform activity evoked by strobe lights. In a Phase 1 trial comparing darigabat to lorazepam, healthy volunteers were assessed using the NeuroCart CNS test battery to characterize the PD of darigabat. Compared with lorazepam, darigabat demonstrated a greater reduction in saccadic peak velocity, a biomarker indicating engagement of alpha-2/3 subunit-containing $GABA_A$ receptors, while having reduced effects on motor coordination (sedation) and cognition. In a Phase 1 MAD trial in healthy volunteers, darigabat showed no dose-related somnolence after the initial titration period, even at dose levels consistent with receptor occupancy of approximately 80%. Taken together, we believe these data suggest that darigabat may have the potential for anti-epileptic activity comparable to currently available BZDs, with reduced sedation, tolerance and withdrawal liabilities that, unlike BZDs, can be dosed chronically.

Based on this extensive clinical data, we initiated REALIZE, a Phase 2 proof-of-concept trial evaluating darigabat as an adjunctive therapy in patients with focal epilepsy, in the second half of 2020, with data expected in the second half of 2022. The focal epilepsy population is the largest subpopulation of epilepsy patients and is often studied to establish proof-of-concept in the development of an anti-epileptic drug, or AED. We also initiated a Phase 1 proof-of-principle trial for acute anxiety in healthy volunteers in the second half of 2020 with data expected in the fourth quarter of 2021.

Tavapadon

We are developing tavapadon for the treatment of both early- and late-stage Parkinson's, a neurodegenerative disorder characterized by the death of dopamine-producing neurons in the brain. Tavapadon was rationally designed as an orally bioavailable, once-daily partial agonist that selectively targets dopamine D1/D5 receptor subtypes with the goal of balancing meaningful motor control activity with a favorable tolerability profile. To our knowledge, tavapadon is the only D1/D5 partial agonist currently in clinical development for Parkinson's and the first oral D1/D5 agonist to have achieved sustained motor control improvement in Phase 2 trials of Parkinson's.

As part of an extensive clinical program, tavapadon has been evaluated in 272 subjects across nine prior clinical trials, including four Phase 1 trials, two Phase 1b trials and three Phase 2 trials. In a Phase 2 trial in early-stage Parkinson's, tavapadon demonstrated a statistically significant and clinically meaningful difference from placebo of -4.8 points on the MDS-UPDRS Part III motor score at week 15 of the treatment period. Separation from placebo was observed as early as week three while still in the titration phase. In a Phase 2 trial in late-stage Parkinson's, tavapadon showed a 1.0-hour improvement versus placebo in "on" time without troublesome

dyskinesias at week 10 with a sustained effect observed through week 15, which we and our clinical advisors believe is clinically meaningful. Across the nine prior clinical trials, tavapadon has consistently demonstrated what we believe to be a favorable tolerability profile as well as a PK profile with a 24-hour terminal half-life, supporting once-daily dosing.

Based on this extensive clinical data, we initiated a registration-directed Phase 3 program beginning in January 2020, which will include TEMPO-1 and TEMPO-2 trials in early-stage Parkinson's, TEMPO-3 in late-stage Parkinson's and TEMPO-4, an open-label safety extension trial. We expect initial data from our Phase 3 program to be available beginning in the first half of 2023.

CVL-871

We are developing CVL-871 for the treatment of dementia-related apathy. Apathy is the leading neuropsychiatric symptom in patients with dementia. It is also one of the strongest symptomatic predictors of disease progression. While clinicians, patients and caregivers have been challenged by this symptom, there are no currently approved therapies for dementia-related apathy. The FDA has demonstrated interest in development of a therapy for this indication, and in June 2021, we announced that the FDA has granted Fast Track Designation for CVL-871 in dementia-related apathy. CVL-871 is a selective partial agonist of dopamine D1/D5 receptor subtypes specifically designed to achieve a modest level of partial agonism, which we believe may be useful in modulating the complex neural networks that govern cognition, motivation and apathy behaviors in neurodegenerative diseases. Dopamine acting on D1/D5 receptor subtypes in the cortex and midbrain plays a key role in the finely-tuned and dynamic neural network that modulates cognitive function, reward-processing and decision-making. In patients with Parkinson's disease, we have observed that improving motor symptoms requires higher levels of partial agonism to offset the large losses in dopaminergic neurons in the motor cortex. In contrast, dementia patients require a more finely-tuned modulation of the neural networks that govern cognition, motivation and behavior to normalize the dynamic range of the mesocortical and mesolimbic neurocircuitry. As such, we have designed CVL-871 to have a lower level of partial agonism than tavapadon. The hypothesis for using D1/D5 receptor subtype partial agonism to treat dementia-related apathy is informed by clinical trials of other compounds where increases in dopamine activity resulted in a statistically significant improvement on apathy scales. We believe CVL-871, while potentially avoiding the cardiovascular effects of stimulant medications, may possess an optimal profile to target this new indication due to the degree to which it activates relevant dopamine circuits within the brain.

CVL-871 has been evaluated in two Phase 1 trials in a total of 58 subjects. In these trials, CVL-871 was observed to be generally well tolerated. We also observed evidence of moderate improvement in motor symptoms, a measure of biological activity, along with a PK profile that supports the potential for once-daily dosing. Based on these findings, we submitted an IND to the FDA in the first quarter of 2021 and we are conducting an exploratory Phase 2a trial for dementia-related apathy with data expected in the second half of 2022.

CVL-936

We are developing CVL-936 for the treatment of SUD, with an initial focus on opioid use disorder, or OUD. In order to maximize potential for activity, CVL-936, a selective dopamine D3-preferring, D2/D3 receptor subtype antagonist, was designed to block D3 signaling within the brain while also simultaneously reducing (but not fully inhibiting) signaling at the D2 receptor subtype. CVL-936 has shown encouraging activity in translationally relevant preclinical models of both cessation and relapse using nicotine and opioid-induced cues. Based on its profile, we expect CVL-936 will allow for dosing to levels that may result in near complete and sustained blockade of D3 signaling within the brain, which may be useful in treating SUD.

We have received a notice of award for cooperative grant funding from NIDA to support the development of this compound in OUD. We initiated a Phase 1 SAD trial in January 2020. We concluded dosing of Cohort 1 of the

Phase 1 SAD trial after receiving sufficient clinical data for the intended purposes for this trial. We intend to conduct a multiple dose canine EEG study prior to additional Phase 1 SAD and MAD evaluations.

Preclinical assets

In addition to the clinical-stage product candidates described above, we plan to further characterize and appropriately advance our preclinical pipeline across multiple potential neuroscience indications. Our preclinical pipeline includes:

- CVL-354, our selective KORA that we are advancing for the treatment of MDD and SUD;
- CVL-047, our selective PDE4 inhibitor (PDE4D-sparing) that we are advancing for the treatment of MDD and schizophrenia;
- our M4 full/partial agonist program for potential use in schizophrenia; and
- our LRRK2 inhibitor program that has the potential to address disease progression in Parkinson's.

We are also pursuing other undisclosed targets, including those with disease-modifying potential. These programs include evaluating those initiated by Pfizer as well as others developed internally through the application of human genetic analyses and new technology platforms, such as artificial intelligence and DNA-encoded chemical libraries to establish novel chemical lead series that is designed to enable better understanding of their therapeutic potential.

Our strategy

We seek to transform the lives of patients with neuroscience diseases by pursuing a targeted approach to neuroscience and leveraging our deep understanding of neurocircuitry, chemistry and receptor pharmacology. Our strategy is to:

- Establish our position as a leader in neuroscience drug discovery and development through the advancement of a diverse and innovative pipeline. We leverage our differentiated understanding of neurocircuitry as well as our innovative clinical trial design and execution to develop our assets across multiple indications. In addition, we are investing in future areas of neuroscience research, including the discovery and development of compounds with disease-modifying potential.
- Rapidly develop our five clinical-stage assets, with six clinical trials underway or expected to start by the end of 2021 and up to seven clinical data readouts expected by the end of 2023. We conducted a Phase 1b MAD trial to assess the safety, tolerability, PK and PD of CVL-231 in patients with schizophrenia. In June 2021, we announced results from this Phase 1b trial. The results of this trial support the advancement of CVL-231 into Phase 2 in schizophrenia. We are also conducting a Phase 2 proof-of-concept trial of darigabat in focal epilepsy and a Phase 1 proof-of-principle trial in acute anxiety in healthy volunteers, with data expected in the second half of 2022 and the fourth quarter of 2021, respectively. In addition, in January 2020, we initiated our registration-directed Phase 3 program for tavapadon. This program includes three Phase 3 trials in both early- and late-stage Parkinson's that will be conducted in parallel as well as an open-label extension trial. If approved, we believe that tavapadon would have the potential to become a cornerstone therapy for Parkinson's patients across the disease spectrum. Furthermore, we are conducting an exploratory Phase 2a trial of CVL-871 for dementia-related apathy in the second quarter of 2021 with data expected in the second half of 2022. Finally, we are developing CVL-936, which is currently in Phase 1 for the treatment of SUD.
- Advance our preclinical portfolio across multiple neuroscience indications. Our preclinical pipeline includes: (1) CVL-354, our selective KORA that we are advancing for the treatment of MDD and SUD; (2) CVL-047, our

selective PDE4 inhibitor (PDE4D-sparing) that we are advancing for the treatment of MDD and schizophrenia; (3) our M4 full/partial agonist for potential use in schizophrenia; and (4) our LRRK2 inhibitor that has the potential to address disease progression in Parkinson's. We are also pursuing a number of other undisclosed targets, including those with disease-modifying potential. These programs include ones initiated by Pfizer as well as others developed internally through the application of new technology platforms, such as artificial intelligence and DNA-encoded chemical libraries.

- Efficiently allocate capital to maximize the impact of our assets. We seek to efficiently allocate capital through stepwise value creation: driving speed to proof-of-principle, speed to proof-of-concept and speed to market. For example, our early-stage clinical trials are designed to elucidate the potential of our compounds and inform future clinical trials, thereby strengthening our probability of success and our efficiency in bringing our therapies to patients. We aim to be resource- and capital-efficient in the development of our product candidates by selectively accessing complementary expertise and infrastructure through strategic partnerships or other collaborations. We are also building a leading neuroscience team that we believe has a differential ability to identify high-potential assets for acquisition or in-licensing and unlock their full value. We plan to opportunistically pursue such assets from time to time and strategically expand our portfolio.
- Opportunistically match sources and uses of capital. Our broad portfolio both requires and provides a basis for diverse financing options. We will seek to maximize growth opportunities, which may include raising additional capital through a combination of private or public equity offerings, debt financings, royalty-based financing, collaborations, strategic alliances, marketing, distribution or licensing arrangements with third parties or through other sources of financing. By matching sources and uses of capital, we can maximize our value creation opportunities while mitigating operational risk through partnerships.
- Maximize the commercial potential of our product candidates and bring new therapies to underserved patient populations. Our development and commercialization strategy will be driven by our understanding of existing treatment paradigms along with patient, physician and payor needs. We expect to build a focused and efficient medical affairs and commercial organization to maximize the commercial potential of our portfolio. Our current plan is to commercialize our product candidates, if approved, in the United States and international markets, either alone or in collaboration with others.

Our team and corporate history

Since our founding in 2018, we have assembled a seasoned management team with expertise in neuroscience research, development, regulatory affairs, medical affairs, operations, manufacturing and commercialization. Our team includes industry veterans who have collectively driven over 20 drug approvals, with prior experience at companies such as Biogen, Bristol-Myers Squibb, Merck, NPS Pharmaceuticals, Onyx Pharmaceuticals, Otsuka Pharmaceutical, Sangamo Therapeutics, Vertex Pharmaceuticals and Yumanity Therapeutics. We have an experienced research and development team focused on utilizing our differentiated understanding of the complex neurocircuitry, receptor pharmacology and genetics that underlie neuroscience diseases. This allows us to develop small molecules with target receptor selectivity and indication-appropriate pharmacology, which we believe are key to enhancing activity and improving tolerability in the treatment of these diseases. We believe that the distinctive combination of our management team and our existing pipeline has the potential to bring to patients the next generation of transformative neuroscience therapies.

In August 2018, we entered into the Pfizer License Agreement, pursuant to which we in-licensed our current pipeline from Pfizer. Under the terms of the Pfizer License Agreement, we are required to pay Pfizer tiered royalties on aggregate net sales of in-licensed products as well as certain regulatory and commercial milestone payments. See "*—Pfizer License Agreement*."

In October 2020, we completed our business combination with ARYA Sciences Acquisition Corp II pursuant to which we debuted as a publicly traded company.

Our product candidates

CVL-231

We are developing CVL-231 for the treatment of schizophrenia. CVL-231 was rationally designed as a PAM that selectively targets the M4 receptor subtype to harness the anti-psychotic benefit believed to be associated with M4 while minimizing the side effects typically associated with pan-muscarinic agonists. We believe CVL-231 has the potential to mark a significant medical advance as the muscarinic acetylcholine pathway has long been associated with mediation of neurotransmitter imbalance and psychosis. To our knowledge, CVL-231 is the only M4-selective PAM currently in clinical development. We conducted a Phase 1b MAD trial to assess the safety, tolerability, PK and PD of CVL-231 in patients with schizophrenia. In June 2021, we announced topline results for the Phase 1b trial. Both doses of CVL-231 demonstrated a clinically meaningful and statistically significant improvement in Positive and Negative Syndrome Scale, or PANSS, total score at 6 weeks and were overall well-tolerated compared with placebo. See “—Our Product Candidates—CVL-231—Phase 1b Multiple Ascending Dose Trial” for more information. The results of this trial support the advancement of CVL-231 to Phase 2 in schizophrenia.

Schizophrenia background

Schizophrenia is a serious, complex and debilitating mental health disorder characterized by a constellation of symptoms, including delusions, hallucinations, disorganized speech or behavior, slowed speech and blunted affect. Schizophrenia is also often associated with significant cognitive impairment, which further limits a patient’s ability to be gainfully employed and maintain relationships. Diagnosis of schizophrenia is usually made in young adulthood and the disease follows a chronic and indolent course characterized by periods of remission and relapse. People with schizophrenia have a 10 to 25-year reduction in life expectancy compared to the general population. An estimated 20 million people worldwide suffer from schizophrenia, including up to 2.1 million people in the U.S.

A disruption in the balance of neurotransmitters, including dopamine, serotonin, glutamate, aspartate, glycine and GABA, is believed to be responsible for the pathogenesis of schizophrenia. Abnormal activity at dopamine receptors, specifically the D2 receptor subtype, in the mesolimbic pathway that results in excess dopaminergic transmission is thought to be associated with many of the psychotic symptoms of schizophrenia. Currently available therapies for schizophrenia are all presumed to work through the antagonism of various dopamine receptors, although the exact mechanisms of action for these agents are unknown. Second-generation atypical antipsychotics, or SGAs, such as risperidone, paliperidone and aripiprazole, are recommended as first- line treatment for schizophrenia. SGAs have a lower risk of extrapyramidal symptoms, including abnormal motor side effects, compared to first-generation antipsychotics, or FGAs, such as chlorpromazine and haloperidol. However, SGAs are more likely to cause weight gain, metabolic syndrome, diabetes and dyslipidemia, leading to long-term cardiovascular morbidity. Both SGAs and FGAs can cause hyperprolactinemia, a hormonal imbalance resulting from D2 receptor blockade, which can lead to enlargement of breast tissue in males and infertility. Approximately 10% of patients are prescribed FGAs as first-line therapy, while 90% of patients start with an SGA.

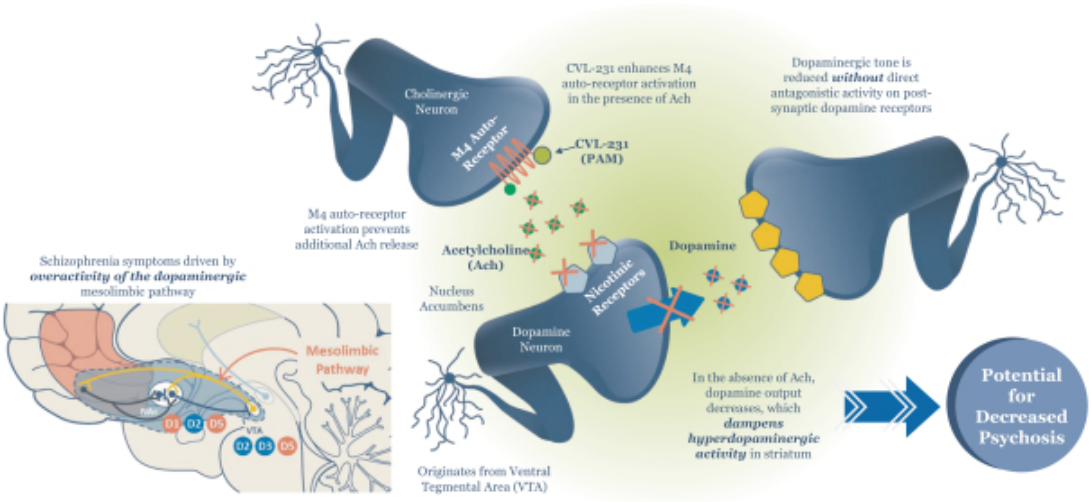
Treatment selection is highly individualized and the current approach is largely one of trial and error across sequential medication choices. Using two or even three different antipsychotic agents together is common, though this practice is not encouraged given the potential for an increased risk of drug-drug interactions, side effects, non-adherence and medication errors.

Despite available therapies, only 20% of patients report favorable treatment outcomes. Medication adherence is poor in patients with schizophrenia, with a compliance rate of about 60% and a discontinuation rate of 74% within 18 months. Patients who discontinue their medication suffer from high relapse rates of 77% at one year and 90% at two years. The further progression of disease is driven by the cycle of repetitive relapse over time. Each relapse in schizophrenia marks a progression in disability, leading physicians to prioritize efficacy in selecting first-line therapy. No new therapies with novel mechanisms of action have been approved for the treatment of schizophrenia in over 20 years. There remains a significant unmet need for more effective therapies with better tolerability profiles in the treatment of schizophrenia.

Muscarinic receptors in schizophrenia

One of the leading theories on the etiology of schizophrenia is that an overactivity of dopamine in certain brain regions is closely associated with the prevailing psychotic symptoms. Current antipsychotics target a direct blockade of dopamine receptors. While this approach is effective at reducing symptoms, it also leads to significant side effects.

Presynaptic expression of the M4 receptor subtypes balances acetylcholine and dopamine in the striatum, which is the region of the brain primarily responsible for psychotic symptoms. The imbalance of acetylcholine and dopamine is hypothesized to contribute to psychosis in schizophrenia. Unlike other muscarinic receptors, M4 receptor subtypes are differentially expressed in the striatum. Activation of muscarinic receptors prevents acetylcholine release, which has been shown to indirectly modulate levels of dopamine without the direct D2/D3 receptor blockade that has been theorized to cause some of the unwanted motor symptoms of current antipsychotics. Thus, selective activation of M4 has the potential to treat the neurobehavioral components such as psychosis, agitation and cognitive deficits that are associated with schizophrenia and other neurodegenerative diseases like Alzheimer's and Parkinson's, while potentially mitigating some of the side effects of current antipsychotics. This mechanism of action is illustrated below:



Clinical trials of xanomeline, a full muscarinic agonist relatively selective for the M4 and M1 subtypes, demonstrated that activation of muscarinic receptors led to dose-dependent improvements in a number of psychiatric symptoms, including psychosis, cognition, agitation and aggression in both schizophrenia and Alzheimer's patients. Despite these compelling results, further clinical development of xanomeline as a monotherapy was halted due to severe gastrointestinal side effects, including a greater than 50% discontinuation rate, which were likely mediated by non-selective M2 and M3 receptor activation. Furthermore,

recent studies in knockout mice with the M4 receptor subtype eliminated suggest that the antipsychotic activity attributed to xanomeline is likely driven primarily by M4 and that a more selective muscarinic activator could potentially convey similar clinical benefits while minimizing gastrointestinal side effects.

Our solution—CVL-231

CVL-231 is a PAM that selectively targets the M4 receptor subtype. We are developing CVL-231 for the treatment of schizophrenia. Key differentiating features of CVL-231 include:

1. Mechanism of action—M4 receptor subtype selectivity: Based on *in vitro* testing, CVL-231 is >600x more selective for M4 than for M1/3/5 and approximately 360x more selective for M4 than for M2. Recent preclinical studies in knockout mice with the M4 receptor subtype eliminated suggest that the antipsychotic activity attributed to xanomeline is likely driven primarily by M4 and that a more selective muscarinic activator could potentially convey similar clinical benefit while minimizing gastrointestinal side effects associated with activity at M2 and M3 receptors.

2. Receptor pharmacology—PAM: CVL-231 is an orally bioavailable, brain-penetrant small molecule with an approximate nine- to 12-hour half-life. As a PAM of the M4 receptor subtype, CVL-231 is designed to enhance normal neurotransmitter release without producing excessive stimulation. In comparison, full agonists can lead to receptor desensitization and an ultimate loss of efficacy. In addition, the available preclinical data for CVL-231 suggest a low potential for drug-drug interactions, which is important in indications like schizophrenia where several drugs are often used in combination.

3. Clinical and preclinical evaluation: CVL-231 demonstrated robust activity in multiple preclinical psychosis models, including potential benefit in improving cognitive endpoints. Our development plan is informed by thorough *in vitro* and *in vivo* PK and PD characterization of CVL-231 as well as data from competitive muscarinic compounds. CVL-231 has been evaluated in a Phase 1 SAD trial in healthy volunteers. In June 2021, we completed a Phase 1b MAD trial to assess the safety, tolerability, PK and PD of CVL-231 in patients with schizophrenia. Both doses of CVL-231 demonstrated a clinically meaningful and statistically significant improvement in Positive and Negative Syndrome Scale, or PANSS, total score at 6 weeks and were overall well-tolerated compared with placebo.

We believe CVL-231 has the potential to be a new generation antipsychotic that could become the treatment of choice for schizophrenia, if approved. Each relapse in schizophrenia marks a progression in disability, leading physicians to prioritize efficacy in selecting first-line therapy. With the potential for antipsychotic activity that we believe may exceed existing atypical antipsychotics, CVL-231 could become an attractive option in newly diagnosed patients. Additionally, given its potentially improved tolerability profile relative to atypical antipsychotics, CVL-231 could displace existing options for patients where there is evidence of treatment-related side effects.

Success in treating psychosis in schizophrenia would potentially open the door to further development in dementia-related psychosis as well as treating the cognitive deficits associated with these diseases.

Clinical trials

CVL-231 has been evaluated in 17 healthy volunteers in a Phase 1 SAD trial and 54 schizophrenia patients in a Phase 1b MAD trial. CVL-231 was generally well tolerated with no serious adverse events, or SAEs, or treatment-related subject discontinuations. However, some moderate treatment-emergent increases in heart rate and blood pressure were observed following single doses of CVL-231 (>10 mg) that were generally transient and returned to baseline in 24 hours. These increases may be mediated by CVL-231's activity on the M4 receptor subtype, either peripherally or centrally;

increased heart rate has been observed in some other antipsychotic drugs due to their anticholinergic properties. Preclinical safety and pharmacology studies have suggested that the increases in heart rate and blood pressure were reversible and can be monitored. In a 13-week canine toxicology study of CVL-231, heart rate increases were observed to be mostly resolved through sustained dosing. This effect was further supported by evaluation of our full M4 agonist product candidate in rodents, in which increases in heart rate and blood pressure were attenuated with repeat dosing. CVL-231 has also been tested in several preclinical models that have been used to characterize known antipsychotic medications. The overall results from our preclinical studies showed the potential of CVL-231 to reduce dopaminergic hyperactivation without resulting in catalepsy, or muscular rigidity. In June 2021, we completed a Phase 1b MAD trial to evaluate the potential safety, tolerability, PK and preliminary PD of repeated daily doses of CVL-231 in patients with schizophrenia. Both doses of CVL-231 demonstrated a clinically meaningful and statistically significant improvement in Positive and Negative Syndrome Scale, or PANSS, total score at 6 weeks and were overall well-tolerated compared with placebo.

Phase 1b Multiple Ascending Dose Trial

In June 2021, we completed a two-part, Phase 1b MAD trial to evaluate the safety, tolerability, PK and preliminary PD of repeated daily doses of CVL-231 in patients with a primary diagnosis of schizophrenia per the Diagnostic and Statistical Manual of Mental Disorders, or DSM-V.

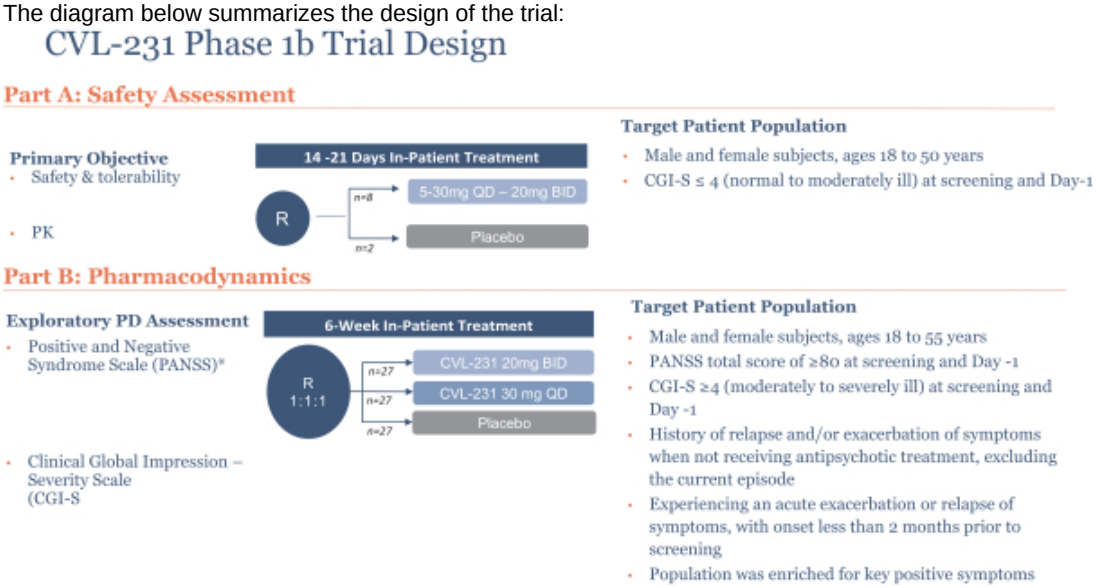
The objectives of Part A of the trial were to characterize physiological effects, identify any dose-limiting tolerability effects, and to identify the maximum tolerated dose of CVL-231 in patients with schizophrenia. The measures used for this evaluation included treatment-emergent AEs, ECG results, vital signs measurement, clinical laboratory tests, physical and neurologic exams, suicidality as assessed by the Columbia-Suicide Severity Rating Scale, or C-SSRS, and extrapyramidal symptoms based on the Simpson-Angus Scale, or the SAS, Abnormal Involuntary Movement Scale, or the AIMS, and Barnes Akathisia Rating Scale, or the BARS, assessments.

Once a dosing regimen was identified in Part A of the trial, further safety, PK and preliminary PD were examined in Part B. The measures used for this evaluation included change from baseline in PANSS total score and subscales (negative, positive and general psychopathology), the Clinical Global Impression of Severity, or CGI-S, and the Brief Assessment of Cognition in Schizophrenia, or BACS, symbol coding test. PANSS is a widely used and validated measure of the severity of the core positive and negative symptoms associated with schizophrenia, as defined by the DSM-V. CGI-S is included as a supplementary scale to provide a global assessment of clinical status. The symbol coding test of the BACS is a highly sensitive measure of cognitive defects in patients with schizophrenia and is included as an exploratory measure to evaluate cognition.

In Part A, the key inclusion criteria included men and women 18 to 50 years of age with a CGI-S £ 4 at screening and at Day -1 and a PANSS total score £ 80 at the time of screening and at Day -1. Daily doses of 5 mg to 40 mg (administered as 20 mg twice daily, or BID) were explored with up to 21 days of administration at target dosage. The Part A MAD safety and tolerability data were supportive of proceeding to 6 weeks of dosing in the subsequent Part B portion of the trial.

In Part B, the key inclusion criteria included (i) men and women 18 to 55 years of age, (ii) a CGI-S ³ 4 at screening and at Day -1, (iii) a PANSS total score ³ 80 at the time of screening and at Day -1, (iv) a history of relapse and/or exacerbation of symptoms when not receiving treatment, excluding the current episode, and (v) experiencing an acute exacerbation or relapse of symptoms, with onset less than two months prior to screening.

The diagram below summarizes the design of the trial:



* Trial not designed to demonstrate statistical significance

In Part B, 81 patients having the following demographics and baseline characteristics were randomized into one of two doses of CVL-231 or placebo.

Phase 1b Part B: Demographics & Baseline Characteristics

	PBO N= 27	CVL-231 30 mg QD N= 27	CVL-231 20 mg BID N= 27	All CVL-231 N= 54	Total N= 81
Demographics					
Age (years) at Screening: Mean (SD)	41 (9.7)	41(8.1)	38 (9.8)	40 (9.0)	40 (9.2)
% Male: N (%)	19 (70%)	23 (85%)	21 (78%)	44 (81%)	63 (78%)
Race: N (%)					
Black or African American	17 (63%)	20 (74%)	19 (70%)	39 (72%)	56 (69%)
White	9 (33%)	7 (26%)	7 (26%)	14 (26%)	23 (28%)
Other	1 (4%)	0	1 (4%)	1 (2%)	2 (2%)
Weight (kg) Prior to Dosing: Mean (SD)	90.0 (16.0)	85.4 (13.3)	85.4 (15.4)	85.4 (14.3)	86.9 (14.9)
Disease Characteristics at Baseline: Mean (SD)					
PANSS Total Score	93 (8.8)	93 (7.3)	97 (7.9)	95 (7.7)	95 (8.1)
PANSS Positive Score	24 (2.7)	25 (3.0)	26 (2.6)	26 (2.8)	25 (2.8)
PANSS Negative Score	23 (3.3)	22 (3.7)	24 (3.8)	23 (3.8)	23 (3.6)
CGI-S Score	5 (0.6)	5 (0.5)	5 (0.7)	5 (0.6)	5 (0.6)

The endpoint used to measure the antipsychotic effect was the PANSS total score. The trial was 59% powered to detect a 7 point difference from placebo on the PANSS total score. Additional endpoints that we evaluated

included the PANSS positive and PANSS negative subscales as well as the CGI-S. The primary pharmacodynamic results from the trial are as follows:

Pharmacodynamic Results Summary*

Week 6 (Day 42)	Placebo N=27	CVL-231 30 mg QD N= 27	CVL-231 20 mg BID N= 27	Combined CVL-231 N=54
PANSS Total Score				
LS Mean Change from Baseline	-6.8	-19.5	-17.9	-18.7
Difference vs Placebo (p-value)†		-12.7†	-11.1†	-11.9†
		p = 0.023	p = 0.047	p = 0.014
PANSS Positive Score				
LS Mean Change from Baseline	-2.5	-6.8	-4.9	-5.8
Difference vs Placebo (p-value)		-4.3	-2.4	-3.3
		p = 0.016	p = 0.166	p = 0.028
PANSS Negative Score at Baseline				
LS Mean Change from Baseline	0.1	-3.0	-3.6	-3.3
Difference vs Placebo (p-value)		-3.1	-3.7	-3.4
		p = 0.009	p = 0.002	p = 0.001

* Trial originally designed to be 59% powered to detect 7 point difference in PANSS total score vs. placebo
† Corresponds to Cohen's D effect sizes at Week 6 of -0.68 for CVL-231 30 mg QD, -0.59 for CVL-231 20 mg BID, and -0.64 for the two doses combined

Both doses of CVL-231 demonstrated clinically meaningful and statistically significant antipsychotic effects, with no meaningful differences in gastrointestinal side effects, extrapyramidal symptoms or weight gain compared with placebo. The 30 mg once-daily group demonstrated an improvement of 19.5 while the 20 mg twice daily cohort showed an improvement of 17.9 from baseline on the PANSS Total score after six weeks of treatment. Both treatment groups had statistically significant reductions relative to placebo of 12.7 and 11.1 respectively, with p-values less than 0.05. These results were further supported by statistically significant and clinically meaningful improvements in the PANSS-negative subscale for both doses – the 30 mg once daily group resulted in a point improvement of 3.1 over placebo with a p-value of 0.009 and the 20 mg twice daily group showed a 3.7 improvement over placebo with a p-value of 0.002. We also observed clinically meaningful improvements on the PANSS positive subscale for both doses, with the 30 mg once-daily group demonstrating a statistically significant reduction of 4.3 points versus placebo.

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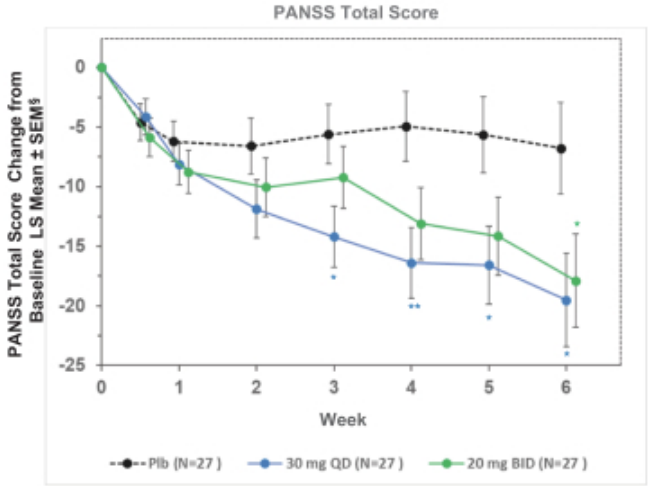
Key Pharmacodynamic Endpoint – PANSS Total Score



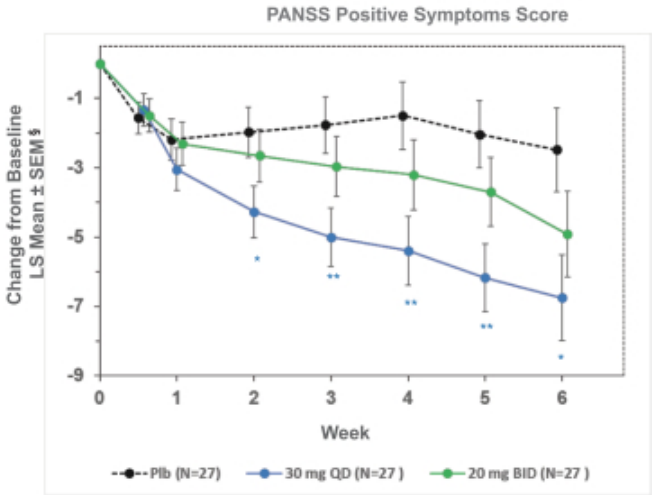
- 30 mg QD: 12.7 Point improvement versus placebo at Week 6 (19.5 of 30 mg QD vs 6.8 placebo) with P=0.023
- 20 mg BID: 11.1 Point improvement versus placebo at Week 6 (17.9 of 20 mg BID vs 6.8 placebo) with P=0.047
- Combined CVL 231: 11.9 Point improvement versus placebo at Week 6 (18.7 of CVL231 vs 6.8 placebo) with P=0.014

* P<0.05 vs Placebo ** P<0.01 vs Placebo

§ Derived from a mixed model for repeated measures (MMRM) with treatment group, visit, treatment group-by-visit interaction as fixed effect, baseline value as a covariate and the measurements within subject as repeated measures. An unstructured covariance matrix was used.

Statistical separation from placebo was achieved in the 30 mg once-daily group beginning at week 3 of the trial. These robust results were also observed when we evaluated the PANSS positive and PANSS negative subscales:

PANSS Positive Symptoms Score

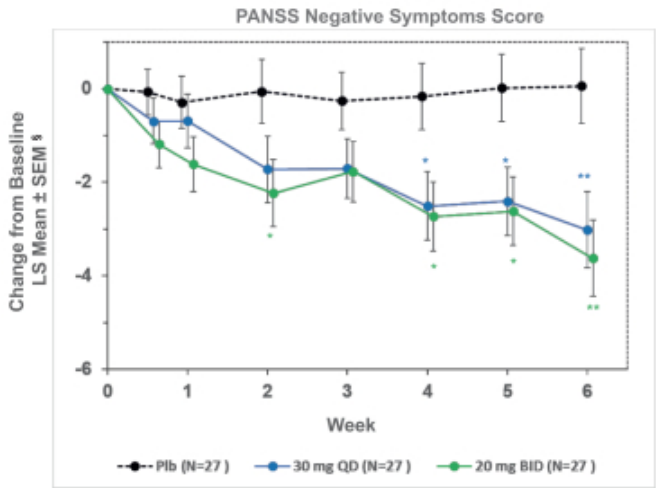


- 30 mg QD: 4.3 Point improvement versus placebo at Week 6 (6.8 of 30 mg QD vs 2.5 placebo) with P=0.016
- 20 mg BID: 2.4 Point improvement versus placebo at Week 6 (4.9 of 20 mg BID vs 2.5 placebo) with P=0.166
- Combined CVL 231: 3.3 Point improvement versus placebo at Week 6 (5.8 of CVL231 vs 2.5 placebo) with P=0.028

* P<0.05 vs Placebo ** P<0.01 vs Placebo

§ Derived from a mixed model for repeated measures (MMRM) with treatment group, visit, treatment group-by-visit interaction as fixed effect, baseline value as a covariate and the measurements within subject as repeated measures. An unstructured covariance matrix was used.

PANSS Negative Symptoms Score



- 30 mg QD: 3.1 Point improvement versus placebo at Week 6 (3.0 of 30 mg QD vs -0.1 placebo) with P=0.009
- 20 mg BID: 3.7 Point improvement versus placebo at Week 6 (3.6 of 20 mg BID vs -0.1 placebo) with P=0.002
- Combined CVL 231: 3.4 Point improvement versus placebo at Week 6 (3.3 of CVL231 vs -0.1 placebo) with P=0.001

* P<0.05 vs Placebo ** P<0.01 vs Placebo

§ Derived from a mixed model for repeated measures (MMRM) with treatment group, visit, treatment group-by-visit interaction as fixed effect, baseline value as a covariate and the measurements within subject as repeated measures. An unstructured covariance matrix was used.

CVL-231 was generally well-tolerated in the clinical trial. The incidence of treatment emergent adverse events for both dose cohorts were similar to placebo, including heart rate and blood pressure increases. The adverse event, or AE, of headache had the highest incidence of reporting across all treatment groups, with placebo at 26%, 30 mg once-daily at 30%, and 26% for the 20 mg twice-daily cohort. Additionally, the rate of nausea was similar between CVL-231 and placebo (4% for placebo and 7% for both 30 mg once-daily and 20 mg twice-daily groups) and rates of other gastrointestinal AEs were very low and similar to placebo. CVL-231 was not associated with a greater incidence of weight gain than placebo and no adverse events related to extrapyramidal symptoms were reported. Serious adverse events reported in the study included COVID-19, accidental overdose, and exacerbation of schizophrenia (one instance of each).

Safety & Tolerability – Adverse Events

	PBO N= 27	**CVL-231 30 mg QD N= 27**	**CVL-231 20 mg BID N= 27**	**All CVL-231 N= 54**
Days on IMP				
Mean (SD)	37 (9.6)	36 (12.8)	35 (13.6)	36 (13.1)
Range	8, 42	4, 42	2, 42	2, 42
Number (%) Subjects with TEAE	14 (52%)	14 (52%)	15 (56%)	29 (54%)
Number (%) Subjects with TEAE Related to IMP	10 (37%)	7 (26%)	12 (44%)	19 (35%)
Number (%) Subjects with Serious TEAE	0	2 (7%)	1 (4%)	3 (6%)
Number (%) Subjects with AE of Special Interest (AESI)	3 (11%)	2 (7%)	4 (15%)	6 (11%)
Number (%) Subjects with TEAE Leading to Discontinuation of IMP	0	2 (7%)	1 (4%)	3 (6%)

The results of this trial support the advancement of CVL-231 to Phase 2 in schizophrenia.

Phase 1 single ascending dose trial

In December 2017, Pfizer completed Trial C2561001, a double-blind, four-period crossover, SAD, Phase 1 trial designed to evaluate the safety and tolerability of CVL-231.

Seventeen healthy volunteers were enrolled into two cohorts. In Cohorts 1 and 2, each subject underwent four treatment periods, receiving three doses of CVL-231 and placebo. CVL-231 and placebo were administered as either an oral solution or suspension. Doses were escalated in each cohort until the maximal tolerated dose was achieved or the maximum pre-defined human exposure limits were reached or projected to be reached. There was a washout period of at least seven days between administered doses. An interleaving cohort design was used such that Cohort 1 received a combination of three of the following doses of CVL-231: 0.3 mg, 3 mg, 15 mg or 30 mg. Cohort 2 received a combination of three of the following doses of CVL-231: 1 mg, 10 mg fed, 10 mg fasted or 30 mg.

In this trial, CVL-231 was observed to be generally well tolerated with no SAEs or treatment-related subject discontinuations. In subjects receiving CVL-231, the most frequently reported adverse events, or AEs, all of which were treatment-related, were fatigue, dizziness, headache and dry mouth. The majority of treatment-related AEs were mild in severity. The moderate treatment-related AEs, which were generally only observed in the highest dose tested, were sinus tachycardia (30 mg); orthostatic hypotension (30 mg); headache (0.3 mg and 30 mg); back pain (30 mg); and postural dizziness (30 mg).

During the course of this trial, moderate treatment-emergent transient increases in blood pressure and pulse rate were observed, which were dose-related and most prominent at the 30 mg dose. Specifically, changes in both supine systolic blood pressure and supine diastolic blood pressure were noted, with mean increases from baseline up to 16.8 mm Hg and 13.0 mm Hg, respectively, in the first 30 mg dose cohort. Similarly, dose-related increases from baseline in supine pulse rate of up to 22.2 bpm were observed in the first 30 mg dose cohort. These observed cardiovascular changes were asymptomatic and transient in nature, generally peaking within one to four hours following an oral dose before being generally resolved within 24 hours without intervention. There was also an AE of orthostatic hypotension that occurred in one subject receiving 30 mg of CVL-231 that was considered by the investigator to be moderately severe and related to treatment. Standing blood pressure values resolved approximately two hours later without intervention. The results from this trial highlight the need to further assess the observed changes in heart rate and blood pressure in a future clinical trial of CVL-231. Preclinical safety and pharmacology studies showed that increases in heart rate and blood pressure were reversible, can be monitored and, in the case of our full M4 agonist product candidate, were observed to be mostly resolved through sustained dosing.

Preclinical studies

CVL-231 was tested in several preclinical models that have been used to characterize known antipsychotic medications. The overall results from our preclinical studies showed the potential of CVL-231 to reduce dopaminergic hyperactivation without resulting in catalepsy. In a mouse study, CVL-231 significantly decreased both spontaneous and amphetamine-induced hyperlocomotion activity to levels similar to haloperidol, which is considered one of the most potent antipsychotics. Furthermore, in a rat pre-pulse inhibition model, an electrical deficit model translatable to patients with schizophrenia, CVL-231 demonstrated a dose-dependent improvement in amphetamine-induced deficits. In order to further explore the potential to affect other symptoms of schizophrenia, like cognitive impairment, CVL-231 was evaluated in a study in rats that measured various aspects of memory function. The results showed improvement in both episodic and working memory, suggesting a potential opportunity for CVL-231 to be differentiated compared to existing medications for schizophrenia.

Planned clinical trials

PET receptor occupancy trials

We will conduct two PET receptor occupancy trials in healthy volunteers to understand the target receptor occupancy and PD of CVL-231. The first trial will evaluate M4 receptor occupancy in various brain regions, using CVL-231 in combination with an M4 PET ligand. This trial will link M4 receptor subtype occupancy with CVL-231 dose/plasma concentration levels. The second trial will evaluate the modulation of striatal levels of dopamine resulting from doses of CVL-231. Reductions in dopamine signaling are believed to be one of the key drivers of antipsychotic effects of currently available medications and are thought to be mediated through antagonism of dopamine receptors. These emerging data will inform dose levels for our later-stage clinical trials and provide data to help us assess the relationship between exposure of CVL-231 to changes in CNS dopamine levels.

Based on the results of the Phase 1b MAD trial and emerging data from the PET receptor occupancy trials, we plan to advance CVL-231 into a Phase 2 program for schizophrenia and further explore opportunities in dementia-related psychosis.

Darigabat (formerly CVL-865)

We are developing darigabat for the treatment of both epilepsy and anxiety. Darigabat was rationally designed as an orally bioavailable, twice-daily PAM that selectively targets the alpha-2/3/5 subunits of the $GABA_A$ receptor. We believe that by having minimal activity via the alpha-1 subunit-containing $GABA_A$ receptor, darigabat can minimize the negative side effects of sedation and potential for tolerance and addiction seen with traditional non-selective $GABA_A$ receptor modulators, such as BZDs. To our knowledge, darigabat is the only alpha-2/3/5-selective $GABA_A$ receptor PAM being evaluated in clinical trials for epilepsy. Based on extensive clinical and preclinical data generated to date, including positive data from a Phase 2 proof-of-principle photoepilepsy trial, we initiated REALIZE, a Phase 2 proof-of-concept trial in patients with focal epilepsy, in the second half of 2020, with data expected in the second half of 2022. The focal epilepsy population is the largest subpopulation of epilepsy patients and is often studied to establish proof-of-concept in the development of an AED. Concurrently, we also initiated a Phase 1 proof-of-principle trial for acute anxiety in healthy volunteers in the second half of 2020, with data expected in the fourth quarter of 2021.

Epilepsy background

Epilepsy is a chronic disorder of the CNS that is characterized by recurrent, unprovoked seizures arising from abnormal electrical discharges in the brain. This may result in alterations of consciousness, involuntary movement or altered sensations. Epilepsy may be related to a brain injury or heredity, but often the cause is unknown. A person is diagnosed as having epilepsy when they have had at least two unprovoked seizures. Epileptic seizures are categorized in two major groups: generalized onset seizures and focal onset seizures. Generalized onset seizures begin with a widespread electrical discharge that involves both sides of the brain at once. Focal onset seizures begin with an electrical discharge in one limited area of the brain.

According to the National Institute of Neurological Disorders and Stroke and the Epilepsy Foundation, approximately 65 million people suffer from epilepsy worldwide. An estimated 57% of all patients with epilepsy experience focal onset seizures while the remaining patients are classified as either having generalized onset seizures (32%) or unknown onset seizures (11%).

The current standard of care for epilepsy is treatment with one or more AEDs, which act through diverse mechanisms of action to reduce abnormal electrical activity in the brain. Example mechanisms include voltage- gated ion channel inhibitors, presynaptic proteins and neurotransmitter receptors such as $GABA_A$ receptors.

Some AEDs have multiple mechanisms and some have only one known mechanism, but many AEDs have dose-limiting side effects and tolerability issues and some patients on AEDs may continue to experience ongoing seizures despite treatment.

Treatment initiation typically starts with a single AED, with dose escalation until seizure control is achieved or AEs become intolerable. Levetiracetam (Keppra), carbamazepine or lamotrigine are often used as a first-line therapy among newly diagnosed patients. Patients who do not respond to monotherapy are started on adjuvant therapy with a preference for a drug with a different mechanism of action. Adding on or switching to new therapies is driven by breakthrough seizures, which indicate suboptimal efficacy, and tolerability issues. Shortcomings of available therapies include adverse effects such as sedation, ataxia (the presence of abnormal, uncoordinated movements), cognitive impairment, agitation, weight gain and tolerance.

Despite the existence of over 30 approved AEDs, approximately 30% of epilepsy patients fail to achieve seizure control even with the use of two or more AEDs (whether as monotherapy or in combination), which the International League Against Epilepsy defines as being drug-resistant. Inability to control seizures may result in severe disability, inability to retain employment and increased rates of mortality. Sudden unexpected death in epilepsy, or SUDEP, is the leading cause of death in patients with uncontrolled epilepsy.

BZDs have been important agents in the management of epilepsy for over 50 years. Of currently available therapies, BZDs are highly efficacious AEDs and may be administered via multiple routes. However, their use is primarily limited to acute or rescue treatment because they are associated with the development of tolerance resulting from repeated use, side effects such as cognitive impairment and sedation, as well as the development of physical and psychological dependence. BZDs commonly used for the acute management of seizures include clonazepam, clorazepate, diazepam, lorazepam, midazolam and clobazam. More than 10 BZDs are available and may be prescribed for treatment of seizures. Clobazam and clonazepam are BZDs approved for chronic adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome, a rare childhood form of epilepsy. Given their drawbacks, including debilitating side effects, risk of withdrawal and development of tolerance, BZDs are not typically prescribed for chronic treatment of focal epilepsy or generalized epilepsy.

GABA is the main inhibitory neurotransmitter that dampens down neuronal hyperexcitation through hyperpolarization. $GABA_A$ receptors are comprised of five subunits and are classified into three major groups (alpha, beta and gamma) and several minor groups. BZDs are non-selective PAMs of the $GABA_A$ receptor, enhancing the effect of $GABA_A$ receptors containing alpha-1/2/3/5 subunits. Alpha-1 subunit-containing $GABA_A$ receptors are broadly expressed throughout the brain and their modulation is believed to underlie many tolerability issues associated with BZD use (including sedation, motor and cognitive impairment) and contribute to desensitization and tolerance. In preclinical studies, the sedative effects of BZDs have been attributed to alpha-1 containing receptors. The role of alpha-1 in sedation is further supported by the clinical use of alpha-1 selective non-BZD Z-drugs such as zolpidem, which are used to treat insomnia. Meanwhile, alpha-2/3/5 containing $GABA_A$ receptors are expressed in more discrete brain regions, primarily within the cortical and thalamic neural networks. In preclinical studies, the anticonvulsant effects of BZDs have been attributed to alpha-1/2, the anxiolytic effects to alpha-2/3, analgesic activity to alpha-2/3/5 and some of the effects on memory function to alpha-5. As such, we believe selectively targeting the alpha-2/3/5 subunits present an attractive treatment option for epilepsy.

Anxiety background

Anxiety disorders are the most common form of mental illness in the United States, affecting over 45 million adults or 15% of the US population. Globally, over 280 million people are impacted by an anxiety disorder of some kind. The most common types of anxiety disorders include obsessive-compulsive disorder, post-traumatic stress disorder, social anxiety, panic disorder, and generalized anxiety disorder, or GAD. GAD, in particular, is a

chronic condition characterized by excessive anxiety and worry that is out of proportion to actual context and causes significant distress or functional impairment. GAD is a common disorder affecting approximately 5.7% of individuals at some point in their life, with approximately one-third of cases considered to be severe. Rates of full remission have been observed to be low, with recovery rates of less than 60% after a 12-year follow-up. In clinical trials of approved treatments, the rates of remission observed are typically less than 50%. The social impact of anxiety disorders includes increased risk of absenteeism, increased risk of suicide and high healthcare costs.

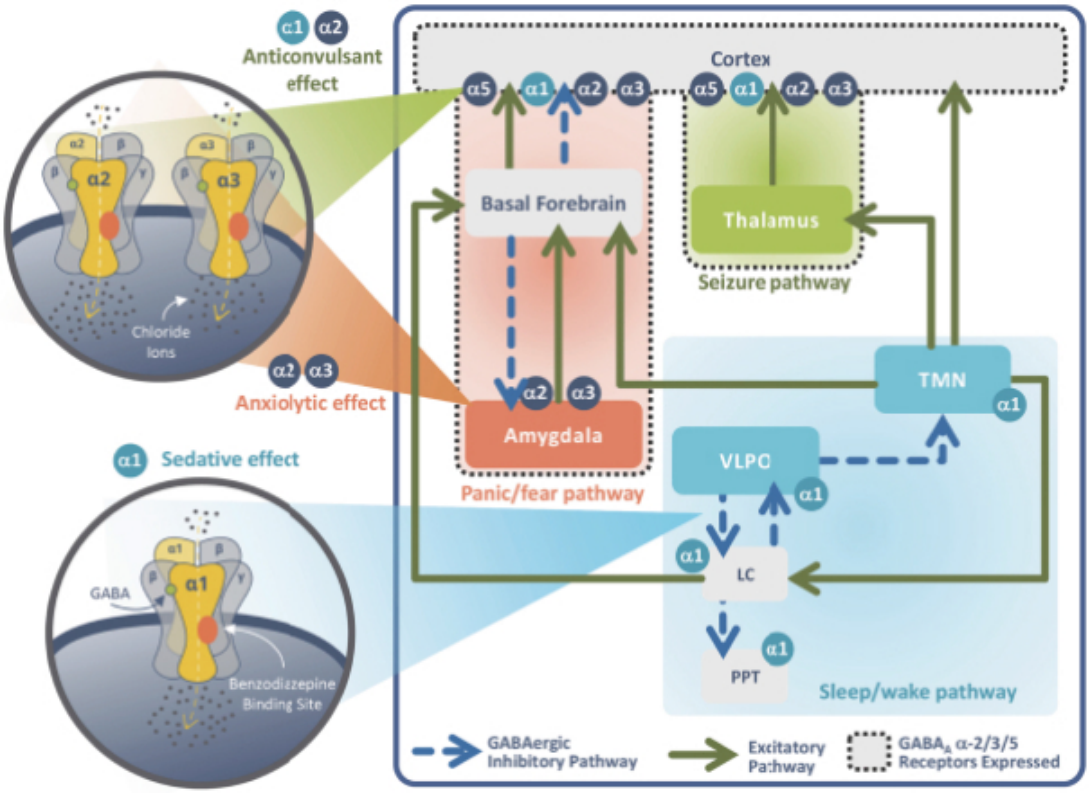
Treatment for anxiety typically consists of a combination of cognitive behavioral therapy and medication. First-line medications for anxiety include antidepressants such as selective serotonin reuptake inhibitors, or SSRIs, serotonin/norepinephrine reuptake inhibitors, or SNRIs, and buspirone, a serotonin 5HT1A receptor agonist. SSRIs, SNRIs and buspirone are used chronically, but they provide only modest relief and their onset of action is slow, taking up to four or more weeks before providing symptom relief. BZDs, which are broad spectrum $GABA_A$ receptor modulators, are known to have strong anxiolytic activity. While highly efficacious, tolerance along with known side effects of BZDs, such as sedation and cognitive impairment, as well as the development of physical and psychological dependence limit their use to short-term treatment or acute anxiety attacks. Due to a lack of sufficient treatment options, diazepam, clonazepam, lorazepam and alprazolam remain commonly prescribed anxiolytics despite their shortcomings. BZDs are often prescribed in combination with SSRIs and SNRIs to provide symptom relief while waiting for those medications to take effect. In addition, treatment-resistant patients are adjunctively administered BZDs despite the potential for abuse and symptom exacerbation.

We believe that by selectively targeting the alpha-2/3/5 subunits of the $GABA_A$ receptor, darigabat has the potential to provide fast-acting anxiolysis while minimizing tolerability issues, such as sedation and cognitive impairment, risk of abuse and development of tolerance seen with BZDs. We believe darigabat has the potential to replace the need for BZDs as an induction therapy while awaiting symptom relief from SSRIs and SNRIs and could also be used chronically, both as monotherapy or in combination with current standard of care.

Our solution—darigabat

Darigabat is a selective PAM that targets $GABA_A$ receptors containing alpha-2/3/5 receptor subunits. We are developing darigabat for the treatment of epilepsy and anxiety. Key differentiating features of darigabat include:

1. **Mechanism of action—alpha-2/3/5 containing $GABA_A$ receptor selectivity**: Darigabat is designed to selectively enhance GABA's inhibitory effect at the alpha-2/3/5 subunit-containing $GABA_A$ receptors, which is expected to suppress aberrant overexcitation that underlies epileptic activity. Although darigabat binds to alpha-1 subunit containing $GABA_A$ receptors, it is *functionally* selective for alpha-2/3/5 subunit-containing $GABA_A$ receptors. Darigabat exhibits significant positive allosteric modulation of alpha-2/3/5 subunit-containing $GABA_A$ receptors (90-140%) but only negligible activity (£20%) at $GABA_A$ receptors containing alpha-1 subunits. Because of its minimal effect on the alpha-1 subunit, we believe darigabat is able to achieve high receptor occupancy within the CNS while potentially reducing the dose-limiting side effects and tolerance associated with alpha-1 containing $GABA_A$ receptors. This mechanism of action is illustrated below:



2. **Receptor pharmacology—PAM**: Darigabat is an orally bioavailable, brain-penetrant, twice-daily small molecule with a novel selectivity profile. Darigabat is designed as a PAM to increase the effect of endogenous GABA without blocking or overexciting normal neural activity and with a lower propensity for development of tolerance. Furthermore, reduced functional activity at alpha-2 subunit containing $GABA_A$ receptors of darigabat relative to the non-selective BZDs has the potential to minimize receptor desensitization that leads to the development of tolerance. We believe anticonvulsant activity with this

optimized activity at alpha-2 subunit-containing $GABA_A$ receptors of darigabat is then achieved potentially through high levels of receptor occupancy due to minimal activity at alpha-1 subunit-containing $GABA_A$ receptors. Based on PET characterization, doses of darigabat used in clinical trials reached at least 80% receptor occupancy without causing dose-limiting AEs. In contrast, non-selective BZDs cause sedation at receptor occupancy levels of approximately 10-20%.

3. **Clinical and preclinical evaluation:** Darigabat has been evaluated in 289 subjects, including healthy volunteers and patients across multiple indications. Across nine prior clinical trials, darigabat was generally well tolerated. In a Phase 1 multiple-dose trial in healthy volunteers, darigabat administration resulted in no reports of sedation and low rates of somnolence compared to that reported with the commonly prescribed BZD lorazepam that generally resolved after titration, even up to dose levels consistent with receptor occupancy of approximately 80%. In addition, darigabat has demonstrated clinical proof-of-principle in a Phase 2 photoepilepsy trial and anti-epileptic activity in multiple rodent models of epilepsy.

Based on these differentiating features, we believe darigabat has the potential for anti-epileptic activity comparable to currently available BZDs but with reduced tolerance, sedation and withdrawal liabilities, which may enable chronic use.

For newly-diagnosed patients, we believe darigabat has the potential to become first-line therapy given the limitations of existing treatments in balancing anti-epileptic activity with acceptable tolerability. For patients on polypharmacy experiencing tolerability issues, darigabat's novel mechanism of action and expected tolerability profile has the potential to enable physicians to replace (after a cross-taper) a higher-risk drug in a patient's regimen. Additionally, for patients on multiple medications who experience breakthrough seizures, the target receptor selectivity and potential improved tolerability profile suggest that darigabat could be added to their current regimen for seizure control.

Pending the results of our planned trials, we believe darigabat could potentially change the paradigm of care for epilepsy, moving $GABA_A$ receptor modulators earlier in the treatment paradigm and from acute therapy to chronic therapy.

Clinical trials

Darigabat has been evaluated in 289 subjects across nine prior clinical trials in both patients and healthy volunteers. In a Phase 2, double-blind, crossover trial in photoepilepsy patients comparing darigabat to the commonly prescribed BZD lorazepam and to placebo, darigabat demonstrated anti-epileptic activity similar to lorazepam. In this trial, six out of seven patients taking darigabat achieved complete suppression of epileptiform activity evoked by flashing lights. In a Phase 1 trial comparing darigabat to lorazepam, healthy volunteers were assessed using the NeuroCart CNS test battery. Compared to lorazepam, darigabat demonstrated a greater reduction in saccadic peak velocity, a biomarker indicating engagement of selective alpha-2/3 subunit-containing $GABA_A$ receptors, while having reduced effects on motor coordination and cognition. Furthermore, in a Phase 1 MAD trial, darigabat showed no dose-related somnolence, even at dose levels consistent with receptor occupancy of approximately 80%. In addition, across several multiple-dose trials, darigabat has shown no evidence of withdrawal effects, a common problem with BZDs. Along with PK, PD and safety margin analyses, dose selection for trials with darigabat was informed by a Phase 1 PET receptor occupancy trial in healthy volunteers. Taken together, we believe these data suggest that darigabat may have the potential for anti-epileptic activity comparable to currently available BZDs, with reduced sedation, tolerance and withdrawal liabilities. We initiated a Phase 2 proof-of-concept trial in patients with focal epilepsy in the second half of 2020, with data expected in the second half of 2022. Concurrently, we also initiated a

Phase 1 proof-of-principle trial for acute anxiety in healthy volunteers in the second half of 2020, with data expected in the fourth quarter of 2021.

The table below provides an overview of all clinical trials of darigabat conducted to date, including trials in indications other than epilepsy.

Trial Number	Phase	Trial end date	Subjects (Darigabat/Total)	Design
B7431001*	Phase 1	July 2014	45/45	First-in-human single ascending dose in healthy volunteers; NeuroCart CNS battery to assess PD; active control (lorazepam) cohort
B7431002	Phase 1	July 2014	40/50	Multiple ascending dose in healthy volunteers
B7431004(1)	Phase 1	Aug 2014	5/5	PET single dose in healthy volunteers
B7431008	Phase 1	Sept 2014	12/12	Food effect single dose in healthy volunteers
B7431003(1)	Phase 1	Nov 2014	19/20	PainCart battery, single dose, crossover with active control (pregabalin) in healthy volunteers
B7431006(1)	Phase 2	Aug 2015	74/222	Placebo- and active-controlled (naproxen), multiple dose in chronic low back pain patients
B7431007(1)	Phase 2	Oct 2015	72/90	Placebo-controlled, multiple dose in generalized anxiety disorder patients
B7431005(1)	Phase 2	Feb 2017	7/7	Placebo- and active-controlled (lorazepam) single dose crossover in photoepileptic patients
B7431011(1)	Phase 1	Feb 2018	15/19	Multiple dose in healthy volunteers

(1) Most relevant trials discussed in greater detail in the following section.

Selected darigabat clinical trials

Phase 2 trial in photoepilepsy

In February 2017, Pfizer completed Trial B7431005, a randomized, placebo- and active-controlled, cross- over, proof-of-principle, Phase 2 trial designed to evaluate the efficacy of darigabat in photoepilepsy using lorazepam as an active control.

Pharmacological effects in photoepilepsy proof-of-principle trials are correlated with a higher likelihood that positive results will be observed in the clinical epilepsy population. As such, it has historically been utilized as a tool to quantitatively predict efficacy in epilepsy. Doses corresponding to a 50% to 100% response in these proof-of-principle trials for a range of well-precedented and clinically characterized anticonvulsive agents were found to be within two-fold of the minimally efficacious doses used in focal or generalized epilepsy. These data provide support for the translatability of the photoepilepsy model to other epilepsy states.

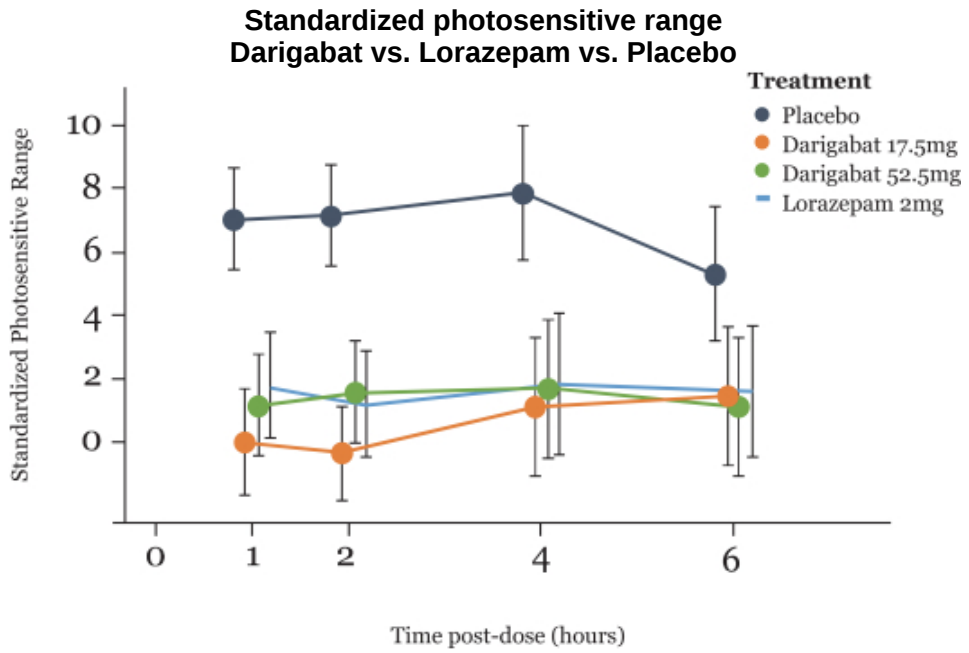
A total of seven patients with documented photoepilepsy were randomized to the four-period crossover trial examining single doses of 17.5 mg and 52.5 mg of darigabat, 2 mg of lorazepam as an active control and placebo, with each patient receiving all treatments in a random order with a one-to-three week washout between treatments. The 52.5 mg dose of darigabat was selected for the trial based on the expectation that it would achieve maximal PD effect in the alpha-2/3 saccadic peak velocity biomarker assessment and maximal

receptor occupancy of approximately 80%. The lower 17.5 mg dose of darigabat was expected to achieve approximately 60% receptor occupancy.

Patients were exposed to intermittent bursts of light with different flash frequencies (intermittent photic stimulation) to establish the standardized photosensitivity range, or SPR, at which EEG epileptiform activity (photoparoxysmal response, or PPR) was observed. Flashes were administered at standard frequencies, with the SPR being the range of frequencies over which EEG epileptiform activity occurred. The maximum SPR was 14 with a minimum of 0, where an SPR of 0 indicates complete suppression of EEG epileptiform activity.

The primary endpoint was the average change in SPR over the first six hours post-treatment. As measured by SPR, the mean response of 17.5 mg and 52.5 mg of darigabat compared to placebo in the most sensitive eye condition was -6.2 and -5.4, respectively. The mean response of 2 mg of lorazepam compared to placebo was -5.2. Mean responses for 17.5 mg and 52.5 mg of darigabat and 2 mg of lorazepam were considered similar to each other and statistically significant relative to placebo at the prespecified one-sided 5% level. Results are summarized in the table and chart below.

Treatment	LSMean (90% CI)	LSMean vs. Placebo (90% CI)
Placebo	6.80 (5.14 to 8.48)	
Darigabat 17.5 mg	0.57 (-1.12 to 2.26)	-6.23 (-8.60 to -3.86)
Darigabat 52.5 mg	1.38 (-0.29 to 3.04)	-5.42 (-7.78 to -3.06)
Lorazepam 2 mg	1.58 (-0.11 to 3.26)	-5.22 (-7.60 to -2.84)



The proportion of participants with complete suppression, partial response and no response to intermittent photic stimulation is summarized in the table below. Six out of seven patients had complete suppression of EEG epileptiform activity following receipt of 17.5 mg of darigabat, 52.5 mg of darigabat or 2 mg of lorazepam,

whereas two out of seven patients had complete suppression following receipt of placebo. Based on these results, along with PK data and PET receptor occupancy-based modeling, we believe that both doses of darigabat in this trial are within the anticipated therapeutic range for anti-seizure effect.

Summary of proportion of participants with categorical responses in the most sensitive eye condition

Response(a)	Placebo	Darigabat 17.5 mg	Darigabat 52.5 mg	Lorazepam 2 mg
Complete suppression	2/7	6/7	6/7	6/7
Partial response	0/7	0/7	0/7	0/7
No response	5/7	1/7	1/7	1/7

(a) Responses defined as follows: Complete suppression: SPR = 0 in all 3 eye conditions at the same time point; Partial response: a reduction in SPR of at least 3 units from baseline for at least 3 time points and no timepoints with at least 3 units of increase, in the most sensitive eye condition, without meeting the complete suppression definition; No response: does not meet complete suppression or partial response definitions.

Consistent with previous trials in healthy volunteers and patients, darigabat was observed to be well tolerated. The most frequently reported AEs in this single-dose trial were somnolence (three subjects each on placebo, 17.5 mg of darigabat and 2 mg of lorazepam and four subjects on 52.5 mg of darigabat) and dizziness (three subjects each on 17.5 mg and 52.5 mg of darigabat and one subject on 2 mg of lorazepam). One of the dizziness AEs and two of the somnolence AEs were moderate in severity. All other somnolence and dizziness AEs were mild in severity. There were no SAEs and no discontinuations due to AEs in this trial. Based on the totality of clinical data for darigabat to date, including the Phase 1 MAD trial in healthy volunteers described below, we believe that titration can help mitigate effects on somnolence and dizziness.

In summary, in this trial, darigabat demonstrated pronounced anticonvulsant activity on par with lorazepam, in patients with photoepilepsy, a clinical epilepsy model translationally relevant to other epilepsy populations.

Phase 1 single ascending dose trial with pharmacodynamic assessments

In July 2014, Pfizer completed Trial B7431001, a first-in-human Phase 1 trial designed to characterize the safety, tolerability, PK and PD of single doses of darigabat in healthy adult volunteers between 18 and 55 years old.

The primary objectives of this trial were to evaluate the safety and tolerability of escalating single oral doses of darigabat, as well as the PK and PD of single doses of darigabat alone and in combination with lorazepam in healthy volunteers. PD effects were assessed using NeuroCart, a test battery which assesses a range of CNS functions, both objective, such as neurophysiologic and cognition, and subjective, such as memory and mood. NeuroCart can be used to correlate a compound's PD activity and PK and provide evidence to test hypotheses regarding mechanism of action. NeuroCart PD measurements rationally selected for this trial were based on known $GABA_A$ receptor pharmacology and included:

- Saccadic peak velocity, or SPV, where a reduction is an indicator of desired alpha-2/3 pharmacology
- Body sway and adaptive tracking to assess undesired alpha-1 pharmacology related to sedation
- Visual-verbal learning test, or VVLT, to assess memory impairment and undesired alpha-1/5 pharmacology

The trial was conducted in two parts. The first part of the trial (Cohorts 1, 2 and 3) was a double-blind, randomized, placebo-controlled, crossover, SAD trial to evaluate the safety, tolerability, PK and PD of single escalating doses of darigabat. Eight subjects in each cohort received darigabat and the remaining two subjects received placebo. Cohorts 1 and 2 were dosed with the first 10 dose levels of darigabat (0.04 mg to 15 mg). Cohort 3 evaluated doses from 25 mg to 100 mg.

The second part of the trial (Cohort 4) was conducted to further explore and compare NeuroCart PD effects of darigabat alone, 2 mg of lorazepam alone and the combination of darigabat with 2 mg of lorazepam. This was

done to explore the PD interaction between the two drugs. Part 2 of the trial was designed as a five-period placebo- and active-controlled crossover trial. Fifteen subjects each received placebo, 2 mg of lorazepam, 15 mg of darigabat, 65 mg of darigabat and 65 mg of darigabat in combination with 2 mg of lorazepam in accordance with one of the sequences shown in the table below.

Treatment sequences for cohort 4

Sequence	Period 1	Period 2	Period 3	Period 4	Period 5
1 (n=3)	Placebo	Lorazepam 2 mg	Darigabat 15 mg	Darigabat 65 mg	Darigabat 65 mg + Lorazepam 2 mg
2 (n=3)	Lorazepam 2 mg	Darigabat 65 mg	Darigabat 65 mg + Lorazepam 2 mg	Darigabat 15 mg	Placebo
3 (n=3)	Darigabat 15 mg	Darigabat 65 mg + Lorazepam 2 mg	Lorazepam 2 mg	Placebo	Darigabat 65 mg
4 (n=3)	Darigabat 65 mg	Darigabat 15 mg	Placebo	Darigabat 65 mg + Lorazepam 2 mg	Lorazepam 2 mg
5 (n=3)	Darigabat 65 mg + Lorazepam 2 mg	Placebo	Darigabat 65 mg	Lorazepam 2 mg	Darigabat 15 mg

Lorazepam has been studied extensively using NeuroCart and has a distinctive signature of its $GABA_A$ receptor related pharmacology, including effects on saccadic eye movements as well as undesired effects on alertness, memory and body sway, many of which are believed to be mediated through alpha-1 pharmacology.

PD activity of darigabat in this trial was observed for the desired alpha-2/3 driven pharmacology, as demonstrated by SPV and surpassed the effect size demonstrated by lorazepam. The undesired, primarily alpha-1-driven pharmacology, as demonstrated by body sway and adaptive tracking, was observed to be less for darigabat than with lorazepam. The full results from this trial are summarized below:

- Effects on alpha-2/3 pharmacology: SPV decreased with increasing doses of darigabat. In Cohort 4, the decrease in SPV for each of darigabat 15 mg and 65 mg and for the combination of 2 mg of lorazepam and 65 mg of darigabat was statistically significantly greater than for 2 mg of lorazepam alone.
- Effects on alpha-1 pharmacology (associated with sedation): Body sway increased with increasing doses of darigabat up to 10 mg, and appeared to plateau between 10 mg and 100 mg. In Cohort 4, the increase in body sway was statistically significantly lower for 15 mg of darigabat than for 2 mg of lorazepam. Adaptive tracking decreased with increasing doses of up to 25 mg of darigabat, and appeared to plateau between 25 mg and 100 mg. In Cohort 4, there was a statistically significant reduction in the impairment on adaptive tracking for both 15 mg and 65 mg of darigabat and the combination of 2 mg of lorazepam and 65 mg of darigabat when compared to 2 mg of lorazepam alone.

- Effects on alpha-1/5 pharmacology (associated with memory and cognition): For VVLT, the numbers of correct words were decreased on both the immediate recall and delayed recall for both doses of darigabat relative to placebo. These effects were not statistically significantly different to 2 mg of lorazepam. The numbers of incorrect words on both immediate and delayed recall were similar to placebo for doses of darigabat and significantly lower than 2 mg of lorazepam. The number of correct words recognized after a period of time (delayed recognition) was decreased relative to placebo but were higher than 2 mg of lorazepam (statistically significant for darigabat 15 mg). Average reaction time and the standard deviation of reaction time for correct words generally increased with doses of darigabat but by less than that observed for 2 mg of lorazepam in Cohort 4.

Dose-response effects of darigabat were also observed on saccadic reaction time, saccadic inaccuracy, VAS alertness and Average Reaction Time for Correct Words.

Results from Part 2 of the trial, illustrated in the table below, demonstrated that, overall, darigabat showed a differentiated profile to lorazepam. Relative to 2 mg of lorazepam, 15 mg of darigabat demonstrated a larger decrease in SPV, corresponding to desired alpha-2/3 pharmacology, and a smaller impairment versus lorazepam on body sway, adaptive tracking and memory tests, corresponding to undesirable alpha-1/5 pharmacology seen with BZDs. The combination of darigabat and lorazepam (not illustrated) showed greater decrease in SPV and less reduction in adaptive tracking in comparison to lorazepam alone, suggesting little PD interaction between the two compounds.

Relevant Pharmacology	Metric	Lorazepam 2 mg N=15 LS mean difference vs. placebo (95% CI)	Darigabat 15 mg N=15 LS mean difference vs. placebo (95% CI)	Darigabat 15 mg vs. lorazepam 2 mg LS mean difference (95% CI)	Interpretation of Results
Alpha 2/3 Saccadic Peak Velocity (SPV)	**SPV change**, degrees per second	-38.6 (-66.2, -11.0)	-72.7 (-99.1, -46.2)	-34 (-61, -7.1)*	**Increased alpha 2/3 target activity vs lorazepam** CVL-865 demonstrated a greater reduction in SPV vs. lorazepam
Alpha 1 (sedation) Body Sway and Adaptive Tracking	**Body Sway**, Ln/MM	0.68 (0.47, 0.90)	0.38 (0.17, 0.59)	-0.31 (-0.52, -0.09)*	**Less undesirable alpha 1 activity vs. lorazepam :** Lorazepam had a greater negative impact on coordination and postural deficits vs. CVL-865
	Adaptive Tracking, average performance %	-10.43 (-13.55, -7.31)	-5.17 (-8.28, -2.06)	5.26 (2.15, 8.37)*	
Alpha 1/5 (memory and cognition) Visual Verbal Learning Tests	**Immediate Recall** – number of correct words	-3.7 (-5.6, -1.7)	-2.7 (-4.7, -0.8)	0.9 (-1.0, 2.9)	**Less undesirable alpha 1/5 activity vs. lorazepam** Lorazepam had a greater negative impact on memory and cognition vs. darigabat as shown by immediate and delayed word recall and word recognition
	Delayed Recall - number of correct words	-4.9 (-7.3, -2.4)	-3.6 (-6.0, -1.2)	1.3 (-1.2, 3.7)	
	Delayed Recognition- number of correct words identified	-5.9 (-8.4, -3.4)	-1.9 (-4.3, 0.6)	4.1 (1.6, 6.6)*	
	Immediate Recall - number of incorrect words	1.7 (0.9, 2.5)	0.1 (-0.7, 0.9)	-1.6 (-2.4, -0.8)*	Lorazepam had a greater negative impact on memory and cognition vs. darigabat as shown by more errors made on immediate and delayed word recall
	Delayed Recall - number of incorrect words	2.2 (1.1, 3.3)	0.4 (-0.6, 1.4)	-1.8 (-2.9, -0.7)*	

*difference statistically significant, p<0.05

All doses of darigabat were observed to be well tolerated. All treatment-related and trial-related AEs reported were mild. A maximum tolerated dose was not established and there were no reports of sedation in the trial. The most common AEs following dosing with darigabat were somnolence, dizziness, bradyphrenia, headache, fatigue, elevated mood and orthostatic hypotension.

Phase 1 multiple ascending dose trial in healthy volunteers

In February 2018, Pfizer completed Trial B7431011, a double-blind, randomized trial designed to evaluate the safety, tolerability and PK of repeat oral doses of darigabat in healthy adult volunteers.

Eighteen healthy adult volunteers were enrolled and randomized into two cohorts and received twice daily, or BID, oral doses of darigabat over 21 days. One additional patient was enrolled into the trial but was withdrawn due to non-compliance. Each cohort included seven or eight subjects dosed with darigabat and two subjects

dosed with placebo. All subjects received increasing doses of darigabat during the titration period in the first seven days, and the target dose was maintained for the remaining 14 days of the treatment period. In Cohort 1, subjects received 5 mg BID for three days, 12.5 mg BID for four days and 25 mg BID for 14 days. In Cohort 2, subjects received 5 mg BID for two days, 12.5 mg BID for two days, 25 mg BID for three days and 42.5 mg BID for 14 days. Serial PK samples were collected at selected time points on days one and 21. Safety evaluations conducted throughout the trial included AE monitoring, clinical laboratory tests, vital signs, ECGs and physical examinations.

Darigabat was rapidly absorbed with Cmax achieved at a median Tmax of one to two hours following both single- and multiple-dose administration. Mean terminal half-life on day 21 was 11.2 hours (25 mg BID) and 11.5 hours (42.5 mg BID), providing a PK rationale for twice-daily dosing.

All reported AEs were mild and a maximum tolerated dose was not identified. As illustrated below, no subjects reported somnolence after the titration period and no somnolence was observed in the 42.5 mg BID group.

	Reaction	Week 1 (Titration)	Week 2 (Maintenance)	Week 3 (Maintenance)	Follow-Up
Placebo	No Reaction	4/4	4/4	3/4	4/4
	Dizziness	—	—	1/4	—
	Somnolence	—	—	—	—
Darigabat 25mg BID	No Reaction	5/8	7/8	8/8	8/8
	Dizziness	2/8	1/8	—	—
	Somnolence	3/8	—	—	—
Darigabat 42.5mg BID	No Reaction	4/7	6/7	6/7	6/7
	Dizziness	3/7	1/7	1/7	1/7
	Somnolence	—	—	—	—

No trial participants experienced withdrawal symptoms when darigabat was discontinued, despite treatment with doses achieving an estimated 80% $GABA_A$ receptor occupancy based on modeling data from the PET trial (B7431004). Changes in micronuclei frequency were measured as an exploratory endpoint in this trial and no changes were observed, providing further evidence that the doses evaluated were below the threshold at which micronuclei formation was observed preclinically. See "*—Additional Clinical Trials with Darigabat*" below.

Based on the results of this trial, which included a dose that exceeded our top target dose for our ongoing Phase 2 proof-of-concept trial in focal epilepsy, we believe darigabat may selectively enhance alpha-2/3/5 GABAergic activity at high receptor occupancy levels without sedation and minimal somnolence that is associated with alpha-1 subunit-containing receptors activation.

Phase 1 PET receptor occupancy trial in healthy volunteers

In August 2014, Pfizer completed Trial B7431004, an open-label Phase 1 trial designed to evaluate the central occupancy of the BZD binding site of $GABA_A$ receptors by using a [11C]Flumazenil PET ligand following single doses of darigabat in healthy adult volunteers. The primary objective was to characterize the relationship between the $GABA_A$ receptor occupancy in the whole brain and the plasma exposure of darigabat. Two doses of darigabat were evaluated in this trial, 10 mg (three subjects) and 65 mg (two subjects). Most of the AEs observed in this trial were mild in severity, with no AEs of severe intensity or SAEs observed. Using data from this trial, modeling was conducted to estimate the receptor occupancy binding in the whole brain at alpha-1/2/3 subunit-containing receptors. We are using the data from this model to inform dosing in our ongoing Phase 2 proof-of-concept trial in focal epilepsy.

Preclinical studies

In preclinical research, the accelerating rotarod is used to identify negative effects on motor function and time to fall from can be used as a measure of motor coordination. The effect of oral darigabat (1-10 mg/kg), vehicle and diazepam (10 mg/kg) were evaluated in the mouse accelerating rotarod. Time to fall was significantly decreased in mice treated with diazepam, but not for mice treated with darigabat compared to vehicle treatment, indicating a less impairing effect of darigabat, even at maximal receptor occupancy. As humans appear to be highly sensitive to alpha-1-mediated effects, an additional pharmacological approach was used with drug discrimination to determine *in vivo* alpha-1 receptor activity. In a drug discrimination study, rats were trained using an operant food-maintained task to discriminate between the presence and absence of zolpidem, a $GABA_A$ alpha-1-selective PAM. Drugs eliciting 80% or greater responding on the drug-trained lever are classified as producing full generalization to the training compound. Oral 10 mg/kg darigabat did not cause generalization to the sedative zolpidem, even at maximal receptor occupancy, confirming the minimal alpha-1 activity observed *in vitro*.

Preclinical models of epilepsy have had an important role in the discovery of novel AEDs. Darigabat has demonstrated activity in widely used and translationally relevant preclinical models of epilepsy. Pentylenetetrazol, or PTZ, a drug known to induce convulsions, has been used in preclinical studies to investigate seizure phenomenon. Non-selective BZDs block PTZ-induced clonic convulsions, which can be interpreted as a measure of their anti-seizure activity. Oral administration of 0.3 mg/kg, 1 mg/kg, 3 mg/kg and 10 mg/kg of darigabat dose-dependently reduced or inhibited convulsions in PTZ-administered mice. When tested orally at 3 mg/kg and 10 mg/kg, darigabat demonstrated significantly inhibited or reduced seizure severity in amygdala kindled rats, a model of focal epilepsy. Darigabat has also shown robust activity in the genetic absence epilepsy rat from Strasbourg, a model of generalized seizures, and the mesial temporal lobe epilepsy model in mice, a model of focal epilepsy, demonstrating a broad spectrum of activity across multiple preclinical models across different types of epilepsy.

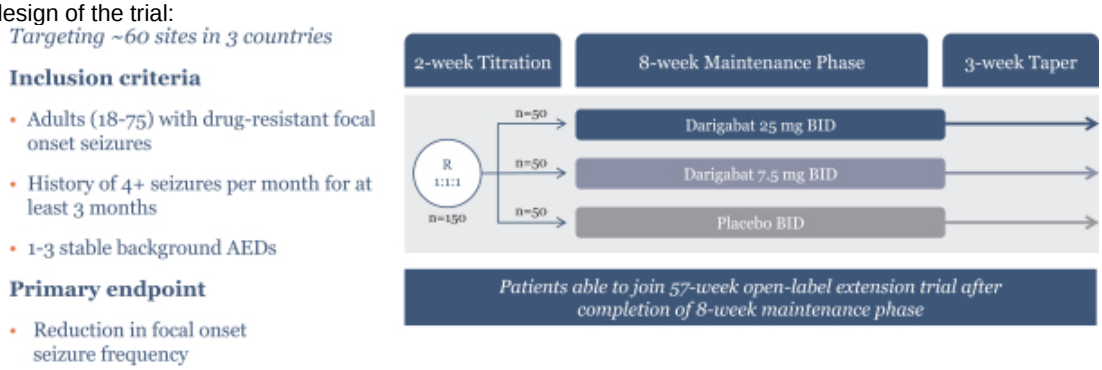
In addition, darigabat demonstrated activity in the elevated plus maze, a behavioral model in mice, widely used to assess the anxiolytic effects of pharmacological agents. An increase in time spent in the open arms reflects anti-anxiety behavior, an outcome that is observed with BZDs. For the darigabat study, comparisons were made between vehicle, diazepam (3 mg/kg) and darigabat following oral doses of 0.1, 0.3, 3.2 and 10 mg/kg. Darigabat (3.2 and 10 mg/kg) produced robust anxiolytic-like effects similar in magnitude to that of diazepam, indicating anti-anxiety behavior of darigabat.

Preclinical good laboratory practices, or GLP, chronic toxicology studies have been completed in rats (26-weeks duration) and canines (39-weeks duration) to enable long-term administration of darigabat at levels that we predict will be clinically relevant. In GLP reproductive toxicology studies, effects on rats and rabbits included malformations that are consistent with a requirement for contraceptive practice to be in place in patients treated with darigabat, which is in line with many other approved AEDs.

Ongoing clinical trials

Realize: Phase 2 proof-of-concept trial in focal epilepsy

We are investigating darigabat in a Phase 2 proof-of-concept trial in 150 patients with focal epilepsy. The focal epilepsy population is the largest subpopulation of epilepsy patients, and it is often studied to establish proof-of-concept in AED development. The diagram below summarizes the design of the trial:



This trial is designed to be a multi-center, randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and tolerability of darigabat as adjunctive therapy in adult patients with focal epilepsy. The trial population will include patients with an appropriate severity level of disease to allow for the detection of anticonvulsant activity with darigabat. The key inclusion criteria include: (i) men and women 18 to 75 years of age with a diagnosis of epilepsy with focal onset as defined by the International League Against Epilepsy as focal aware, focal impaired awareness and focal to bilateral tonic-clonic seizures for at least two years; (ii) drug resistance, defined as lack of seizure control despite the use of at least two prior AEDs; (iii) current treatment with at least one but no more than three AEDs and (iv) a history of an average of four or more spontaneous and observable seizures per 28-day period for at least three months.

After the eight-week screening period, 150 eligible patients who have suffered at least eight focal onset seizures during the screening period will be randomized 1:1:1 to one of the following three arms: 25 mg BID of darigabat; 7.5 mg BID of darigabat or placebo BID. The two doses of darigabat have been selected based on the safety and tolerability data from previous Phase 1 trials, the receptor occupancy modeling based on PET characterization and the doses used in the Phase 2 proof-of-principle photoepilepsy trial.

Throughout the screening period and over the course of the trial, patients will use an electronic seizure diary to capture their seizure events, which will enable assessment of change in seizure frequency between baseline, as assessed during the screening period, and following treatment. Following the eight-week screening period, eligible patients will enter a 13-week treatment period, which includes (i) a two-week titration phase, which was designed with the knowledge from prior clinical trials that somnolence side effects of darigabat may be mitigated by titration, (ii) an eight-week maintenance phase and (iii) either a three-week taper period or enrollment into REALIZE OLE, a 57-week open-label extension trial. The three-week taper phase is designed to mitigate possible risks of rebound seizures from too-rapid withdrawal from darigabat.

The primary endpoint to evaluate the efficacy of darigabat will be the reduction in frequency of focal onset seizures during the maintenance phase versus baseline as compared to the placebo group. This will be calculated as Rratio=(T-B)/(T+B) ×100, where T represents the seizure frequency rate per week in the maintenance phase and B represents the seizure frequency rate per week in the baseline screening period. The Rratio is between -100 and 100, where negative values will indicate reduction in seizure rate and positive values indicate increase in seizure rate during treatment. Reduction in seizure frequency using Rratio has been used as

the primary endpoint in prior registrational trials of drugs for adjunctive treatment of focal epilepsy. Key secondary efficacy endpoints will include responder rate, defined as the percent of patients who experience at least a 50% reduction in focal onset seizure frequency compared to baseline, and seizure frequency per week over the eight-week maintenance phase. Safety parameters will include assessment of withdrawal symptoms during the taper phase of the trial.

We initiated the REALIZE trial in the second half of 2020, with data expected in the second half of 2022. The totality of the activity and tolerability data that will be generated in REALIZE, the Phase 2 proof-of-concept trial, and REALIZE OLE, the 57-week open-label extension trial, will guide further clinical development of darigabat in epilepsy. We also plan to conduct additional clinical pharmacology studies as appropriate.

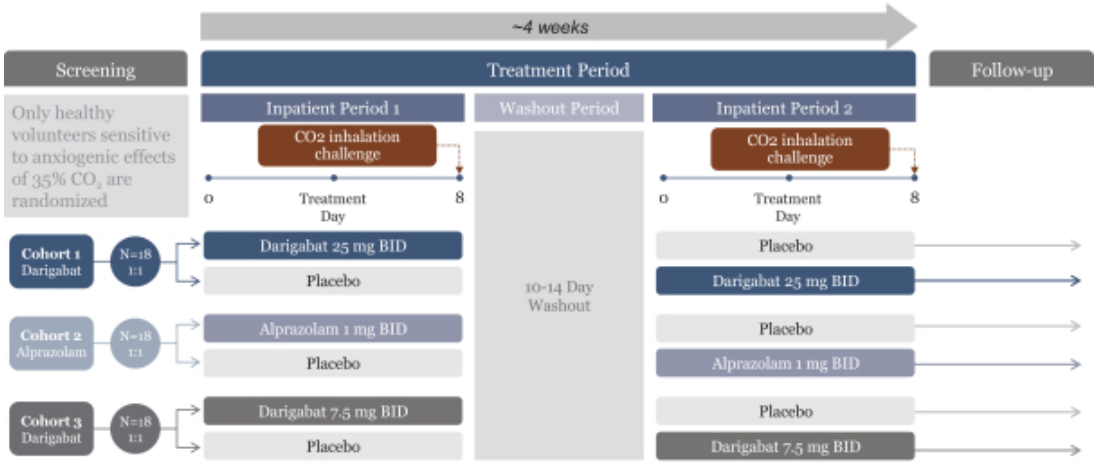
Phase 1 proof-of-principle trial in acute anxiety

In the second half of 2020, we also initiated a Phase 1 proof-of-principle trial to evaluate darigabat in acute anxiety in healthy volunteers, with data expected in the fourth quarter of 2021. As described below under "*—Additional Clinical Trials with Darigabat*," Pfizer previously conducted a Phase 2 trial in GAD which was terminated early for non-safety reasons. We believe the prior trial did not achieve sufficient receptor occupancy levels to demonstrate anxiolytic effect because the full therapeutic dose range of darigabat was not explored. The results of our proof-of-principle trial will inform future decisions around the development of darigabat in anxiety.

In this trial, the anxiolytic effects of multiple doses of darigabat will be assessed in a CO_2 inhalation model in a three-cohort, randomized, double-blind, placebo- and active-controlled, crossover trial of healthy volunteers. The PD effect of multiple doses of darigabat and alprazolam will be examined.

The primary objectives of the trial will be to evaluate the anxiolytic effects of multiple doses of darigabat using an experimental medicine model of CO_2 inhalation that is associated with symptoms of anxiety/panic in healthy volunteers and is known to be sensitive to the effects of marketed BZDs. The primary endpoint of this study is change in the Panic Symptoms List, which includes 13 symptoms scored across a range of 0 (absent) to 4 (very intense) that is used to assess panic/anxiety. Safety and tolerability will be evaluated by reports of treatment-emergent AEs, clinically significant changes in ECGs, vital sign measurements, and physical and neurological examination results. Suicidality will be assessed using the C-SSRS. Plasma exposure of darigabat and alprazolam (if required) will also be evaluated.

The trial will be conducted as a randomized, double-blind, placebo- and active-controlled, two-period, two-sequence crossover design comparing multiple doses of high-dose darigabat (25 mg BID), low-dose darigabat (7.5 mg BID), and alprazolam (1 mg BID) against placebo. Three cohorts of 18 subjects each will be enrolled for a total of 54 subjects. Within each of these cohorts, the subjects will be randomized equally to one of two treatment sequences as shown in the diagram below:



1. The Panic Symptom List (PSL) includes 13 symptoms scored across a range of 0 (absent) to 4 (very intense) that is used to assess panic anxiety. Liebold et al. Trans Psychiatry. 2016.; Bailey et al. J Psychopharm. 2011.; Maliziaet al. Arch Gen Psychiatry. 1998.; Salvatore et al. Translational Psychiatry 2020.

This trial is designed with a maximum duration of approximately thirteen weeks and consists of a screening/baseline period, a treatment period and a follow-up period. During the screening/baseline period, subjects will be exposed to the CO_2 challenge and only subjects that are sensitive to the anxiogenic effects of 35% CO_2 double-breath inhalation at screening will be eligible for randomization during the treatment period. Each treatment period will consist of eight days of dosing followed by the CO_2 challenge performed after dosing on Day 8.

The top dose of 25 mg BID was selected to evaluate the therapeutic potential of darigabat. This dose level achieves exposure levels of darigabat comparable to those at which the peak effects in SPV, a reliable biomarker of alpha-2/3 activity, were observed in prior studies and at which receptor occupancy of >80% can be achieved. The lower 7.5 mg BID dose of darigabat is anticipated to have a physiologically significant but submaximal effect based on the same neurofunctional endpoints described above, with an average steady-state exposure level high enough to produce alpha-2 receptor occupancy in the range of up to 60%. Additionally, the lower dose is intended to provide sufficient data to fully understand the relationship between exposures and clinical endpoints to facilitate rational dose selection in future trials.

We initiated this trial in the second half of 2020, with data expected in the fourth quarter of 2021. The data that will be generated in this trial will guide further clinical development of darigabat in anxiety.

Additional clinical trials with darigabat

Pfizer conducted multiple additional Phase 1 and Phase 2 trials earlier in the development of darigabat to further characterize its activity in both healthy volunteers and in patients. At the time of these trials, Pfizer had self-imposed a C_{max} dosing cap in multi-dose clinical trials, which stipulated that plasma exposure should not exceed one-tenth of the no observed adverse effect level, or NOAEL. This dose cap was established as an added precaution based on a micronuclei formation observed in preclinical rat studies and equated to approximately

7.5 mg BID. Because of this dose cap, the full therapeutic dose range of darigabat was not explored in the Phase 2 trials of chronic low back pain and GAD, as discussed below. Subsequently, Pfizer conducted additional genotoxicity studies, which showed that micronuclei formation was observed in rats at doses equivalent to 5x the maximum human clinical dose expected to be studied in our planned trials of darigabat. Based on these data, the FDA provided feedback that permitted our evaluation of doses in clinical trials of up to 50 mg. The Phase 2 trials described below were generally conducted prior to this FDA feedback and thus evaluated doses that we believe were sub-therapeutic based on the results from our NeuroCart and PET receptor occupancy trials.

Phase 2 generalized anxiety disorder trial

In October 2015, Pfizer concluded Trial B7431007, a double-blind, randomized, placebo-controlled Phase 2 trial designed to evaluate the effect of darigabat on patients with GAD. A total of 90 patients of the planned 384 patients were randomized before Pfizer decided to terminate the trial based on internal portfolio reprioritization.

Darigabat was evaluated as an adjunct to current GAD treatment in a sequential parallel comparison trial in patients with GAD who showed an incomplete response to current standard-of-care pharmacotherapy. Two doses of darigabat, 2.5 mg BID and 7.5 mg BID, were compared to placebo over four weeks of dosing. Neither dose of darigabat differentiated from placebo at week four compared to baseline with respect to the primary endpoint of Hamilton Anxiety Inventory total score or on the secondary endpoint of Sheehan Disability Scale total score. AEs observed in this trial included dizziness, headache and somnolence. However, when measured by the Epworth Sleepiness Score, there was no meaningful increase in sleepiness with either darigabat 7.5 mg, darigabat 2.5 mg or placebo at week 2 and week 4.

A factor potentially contributing to the lack of anxiolytic effect is the potential of the doses evaluated being sub-therapeutic and not achieving sufficient receptor occupancy to drive activity in anxiety. Notably, the 2.5 mg BID and 7.5 mg BID doses used in this trial were consistent with approximately 25% and 60% receptor occupancy, respectively. These receptor occupancy levels resulted in submaximal pharmacology observed in the selective alpha-2/3-biomarker saccadic peak velocity measured in NeuroCart. Based on these observations, we believe that the anxiolytic potential of darigabat has never been investigated at sufficiently high receptor occupancy levels. In addition, this trial enrolled patients with treatment-resistant anxiety, defined as persistent symptoms of anxiety despite treatment with background standard of care therapy. The selection of this particularly treatment-resistant patient population may have contributed to a negative result. As such, we believe the anxiolytic potential of darigabat has not been fully evaluated, and we are exploring higher doses of darigabat in our proof-of-principle Phase 1 trial in acute anxiety.

Phase 1 paincart trial in healthy volunteers

In November 2014, Pfizer completed Trial B7431003, a randomized, placebo- and active-controlled, four- period crossover, Phase 1 trial designed to provide information on the analgesic potential of darigabat. The PD effect of single 15 mg and 65 mg doses of darigabat was evaluated on evoked pain endpoints in 20 healthy male volunteers and compared to pregabalin (active control) and placebo. In the pressure pain task, increasing pressure was applied using a tourniquet cuff on the calf until the subject indicated their pain tolerance threshold had been reached. In the cold pressor task, subjects placed their non-dominant hands into cold water baths and indicated their pain detection threshold, the point at which sensation changed from non-painful to painful. At the 65 mg dose of darigabat, increases in both cold pressor and pressure pain tolerance thresholds, indicative of analgesic potential were observed. The 15 mg dose of darigabat only showed positive effects in the pressure pain tolerance threshold. These results demonstrate the analgesic potential of darigabat at doses that did not induce significant sedation.

Phase 2 chronic low back pain trial

In August 2015, Pfizer concluded Trial B7431006, a double-blind, randomized, placebo- and active- controlled, Phase 2 trial designed to evaluate the effect of darigabat on chronic low back pain. The trial consisted of a one-week, single-blind, placebo run-in phase that was designed to exclude patients with placebo response and suboptimal compliance, followed by a four-week double-blind treatment phase. Patients who continued to meet the eligibility criteria after the placebo run-in period, including level of pain severity and compliance with a daily pain diary and with tablet administration, were randomized to receive either darigabat (administered as 2.5 mg BID for one week followed by 7.5 mg BID for three weeks), naproxen (active control) or placebo BID for four weeks. The primary endpoint was the numerical rating score of low back pain intensity after four weeks of active treatment. The trial was stopped following a planned interim analysis, having met the pre-defined stopping criteria. At this time, a total of 222 patients were randomized and the mean darigabat four-week response on the low back pain intensity was 0.16 units higher (worse) than placebo. The effects of naproxen on low back pain intensity were in-line with expectations based on previous clinical trials in chronic low back pain. Darigabat was generally well tolerated. The most common treatment-related AEs in the darigabat arm were somnolence (five mild and four moderate cases), dizziness (two mild and three moderate cases) and nausea (two mild cases). One patient in this trial experienced an SAE of transient ischemic attack that was determined by the investigator to be related to darigabat. This patient had a history of multiple cardiovascular risk factors and was subsequently diagnosed with Type 2 diabetes mellitus. Factors potentially contributing to the lack of analgesic activity observed in this trial included the use of a potentially sub-therapeutic dose and therefore not achieving sufficient receptor occupancy to drive analgesic activity.

Tavapadon

We are developing our most advanced product candidate, tavapadon, as both a monotherapy and adjunctive therapy to levodopa, or L-dopa, as a treatment for early- and late-stage Parkinson’s, a neurodegenerative disorder characterized by the death of dopamine-producing neurons in the brain, respectively. Tavapadon was rationally designed as an orally bioavailable, once-daily partial agonist that selectively targets dopamine D1/D5 receptor subtypes with the goal of balancing meaningful motor control activity with a favorable tolerability profile. To our knowledge, tavapadon is the only D1/D5 partial agonist currently in clinical development for Parkinson’s and the first oral D1/D5 agonist to have achieved sustained motor control improvement in Phase 2 trials of Parkinson’s. Based on extensive clinical data generated to date, including from three Phase 2 trials, we initiated a registration-directed Phase 3 program beginning in January 2020, which includes two trials in early-stage Parkinson’s, known as TEMPO-1 and TEMPO-2, one trial in late-stage Parkinson’s, known as TEMPO-3, and an open-label safety extension trial, known as TEMPO-4. We expect initial data from our Phase 3 program to be available beginning in the first half of 2023.

Parkinson’s disease background

Parkinson’s is a chronic neurodegenerative disorder that primarily results in progressive and debilitating motor symptoms, including decreased bodily movement, or hypokinesia, slowness of movement, or bradykinesia, rigidity, tremor and postural instability. Dopamine is a neurotransmitter that drives motor function through a complex interaction between the striatum, the region of the brain responsible for motor control, the thalamus and the motor cortex. Patients with Parkinson’s lose dopamine-producing neurons in the substantia nigra, leading to increasingly reduced levels of dopamine in the striatum, which is believed to drive Parkinsonian motor symptoms. Parkinson’s is progressive in nature, and the later stages of the disease are marked by progressively lower levels of native dopamine production as an increasing number of dopamine-producing neurons die. The disease typically advances over decades before ultimately causing conditions that can lead to death.

According to the Parkinson's Foundation, approximately one million people in the United States and approximately 10 million people worldwide suffer from Parkinson's. Parkinson's typically develops between the ages of 55 and 65 years and affects approximately 1% of people 60 years of age or older. As the overall global population continues to age, we expect that Parkinson's will afflict an increasing number of patients.

The clinical diagnosis for Parkinson's is well established and is based on the evaluation of both motor and non-motor symptoms. At the time of initial diagnosis, patients usually have a variety of mild, seemingly unrelated symptoms that are collectively non-debilitating. The current standards of care and their shortcomings are well understood. Treatments for early-stage Parkinson's include monoamine oxidase-B, or MAO-B, inhibitors, which reduce the rate of endogenous dopamine metabolism, D2/D3-preferring dopamine agonists, which replace lost dopamine tone, and L-dopa, which increases dopamine concentration. Although these initial treatments for Parkinson's are widely used, each treatment class has limitations that force patients to compromise between tolerability and efficacy.

MAO-B inhibitors are generally well tolerated, but normally demonstrate only modest impact on motor control, limiting use of these drugs to patients with mild symptoms or as an adjunctive therapy. Within two years, approximately 65% of patients on MAO-B inhibitors add medication and approximately 35% of patients on MAO-B inhibitors discontinue use.

Approved D2/D3-preferring agonists are full agonists of the D2/D3 receptor subtypes that are associated with meaningful motor control benefit, but have a challenging side-effect profile, including daytime sedation, or somnolence, compromised impulse control and risk of psychotic symptoms including hallucinations. Within two years, approximately 40% of patients on D2/D3-preferring agonists add medication and approximately 25% of patients on D2/D3-preferring agonists discontinue use. D2/D3 receptor subtypes are widely distributed in multiple non-motor-related brain circuits where over-activation can drive unwanted side effects. For example, repeated activation of D3 receptor subtypes in the reward-related nucleus accumbens may underpin the dysregulation of impulse control. D2/D3-preferring full agonism may also be associated with overexcitation of dopamine receptors, which may lead to increased dyskinesias when used adjunctively with L-dopa. The side effects of D2/D3-preferring agonists can negatively impact quality of life and may outweigh the benefits of treatment, especially in a population of early-stage Parkinson's patients that are otherwise highly functional.

As the disease progresses, patients' treatment regimens increasingly incorporate the use of L-dopa as either monotherapy or in combination with D2/D3-preferring agonists or MAO-B inhibitors. L-dopa is available in a number of formulations, including combinations with carbidopa, which is meant to allow for the use of lower doses of L-dopa to reduce nausea and vomiting side effects. Initial treatment with L-dopa typically results in a period of symptomatic relief for patients because L-dopa therapy transiently increases dopamine levels and affords rapid improvement of motor symptoms. Patients are typically initiated on L-dopa doses of 100 mg administered three times per day.

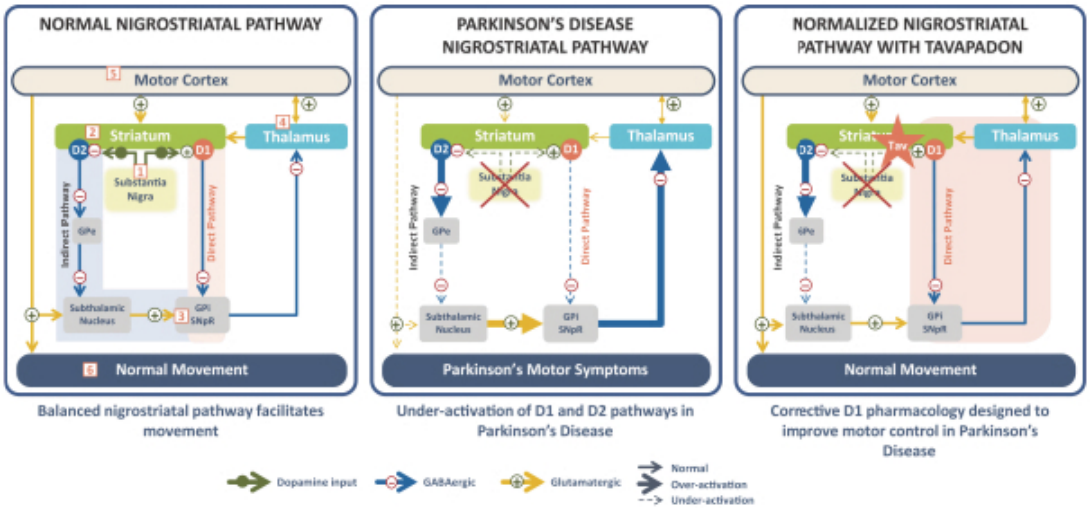
However, due to its short half-life, L-dopa transiently floods neurons with dopamine, resulting in fluctuating periods of high and low dopamine levels. These large fluctuations can cause the neurons in the brain to alter their response over time. With extended dosing, patients who use L-dopa begin to experience fluctuations between periods of insufficient motor control associated with Parkinson's, known as "off" time, and periods of "on" time when they are not bothered by Parkinsonian motor deficits, but can be plagued by therapy-induced involuntary movement, known as dyskinesias. After starting L-dopa therapy, approximately 40% of patients experience "off" time within three to five years and between 30% and 40% of patients experience dyskinesias within five years. As the disease progresses, patients generally need to increase their L-dopa dose and frequency to maintain motor control. In the most advanced stages of disease, L-dopa doses can be as high as 2,000 mg total per day, requiring up to eight doses of L-dopa per day. This further exacerbates fluctuations and leads to more dyskinesias. The onset and intensity of L-dopa-induced dyskinesias are typically correlated with

doses of at least 400 mg per day. The substantial and unpredictable swings between “off” time and dyskinesias can be attributed, in part, to the short half-life of L-dopa. In addition, high doses of L-dopa can be associated with psychosis, which may be further exacerbated by adjunctive use of D2/D3-preferring agonists. In order to delay the onset of such side effects, clinicians may delay recommending L-dopa until patients progress to later stages of Parkinson’s.

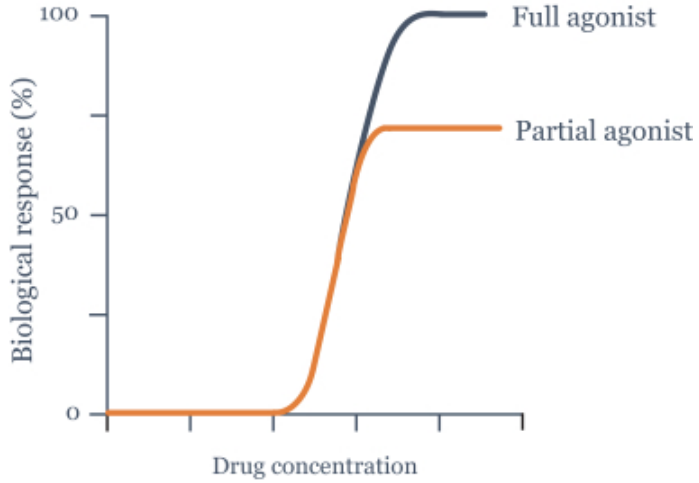
Our solution—tavapadon

Tavapadon is a selective partial agonist of the dopamine D1/D5 receptor subtypes expressed within the direct motor pathway that we are developing for the treatment of both early- and late-stage Parkinson’s. Key differentiating features of tavapadon include:

1. **Mechanism of action—D1/D5 receptor subtype selectivity**: Dopamine D1/D5 receptor subtypes differentially activate the direct motor pathway of the basal ganglia. Tavapadon is >400x more selective for D1/D5 receptor subtypes than for D2/D3 receptor subtypes. It therefore has the potential to drive motor benefit through targeting of the direct motor pathway while avoiding the side effects of D2/D3-preferring agonists, which target the indirect motor pathway. This mechanism of action as it applies to motor function is illustrated below:



2. **Receptor pharmacology—partial agonist:** Tavapadon is an orally bioavailable, brain-penetrant small molecule with a 24-hour half-life that is designed to enable once-daily dosing by providing sustained motor benefit during the crucial morning wake period and throughout the day. Tavapadon is designed as a partial agonist of the D1/D5 receptor subtypes to (1) act as a surrogate for the natural dopamine production lost as a result of the death of dopamine-producing neurons and (2) to activate the D1/D5 receptor subtypes at levels that maximize motor benefit while reducing the prolonged receptor overexcitation and desensitization caused by full agonists, which can lead to dyskinesias and exacerbation of “off” time resulting from L-dopa. Despite the recognized therapeutic potential of selective D1 activation, earlier attempts by others to develop D1/D5 agonists failed due to limited oral bioavailability and brain penetration, short half-lives and other PK limitations. Tavapadon has been designed with a novel chemical structure that is intended to avoid the shortcomings of prior compounds. Tavapadon’s partial agonism is illustrated below. As compared to a full agonist, tavapadon avoids sustained full activation of D1/D5 receptor subtypes.



3. **Clinical and preclinical evaluation**: Tavapadon has been evaluated in 272 subjects in multiple Phase 1 and Phase 2 trials, including in both the early- and late-stage Parkinson's patient populations required for a broad Parkinson's indication. Across all Phase 1b and Phase 2 trials conducted to date, tavapadon has demonstrated motor control benefit with lower levels of somnolence and impulse control side effects than would be anticipated with D2/D3-preferring agonists. In addition, preclinical studies of tavapadon in a translationally relevant non-human primate model demonstrated robust and persistent activity and reduced incidence of dyskinesias. Tavapadon's lack of abuse potential was also supported by a series of non-human primate studies.

We believe the expected clinical profile of tavapadon has the potential to become a standard of care across the treatment spectrum for both early- and late-stage Parkinson's patients.

High-functioning early-stage Parkinson's patients have adequate motor control on monotherapy with D2/D3-preferring agonists, but the side effects of these therapies are often more debilitating than Parkinson's symptoms. On the other hand, while MAO-B inhibitors have a favorable side effect profile, only a small percentage of early-stage Parkinson's patients are well-controlled on this class of drug due to limited efficacy. We believe that tavapadon's potential for motor benefit similar to D2/D3-preferring agonists with a lower likelihood of their commonly-occurring side effects (such as excessive somnolence, hypotension and impulsive behavior) could ultimately enable tavapadon to displace these agents as the current standard of care among early-stage Parkinson's patients.

For the more advanced Parkinson's patient who is no longer adequately treated with D2/D3-preferring agonists, tavapadon's potential motor control benefit may create a treatment option to address motor control symptoms before adding L-dopa to the regimen. Furthermore, we believe tavapadon could be a preferred adjunctive treatment with L-dopa due to its longer half-life, potentially improved tolerability profile and reduced incidence of dyskinesias.

Finally, for the late-stage Parkinson's patient already experiencing "off" time while on L-dopa, tavapadon use as an adjunctive therapy with L-dopa may provide 24-hour coverage and delay the need for L-dopa dose escalation, thus increasing "on" time without troublesome dyskinesias.

We believe our registration-directed Phase 3 program for tavapadon has the potential to establish tavapadon as the cornerstone treatment across the spectrum of Parkinson's disease therapy—the preferred choice for the newly diagnosed patient and the ideal adjunctive therapy as the disease progresses.

Clinical trials

As part of an extensive clinical program, tavapadon has been evaluated across nine prior clinical trials, including four Phase 1 trials, two Phase 1b trials and three Phase 2 trials. A total of 272 subjects, including 99 healthy volunteers and 173 patients with Parkinson's, have been exposed to tavapadon.

Tavapadon has demonstrated activity in the treatment of motor symptoms, both as a monotherapy and as adjunct to L-dopa. An open-label, multi-dose, Phase 1b trial of tavapadon demonstrated reduction in motor symptoms at the 15 mg dose, with a magnitude of effect comparable to results seen in the L-dopa arm of the trial and a duration consistent with tavapadon's 24-hour half-life.

In a Phase 2 trial in early-stage Parkinson's, tavapadon demonstrated a statistically significant and clinically meaningful difference from placebo of -4.8 points on the MDS-UPDRS Part III motor score at week 15 of the treatment period. Separation from placebo was observed as early as week three while still in the titration phase. Statistical significance (p=0.0407) for this endpoint was achieved despite the trial being terminated early when only 65% of the planned trial population had been enrolled and even though only 42% of the patients who reached the maintenance period had received the top dose of 15 mg. In addition, at week 15, 50% of patients treated with tavapadon reported being "much improved" or "very much improved" on the Patient Global Impression of Improvement, an important qualitative assessment of meaningful change in overall patient condition and well-being.

A Phase 2 trial in late-stage Parkinson's was terminated by Pfizer based on the results of an interim analysis, which determined that the probability of meeting the efficacy criterion for the primary endpoint of improvement in "off" time reduction compared to placebo at week 10 was lower than a pre-specified efficacy hurdle. As explained in more detail herein, we believe the pre-specified efficacy hurdle was a significant threshold to overcome given the limited duration of the trial. Despite the early termination of this trial, tavapadon showed a 1.0 hour improvement versus placebo in "on" time without troublesome dyskinesias at week 10 with a sustained effect observed through week 15, which, while not statistically significant, we and our clinical advisors believe is clinically meaningful.

Across the nine clinical trials conducted to date, tavapadon has consistently demonstrated what we believe to be a favorable tolerability profile as well as a PK profile with a 24-hour terminal half-life. The most commonly reported AEs leading to discontinuation of tavapadon across all the clinical trials were nausea, vomiting, dyskinesia, falling, fatigue and sleep disorder. The occurrence of nausea increased with tavapadon dose and was often related to the rate of titration, which is a well-known occurrence with most dopamine receptor agonists. We believe that these gastrointestinal effects may be mitigated by the slower titration method that we plan to use in our registration-directed Phase 3 program. Headache was the most commonly reported CNS-related event across all clinical trials. Other commonly reported CNS-related AEs included dizziness, somnolence and tremor. The majority of all observed AEs were mild to moderate.

In addition, preclinical studies of tavapadon in the well-established MPTP non-human primate model of Parkinson's demonstrated robust and persistent activity and reduced incidence of dyskinesias relative to L-dopa. Tavapadon's lack of abuse potential was also supported in a series of non-human primate studies.

We believe the results observed in the Phase 2 trials in Parkinson's, together with the tolerability profile demonstrated throughout the clinical program to date, support an encouraging benefit-risk profile and strong rationale for our registration-directed Phase 3 program in Parkinson's as well as tavapadon's potential commercial impact.

The table below provides an overview of all clinical trials conducted to date for tavapadon.

Trial Number	Phase	Trial end date	Patients (Tavapadon/ Total)	Design
B7601001	Phase 1	Feb 2014	18/18	Single ascending dose in healthy volunteers
B7601002	Phase 1	Apr 2015	61/77	Multiple ascending dose in healthy volunteers
B7601007	Phase 1	Dec 2014	9/9	Single ascending dose in healthy volunteers with an antiemetic
B7601006	Phase 1	Sept 2017	11/11	CYP3A drug-drug interaction
B7601009(2)	Phase 1b	Feb 2016	18/18(1)	Placebo-controlled single ascending dose in Parkinson's patients who were receiving L-dopa
B7601005(2)	Phase 1b	Mar 2016	45/50(1)	Open-label multiple ascending dose in Parkinson's patients with L-dopa
B7601003(2)	Phase 2	Nov 2017	85/108(1)	Adjunct with L-dopa in late-stage Parkinson's patients
B7601011(2)	Phase 2	Jan 2018	29/57	Monotherapy in early-stage Parkinson's patients
B7601017	Phase 2	Oct 2017	5/5(1)	Open-label extension for patients in Trial B7601003

(1) Note: Four patients participated in both Trials B7601005 and B7601003; three subjects participated in both Trials B7601009 and B7601005; four patients participated in both Trials B7601017 and B7601003.

(2) Most relevant trials discussed in greater detail in the following section.

Our prior and future trials with tavapadon in Parkinson's utilize three scales for patient selection: (1) either the Hoehn and Yahr scale or the modified Hoehn and Yahr scale; (2) the Movement Disorder Society-Unified Parkinson's Disease Rating Scale, or MDS-UPDRS; and (3) the Hauser motor fluctuation patient diary. Two of these scales, MDS-UPDRS and the Hauser diary, are also used to measure therapeutic benefit.

The Hoehn and Yahr scale and modified Hoehn and Yahr scale are commonly accepted reference scales to measure disease progression in Parkinson's, with stage one being the earliest and stage five being the most advanced. In clinical trials of tavapadon, the Hoehn and Yahr scale and the modified Hoehn and Yahr scale are used primarily for patient selection and enrollment.

Hoehn and Yahr scale	Modified Hoehn and Yahr scale
1: Unilateral involvement only usually with minimal or no functional disability	1.0: Unilateral involvement only
	1.5: Unilateral and axial involvement
2: Bilateral or midline involvement without impairment of balance	2.0: Bilateral involvement without impairment of balance
3: Bilateral disease: mild to moderate disability with impaired postural reflexes; physically independent	2.5: Mild bilateral disease with recovery on pull test
	3.0: Mild to moderate bilateral disease; some postural instability; physically independent
4: Severely disabling disease; still able to walk or stand unassisted	4.0: Severe disability; still able to walk or stand unassisted
5: Confinement to bed or wheelchair unless aided	5.0: Wheelchair bound or bedridden unless aided

The MDS-UPDRS or its predecessor are the most widely used assessment for clinical evaluation of Parkinson's, and, to our knowledge, based on a review of the FDA's approved drugs database, Part III scores (alone or in combination with Part II) have been used in some way as the primary basis for evaluation and approval of the three D2/D3-preferring agonists and one MAO-B inhibitor that are currently FDA approved as monotherapies for the treatment of early Parkinson's symptoms. The MDS-UPDRS utilizes a combination of physician and patient assessments. A negative change from baseline in total score represents an improvement in symptoms. A decrease of 3.25 points or greater on the Part III total score and a decrease of 4.9 points or greater on the Part II and III combined total score have been previously identified as clinically relevant changes on these measures. The four parts of the MDS-UPDRS are described below, along with the number of items evaluated in each part and the possible total score range:

MDS-UPDRS Part	Description	Number of items evaluated	Total score range
Part I	Non-motor aspects of experiences of daily living	13	0 to 52
Part II	Motor aspects of experiences of daily living	13	0 to 52
Part III	Motor examination	18	0 to 132
Part IV	Motor complications	6	0 to 24

A cross-sectional study of over 3,000 patients with Parkinson's identified the following mean MDS-UPDRS Part II and Part III scores based on Hoehn and Yahr stage:

Hoehn and Yahr stage	Mean MDS-UPDRS Part II score	Mean MDS-UPDRS Part III score
Stage One	6.5	14.4
Stage Two	11.2	28.8
Stage Three	17.5	40.5

The Hauser diary assesses patient-defined motor function and provides a measure of change in "off" time and "on" time. The Hauser diary asks patients to rate their daily mobility for each 30-minute period over 24 hours, and to record their status for the majority of the period in one of five categories: "on" time without dyskinesias, "on" time with non-troublesome dyskinesias, "on" time with troublesome dyskinesias, "off" time or asleep. To our knowledge, improvements in "off" and "on" time have been used as the primary evaluation of benefit for all

treatments that have been approved by the FDA as adjunctive therapy to L-dopa in patients with advanced Parkinson's experiencing motor fluctuations.

Phase 1b trials in parkinson's disease

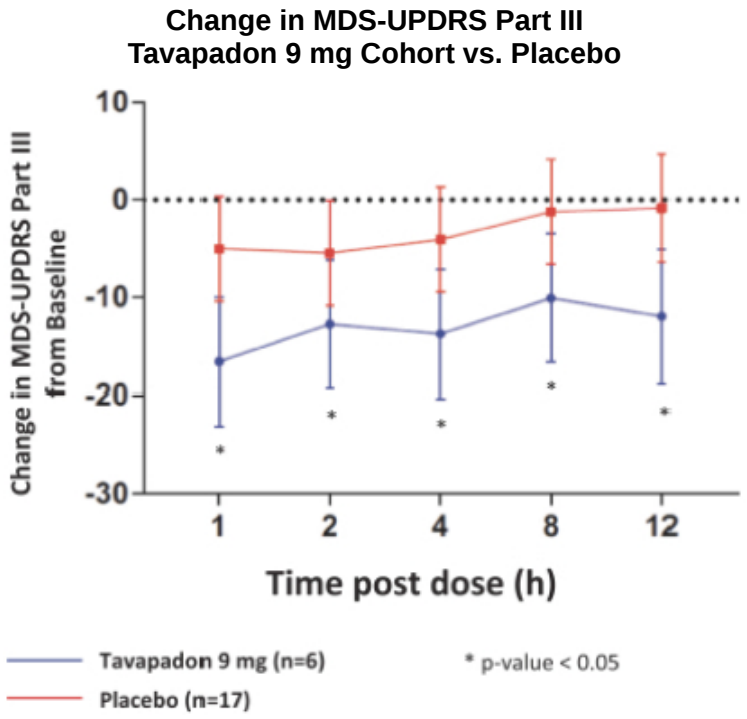
Single ascending dose trial

In February 2016, Pfizer completed Trial B7601009, a double-blind, placebo-controlled Phase 1b trial in 18 Parkinson's patients who were receiving L-dopa. This trial was designed to evaluate the safety and tolerability of tavapadon in Parkinson's patients, with secondary objectives of evaluating the PK and PD of single ascending doses of tavapadon.

Enrolled patients had either stage two or three Parkinson's, as measured on the Hoehn and Yahr scale. Patients were randomized in two cohorts to receive placebo and two dose levels of tavapadon in a crossover fashion. As part of the trial, L-dopa was withdrawn for at least 12 hours before administration of tavapadon or placebo.

The primary objective of the trial was to evaluate safety and tolerability of single ascending doses ranging from 0.75 mg to 9 mg of tavapadon. The trial also evaluated a secondary endpoint of change from baseline in MDS-UPDRS Part III motor score, which was measured at baseline and at one, two, four, eight and 12 hours post-dose.

Analyses of MDS-UPDRS Part III motor scores showed that tavapadon was associated with a statistically significant decrease, or improvement, from baseline in total motor score compared to placebo. In the six patients treated with a single dose of 9 mg of tavapadon, MDS-UPDRS Part III motor scores improved significantly by between 7.27 and 11.58 points compared to placebo at all post-dose time points (p-values of 0.0005, 0.0285, 0.0037, 0.0079 and 0.0028 at one, two, four, eight and 12 hours post-dose, respectively), as illustrated below.



The mean decreases from baseline in total MDS-UPDRS Part III motor score at one, two, four, eight and 12 hours for patients in the tavapadon 3 mg and 6 mg treatment groups were numerically greater than the placebo group, but were not statistically significant. Other doses of tavapadon evaluated in this trial were considered sub-therapeutic.

There were no SAEs in the trial or any discontinuations due to AEs. The most common AEs were headache, nausea and vomiting, all of which were mild to moderate in severity. Nausea and vomiting appeared to be dose- dependent, with increased frequency observed at higher doses of tavapadon.

Multiple ascending dose trial

In March 2016, Pfizer completed Trial B7601005, a two-period, open-label, dose escalation Phase 1b trial designed to evaluate the safety and tolerability of tavapadon in Parkinson's patients, with a secondary objective of characterizing the PK of tavapadon when used in combination with L-dopa and exploring the effect of tavapadon on motor performance and dyskinesia.

The trial enrolled 50 patients with stage one to three Parkinson's as measured on the Hoehn and Yahr scale and a documented history of experiencing "off" time with their current L-dopa dose. Patients were randomized into four cohorts to receive three different target doses of tavapadon. One cohort received a target dose of 5 mg once-daily, or QD, one cohort received a target dose of 25 mg QD and two separate cohorts received target doses of 15 mg QD, with one of the two cohorts including only patients with Parkinson's with documented L-dopa-induced dyskinesias and using a similar but more flexible up-titration schedule.

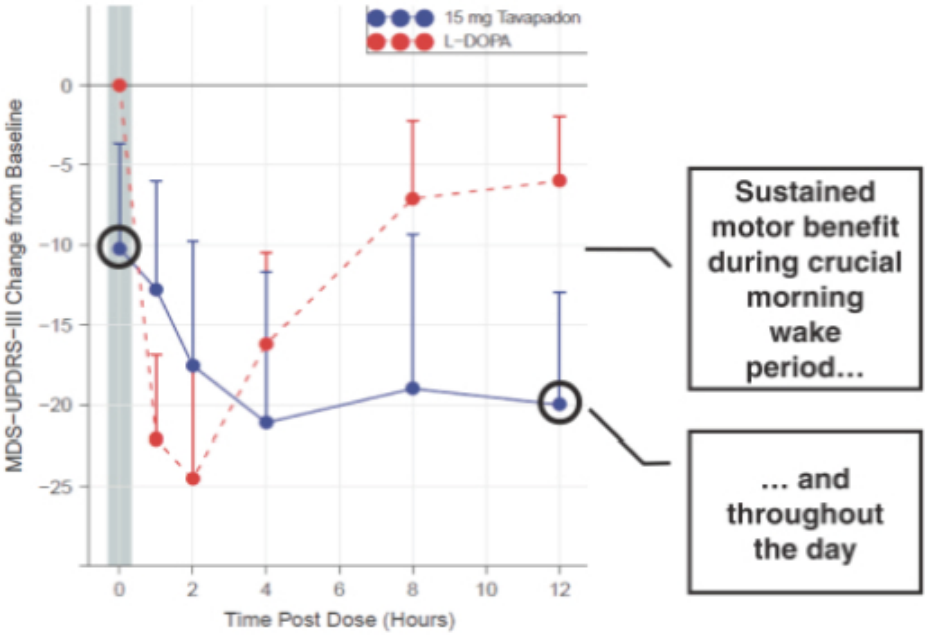
In Period 1 of the trial, 50 patients were treated with a single individualized dose of L-dopa, representing approximately one-third of each patient's normal total daily L-dopa equivalent dose, to confirm L-dopa responsiveness. L-dopa responsiveness was evaluated after an overnight washout of the medication. A typical L-dopa regimen includes at least three doses per day, so this approach was taken to standardize the trial while also administering a test dose of L-dopa that was equivalent to or greater than a typical L-dopa dose for each patient. In Period 2 of the trial, 45 patients were administered increasing doses of tavapadon up to the target dose of their respective cohorts. Target tavapadon doses were attained using titration schemes over an 11-day period. Tavapadon was added to the regimen while L-dopa therapy was simultaneously tapered down with the intent to withdraw L-dopa entirely over two weeks. Once the target tavapadon daily dose of 5 mg, 15 mg or 25 mg for each cohort was reached, the respective target dose levels were maintained for at least 10 days. L-dopa use was permitted as a rescue treatment throughout the trial.

The objectives of the trial were to evaluate the safety and tolerability of multiple doses of tavapadon in patients with Parkinson's, to characterize the PK of L-dopa following a single dose and the PK of tavapadon following multiple doses and to explore the effect of tavapadon on motor performance and dyskinesia. Exploratory objectives included evaluating changes in MDS-UPDRS Part III motor scores before and after treatment, both acutely and after multiple doses of tavapadon without the concurrent use of L-dopa. L-dopa was withdrawn overnight before evaluation of MDS-UPDRS Part III motor scores on days 7, 13 and 22 in Period 2.

As shown below, on day 22, the last day of Period 2, administration of tavapadon in one of the 15 mg cohorts of 11 patients demonstrated a sustained MDS-UPDRS Part III motor score benefit for up to 12 hours. The magnitude of motor benefit was comparable to what had been observed following a single administration of L-dopa in Period 1, the previously discussed L-dopa responsiveness test, in this cohort. A reduction of about 10 points from baseline was observed at time zero, just before dosing, on Day 22, demonstrating the sustained effect of tavapadon 24 hours after the previous dose. We believe this observation of sustained benefit supports the potential for once-daily dosing of tavapadon. Patients in the 5 mg and 25 mg cohorts also observed sustained and what we believe to be clinically relevant motor benefit over eight hours, albeit with less magnitude than the

15 mg cohort. In the 15 mg cohort with dyskinetic patients, only three of the six patients dosed with tavapadon completed the trial, resulting in too small of a dataset to draw meaningful conclusions.

Change in MDS-UPDRS Part III in Cohort 4
on Day 1 (L-Dopa Responsiveness Test) and Day 22 (Tavapadon 15 mg QD)



Based on the results of this trial, multiple ascending doses of tavapadon of up to 25 mg were considered to be generally well tolerated. A total of 11 patients, including four of 17 patients in the two 15 mg cohorts and seven of 19 patients in the 25 mg cohort, discontinued tavapadon due to AEs. Headache (four occurrences) and abnormal dreams (two occurrences) were the most common AEs leading to discontinuation. Headache, nausea, abnormal dreams, dizziness and vomiting were the most common AEs across all cohorts, the majority of which were mild to moderate in severity, with six severe adverse events and one SAE observed. One patient in the 25 mg cohort experienced an SAE of palpitations, which occurred at the 1 mg titration dose and was determined by the investigator as not related to treatment. The majority of AEs occurred during the titration period, with the gastrointestinal AEs appearing to be dose related. Most AEs appeared to be related to the pace and increment of up-titration rather than maximum exposure to tavapadon.

Phase 2 trials in early-stage and late-stage parkinson's

Early-stage parkinson's

In January 2018, Pfizer concluded Trial B7601011, a 15-week, double-blind, randomized, placebo-controlled, flexible dose Phase 2 trial designed to evaluate the efficacy, safety and tolerability of tavapadon in patients with early-stage Parkinson's. As discussed below, Pfizer terminated this early-stage Parkinson's trial early based on the results from the Phase 2 late-stage Parkinson's trial.

The trial enrolled 57 early-stage Parkinson's patients with stage one to three Parkinson's as measured on the Hoehn and Yahr scale. Prior to early termination of the trial by Pfizer, 88 patients had been planned to be

enrolled in the trial. Patients were randomized on a 1:1 basis into two arms to receive 15 weeks of treatment with tavapadon or placebo. The 15-week treatment period included nine weeks of dose titration and optimization followed by six weeks of stable dosing at up to 15 mg of tavapadon. The primary endpoint was the change in MDS-UPDRS Part III motor score from baseline at week 15. Exploratory endpoints included the Patient Global Impression of Improvement, or the PGI-I, and the Epworth Sleepiness Scale, or the ESS.

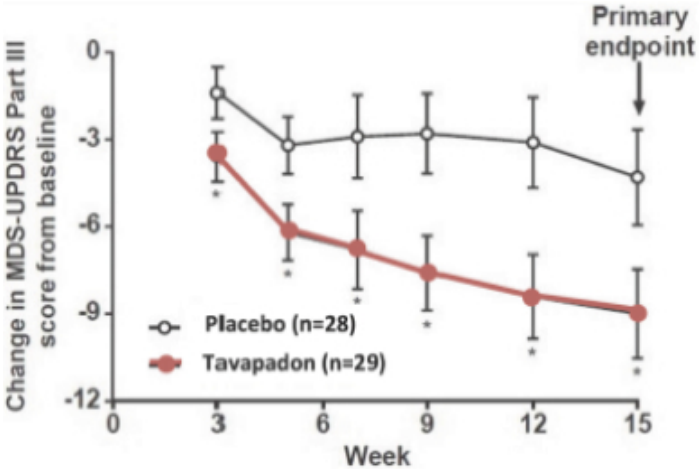
As part of the trial design, there was a pre-determined decision to terminate the trial early if the concurrent Phase 2 trial in late-stage Parkinson's (Trial B7601003) did not meet a strategic pre-set threshold for efficacy at the interim analysis. As described below, the late-stage Parkinson's trial was terminated early, which resulted in the early termination of this trial as well. At the time of the trial termination, only 11 of 26 patients that reached the six-week maintenance period were on the 15 mg target dose.

This trial enrolled treatment-naïve Parkinson's patients that had no prior exposure to Parkinson's medications as well as Parkinson's patients with prior or current use of MAO-B inhibitors, amantadine and anticholinergics. Concurrent use of these medications was permitted during the trial as long as dosing had been stable for at least 42 days prior to randomization. Patients with incidental prior exposure to L-dopa or a dopamine agonist for less than a total of 28 days were also permitted, as long as such exposure had not occurred within seven days of randomization. In total, 57 patients were randomized, with 29 patients in the active arm and 28 patients in the placebo arm. Due to the early termination of the trial, only 65% of target enrollment was reached and 25 active patients and 22 placebo patients completed the trial. Despite the reduced sample size of patients completing the trial, the trial demonstrated a statistically significant improvement in MDS-UPDRS Part III motor scores from baseline at week 15 for patients on tavapadon as compared to placebo. The trial originally planned to enroll 88 patients to power for the conventional threshold for statistical significance of p=0.05, based on a predicted treatment effect of at least -3.6 points on the primary endpoint of change in MDS-UPDRS Part III motor score from baseline at week 15. Since the actual observed treatment effect of -4.8 points was in excess of the expected treatment effect of -3.6 points used to power the trial, fewer than expected patients were required for sufficient power to demonstrate statistical significance. While the trial was terminated early, resulting in fewer patients being enrolled into and dosed in the trial than originally expected, such early termination of recruitment did not affect the validity of the trial or the results achieved as they relate to the patients that actually completed the dosing regimen as originally planned. Additionally, the early termination of the trial did not result in the dosed patients being treated for a shorter duration than planned or in a different manner than was contemplated by the protocol. Furthermore, the early termination of the trial did not introduce selection or allocation bias with respect to randomization. The early termination of recruitment did not alter the enforced inclusion or exclusion criteria that defined the target patient population, the 1:1 balanced and double-blind randomization or assignment of subjects to treatment arms, nor the treatment duration contemplated by the original trial design. Although the overall number of patients dosed decreased as a result of early termination, these patients studied were representative of the target population of early-stage Parkinson's patients. In the dosed trial population, the variance of the results did not exceed what was expected in the original powering assumptions for the trial, nor what was consistently observed among prior early-stage Parkinson's trials.

The results of the trial on the full dataset are summarized below.

- As illustrated below, the mean change from baseline at week 15 in the MDS-UPDRS Part III motor score was -9.0 for tavapadon across all dose levels administered in the maintenance phase and -4.3 for placebo, with a least squares mean improvement over placebo of -4.8 in favor of the tavapadon group (p=0.0407). These changes are well above the 3.25-point improvement that is recognized as clinically meaningful on the MDS-UPDRS Part III motor score. Mean baseline MDS-UPDRS III motor scores were 24.3 and 25.8 for the tavapadon and placebo groups, respectively.

Change in MDS-UPDRS Part III



* Indicates two-sided p-value of less than or equal to 0.1.

- At week 15, 50% of patients treated with tavapadon reported being “much improved” or “very much improved” on the PGI-I, compared with 25% in the placebo group (p=.0393). The PGI-I is a patient-reported outcome and an important qualitative assessment of meaningful change in overall patient condition and well-being.
- At weeks 9 and 15, across all dose levels, tavapadon demonstrated a 1.0 and 1.1 point improvement, respectively, relative to placebo on the MDS-UPDRS Part II total score, which measures motor aspects of experiences of daily living. Because sample sizes were small and the trial was not powered to show significance on this endpoint, these changes were not statistically significant. Since each item evaluated by the MDS-UPDRS II total score measures daily function, we believe that any measurable improvements over placebo would be considered clinically relevant.
- At weeks 9 and 15, there was no statistically significant difference between the tavapadon and placebo groups in somnolence as measured by the ESS. Somnolence is a known side effect of D2/D3-preferring agonists.
- Tavapadon demonstrated the potential for a favorable tolerability profile, with the majority of AEs reported as mild or moderate and one SAE of suicidal ideation observed, which was considered related to the investigational product by the investigator but not related by the sponsor, and which was resolved on the same day. The most frequently reported AEs in patients treated with tavapadon were nausea, headache, dry mouth, tremor and fatigue. Treatment compliance was high in both the tavapadon and placebo groups, with 86% of patients who received tavapadon completing the trial.

The trial results described above are based on nine weeks of dose titration and optimization and only six weeks of stable dosing. Past Parkinson’s trials for other compounds have indicated that the results observed in placebo subjects on measures such as the MDS-UPDRS scale may peak between eight and 18 weeks of treatment and then deteriorate over a longer timeframe, resulting in a greater difference between active treatment and placebo at six months. We believe a longer treatment duration of six months could result in further improved results compared to placebo.

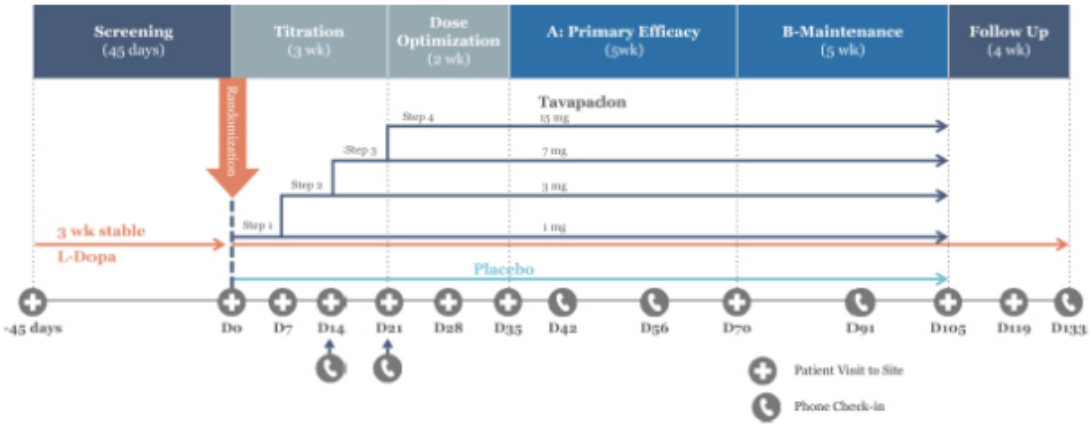
The table below summarizes treatment-emergent AEs that occurred during the trial:

Number (%) of Subjects with AEs	Tavapadon (N=29)	Placebo (N=28)
With Any AEs	**25 (86.2)**	**18 (64.3)**
Gastrointestinal Disorders	**16 (55.2)**	**7 (25.0)**
Diarrhea	1 (3.4)	3 (10.7)
Dry mouth	5 (17.2)	0
Dyspepsia	1 (3.4)	2 (7.1)
Nausea	9 (31.0)	2 (7.1)
General Disorders and Administration Site Conditions	**7 (24.1)**	**8 (28.6)**
Fatigue	3 (10.3)	3 (10.7)
Infections and Infestations	**6 (20.7)**	**3 (10.7)**
Nasopharyngitis	2 (6.9)	1 (3.6)
Urinary tract infection	3 (10.3)	0
Metabolism and Nutrition Disorders	**4 (13.8)**	**2 (7.1)**
Decreased appetite	3 (10.3)	0
Musculoskeletal and Connective Tissue Disorders	**11 (37.9)**	**3 (10.7)**
Arthralgia	3 (10.3)	0
Back pain	3 (10.3)	1 (3.6)
Nervous System Disorders	**14 (48.3)**	**6 (21.4)**
Dizziness	2 (6.9)	1 (3.6)
Dysgeusia	2 (6.9)	0
Dystonia	2 (6.9)	0
Headache	7 (24.1)	2 (7.1)
Hypoaesthesia	2 (6.9)	0
Paraesthesia	2 (6.9)	0
Somnolence	4 (13.8)	1 (3.6)
Tremor	4 (13.8)	2 (7.1)
Psychiatric Disorders	**8 (27.6)**	**4 (14.3)**
Abnormal dreams	2 (6.9)	0
Anxiety	2 (6.9)	1 (3.6)
Depression	2 (6.9)	0
Insomnia	2 (6.9)	2 (7.1)
Irritability	2 (6.9)	0
Restlessness	2 (6.9)	0
Vascular Disorders	**4 (13.8)**	**1 (3.6)**
Hot flush	3 (10.3)	0
Hypotension	2 (6.9)	0

Late-stage parkinson's

In November 2017, Pfizer concluded Trial B7601003, a randomized, double-blind, placebo-controlled dose-ranging Phase 2 trial designed to evaluate the efficacy, safety and tolerability of tavapadon as an adjunct therapy for patients on L-dopa experiencing motor fluctuations due to Parkinson's.

The trial was designed to enroll approximately 198 patients with late-stage Parkinson's on stable doses of at least 400 mg of L-dopa four times per day and experiencing at least 2.5 hours of "off" time per day for three consecutive days based on the Hauser diaries collected during screening. After the screening period, patients who met the screening criteria were randomized to four treatment groups of tavapadon or placebo as an add-on therapy to L-dopa: 15 mg QD, 7 mg QD, 3 mg QD, 1 mg QD or placebo. The trial duration was approximately 25 weeks, including a 45-day screening period, a 15-week double-blind treatment period and an approximately 28-day follow-up period. The treatment period was comprised of up to three weeks of dose titration, two weeks of dose optimization and Period A, five weeks of maintenance, followed by Period B, either five additional weeks of maintenance with concurrent down-titration of L-dopa dosing or five additional weeks of maintenance with the current L-dopa regimen kept stable. The design of the trial is summarized below:



The primary endpoint was the change from baseline in daily hours of "off" time at the end of Period A (week 10), based on patient-reported Hauser diaries. Key secondary and exploratory endpoints included change in "on" time without troublesome dyskinesias, the PGI-I, the ESS and performance on MDS-UPDRS Parts I-IV motor scores.

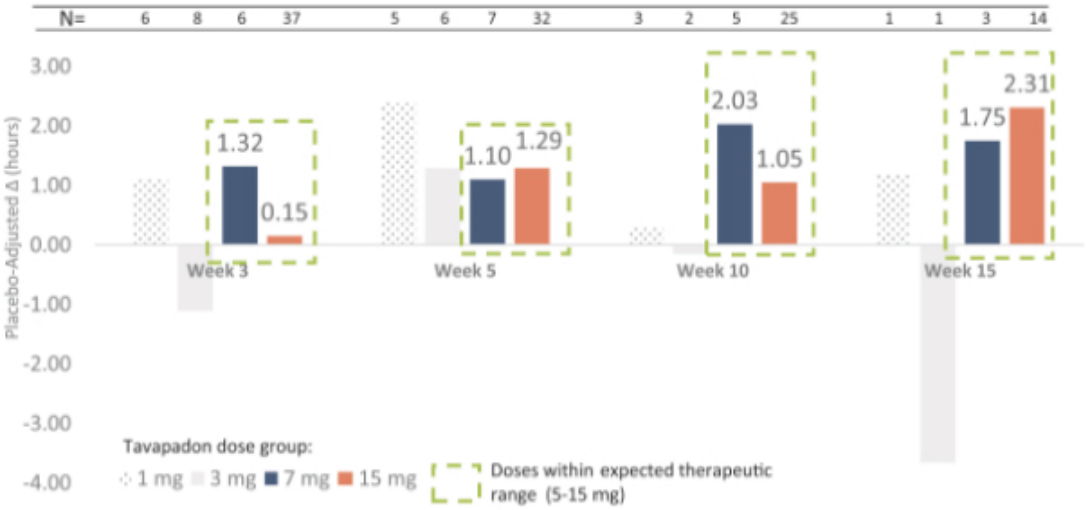
As part of the initial trial protocol, Pfizer established a pre-defined early termination criterion based on the likelihood of achieving a pre-specified efficacy hurdle. We believe this efficacy hurdle was set disproportionately high given the treatment duration of the trial. Specifically, an interim analysis was conducted when 108 patients of the targeted 198 patients were enrolled to determine if there was a less than 10% predictive probability of demonstrating an absolute placebo-adjusted reduction in "off" time of 1.5 hours or more at week 10. The interim analysis revealed that this pre-defined efficacy hurdle was not met by any of the doses of tavapadon evaluated in this trial. At the time of the interim analysis, approximately 50 patients had completed treatment through week 10 of the trial. Based on these interim results, Pfizer made a decision to terminate both this trial as well as the concurrent Phase 2 early-stage Parkinson's trial described above (Trial B7601011).

We believe the pre-defined efficacy criterion was a significant hurdle to meet given the limited duration of the trial, where patients spent the first three weeks of treatment titrating up to the maximum 15 mg target dose of tavapadon, if tolerated, and only seven weeks of treatment at the maintenance dose. Based on historical data from past Parkinson's clinical development programs, we believe that a minimum of six months of treatment, inclusive of dose titration to a target maintenance dose, would be necessary to see an absolute placebo-adjusted reduction in "off" time of 1.5 hours or more.

In the final analysis of the primary endpoint, the placebo-adjusted reduction from baseline to week 10 in average daily "off" time was 0.63 hours for the tavapadon 15 mg QD group (n=41), which, although not

statistically significant, we believe to be clinically relevant. For example, the approval of Nourianz (istradefylline) as adjunctive treatment with L-dopa in Parkinson's was based on placebo-adjusted improvements in "off" time of less than one hour. Furthermore, the final analysis also showed a clinically meaningful one-hour improvement in "on" time without troublesome dyskinesias at week 10 for the tavapadon 15 mg QD group as compared to placebo. For doses of tavapadon below 15 mg, the sample sizes were too small to draw meaningful conclusions (nine patients in the 3 mg QD group, nine patients in the 7 mg QD group and seven patients in the 1 mg QD group).

Placebo-adjusted change in "on" time without troublesome dyskinesias



Although the endpoints in this trial did not achieve statistical significance, we believe that if the trial had been completed with the full sample size, there would have been a reasonable possibility of observing a treatment effect and statistical separation from placebo on both the "off" time and "on" time without troublesome dyskinesias endpoints.

A further pre-specified analysis of secondary endpoints was also completed for the 21 patients who completed treatment through week 15 of the trial, while keeping their L-dopa dose unchanged. This analysis showed a placebo-adjusted reduction from baseline in average daily "off" time of 3.52 hours and an increase in average daily "on" time without troublesome dyskinesias of 2.31 hours. The increases in treatment effect from week 10 to week 15 were primarily driven by a worsening of motor fluctuations in the placebo arm, with tavapadon activity remaining comparable to what was observed at week 10. Although based on only 21 patients (14 patients in the tavapadon 15 mg group and seven patients in the placebo group), which represented approximately half of the patients available at week 10, the observed durability of the treatment effect through week 15 strengthens our belief that the motor control improvements observed with tavapadon are reliable and support our decision to proceed to a registration-directed Phase 3 trial.

Historically, the FDA considered the "off" time endpoint to be an appropriate assessment of therapeutic benefit in patients with late-stage Parkinson's. However, the FDA's view has evolved, and the agency now considers the change from baseline in average daily "on" time without troublesome dyskinesias to be the most appropriate assessment of therapeutic benefit for this patient population. Based on the above data, we plan to utilize the change from baseline in "on" time without troublesome dyskinesias as the primary endpoint in our Phase 3 trial of tavapadon as an adjunct to L-dopa in late-stage Parkinson's patients.

The table below summarizes treatment-related AEs occurring in two or more subjects during this trial, which were generally consistent with the other clinical trials of tavapadon conducted to date:

Number (%) of Subjects with AEs	Placebo (N=23)	Tavapadon 1 mg QD (N=13)	Tavapadon 3 mg QD (N=15)	Tavapadon 7 mg QD (N=13)	Tavapadon 15 mg QD (N=44)	Total (N=108)
With Any AE	**7 (30.4)**	**4 (30.8)**	**7 (46.7)**	**6 (46.2)**	**29 (65.9)**	**53 (49.1)**
Gastrointestinal Disorders	**1 (4.3)**	**2 (15.4)**	**2 (13.3)**	**1 (7.7)**	**12 (27.3)**	**18 (16.7)**
Gastroesophageal reflux disease	0	0	0	0	2 (4.5)	2 (1.9)
Nausea	1 (4.3)	2 (15.4)	2 (13.3)	0	8 (18.2)	13 (12.0)
Vomiting	0	0	1 (6.7)	0	1 (2.3)	2 (1.9)
General Disorders and Administration Site Conditions	**1 (4.3)**	**2 (15.4)**	**1 (6.7)**	**2 (15.4)**	**3 (6.8)**	**9 (8.3)**
Fatigue	1 (4.3)	1 (7.7)	1 (6.7)	2 (15.4)	1 (2.3)	6 (5.6)
Metabolism and Nutrition Disorders	**0**	**1 (7.7)**	**0**	**1 (7.7)**	**3 (6.8)**	**5 (4.6)**
Decreased appetite	0	1 (7.7)	0	1 (7.7)	3 (6.8)	5 (4.6)
Musculoskeletal and Connective Tissue Disorders	**1 (4.3)**	**1 (7.7)**	**0**	**1 (7.7)**	**3 (6.8)**	**6 (5.6)**
Musculoskeletal stiffness	0	1 (7.7)	0	0	1 (2.3)	2 (1.9)
Pain in extremity	1 (4.3)	0	0	0	1 (2.3)	2 (1.9)
Nervous System Disorders	**2 (8.7)**	**2 (15.4)**	**4 (26.7)**	**5 (38.5)**	**19 (43.2)**	**32 (29.6)**
Balance disorder	1 (4.3)	0	0	1 (7.7)	0	2 (19)
Dizziness	0	0	1 (6.7)	1 (7.7)	4 (9.1)	6 (5.6)
Dyskinesia	0	1 (7.7)	1 (6.7)	2 (15.4)	7 (15.9)	11 (10.2)
Dystonia	1 (4.3)	0	0	0	1 (2.3)	2 (1.9)
Headache	0	1 (7.7)	1 (6.7)	2 (15.4)	10 (22.7)	14 (13.0)
Parkinson's disease[(1)]	0	0	1 (6.7)	0	1 (2.3)	2 (1.9)
Somnolence	0	0	1 (6.7)	1 (7.7)	0	2 (1.9)
Psychiatric Disorders	**4 (17.4)**	**1 (7.7)**	**2 (13.3)**	**2 (15.4)**	**12 (27.3)**	**21 (19.4)**
Abnormal dreams	1 (4.3)	0	1 (6.7)	0	3 (6.8)	5 (4.6)
Anxiety	0	0	0	0	3 (6.8)	3 (2.8)
Depersonalization/derealization disorder	0	1 (7.7)	0	0	1 (2.3)	2 (1.9)
Depressed mood	1 (4.3)	0	0	0	1 (2.3)	2(1.9)
Insomnia	2 (8.7)	1 (7.7)	0	1 (7.7)	1 (2.3)	5 (4.6)
Irritability	0	0	0	0	3 (6.8)	3 (2.8)
Sleep disorder	0	0	1 (6.7)	1 (7.7)	1 (2.3)	3 (2.8)
Vascular Disorders	**0**	**0**	**2 (13.3)**	**0**	**1 (2.3)**	**3 (2.8)**
Orthostatic hypotension	0	0	1 (6.7)	0	1 (2.3)	2 (1.9)
Total Events	**10**	**11**	**13**	**19**	**84**	**137**

(1) Indicates worsening of Parkinson's symptoms.

Safety and tolerability data

To date, 272 subjects have received at least one dose of tavapadon across nine clinical trials, including healthy volunteers in four Phase 1 trials and patients with Parkinson's in two Phase 1b trials and three Phase 2 trials. Across these trials, tavapadon was generally well tolerated up to a titrated dose of 25 mg QD. A dose-dependent increase in the frequency of nausea and headache was observed across all trials. Most AEs were self-limited and mild to moderate in severity, with nausea, vomiting, dyskinesia, fall, fatigue, sleep disorder and tremors being the most common AEs leading to discontinuation of tavapadon, with a total of 29 patients with Parkinson's (including seven patients at the 25 mg dose, which is not being pursued in our registration-directed Phase 3 program) and nine healthy volunteers across all trials discontinuing tavapadon due to AEs.

As expected for a dopaminergic agent, there was a marked difference in tolerability in healthy volunteers who do not have a preexisting dopamine deficit when compared to Parkinson's patients. For example, a single dose of 9 mg in our Phase 1b SAD trial was generally well tolerated in Parkinson's patients, while a single dose of 1.5 mg in our Phase 1 SAD trial was associated with a high rate of nausea and vomiting in healthy volunteers. This difference is also seen with other dopaminergic drugs such as L-dopa and D2/D3-preferring agonists. These agents are titrated when used as Parkinson's treatments to improve tolerability to gastrointestinal and other side effects. The speed of titration may also play a role in the tolerability of side effects such as nausea and vomiting. We will titrate more slowly in our ongoing registration-directed Phase 3 program, which we believe will help mitigate such side effects.

There were no observations of notable differences in laboratory results, parameters or suicidality assessments between tavapadon and placebo. An analysis of multi-dose cohorts in Phase 1 trials in healthy volunteers and Parkinson's patients, including patients who were treated at doses of up to 25 mg QD of tavapadon, did not suggest that tavapadon prolongs the QTc interval, an electrocardiogram, or ECG, measurement used to assess the risk of potential cardiac arrhythmias, corrected for heart rate by Fridericia's formula. Transient prolongation of group mean QTc interval of up to 11 milliseconds was observed in single dose trials in healthy volunteers and in Parkinson's patients. However, QTc interval prolongation was not observed in any multi-dose trials. Based on our end-of-Phase 2 meeting with the FDA where we presented single-dose ECG, multiple-dose ECG and a model-based analysis of Phase 1 data, we plan to collect time- matched PK and ECG measures in a subset of patients as a sub-study in our ongoing Phase 3 fixed-dose early-stage Parkinson's trial. A stand-alone thorough QT study was not required by the FDA and is not planned.

Clinical trials of longer treatment duration of up to 15 weeks suggest a modest tavapadon dose-related decrease from baseline in systolic and/or diastolic parameters, with some cases of asymptomatic hypotension. Postural hypotension is a common finding in the population of Parkinson's patients. The occurrence of symptomatic and acute symptomatic orthostatic hypotension with use of L-dopa and D2/D3-preferring agonists is a well-documented risk. Based on preclinical and clinical data observed to date and on tavapadon's partial agonism pharmacology, we believe the risk of hypotension is reduced with tavapadon relative to full dopamine agonists.

Preclinical studies

In preclinical studies using the well-established MPTP non-human primate model of Parkinson's, tavapadon demonstrated a sustained and improved reduction of Parkinson's symptoms and reduced dyskinesias compared to L-dopa treatment over a six-hour time course. The MPTP non-human primate model exhibits the motor symptoms of Parkinson's as a result of dopaminergic cell death in the substantia nigra. L-dopa treatment has been demonstrated to reverse Parkinson's symptoms in this model, and similar to Parkinson's patients, chronic treatment induces dyskinesias. In the MPTP model, tavapadon treatment demonstrated achievement of similar improvement in disability score compared to L-dopa with reduced dyskinesias relative to those observed with L-dopa across a seven-month study period. In addition, a series of preclinical GLP studies in non-human

primates demonstrated a profile with low abuse potential. Based on these results, the FDA did not request a human abuse potential study during our end-of-Phase 2 meeting.

Preclinical safety and toxicology studies up to 26 and 39 weeks have been completed in rats and primates to allow for chronic dosing in humans. Preclinical safety and pharmacology studies showed effects on lowering blood pressure, which is routinely seen with dopaminergic agents, and an acute prolongation of the QT interval. Other safety studies, including preclinical reproductive, developmental and genetic toxicology studies, have not revealed any signals of note. Additional toxicology studies are ongoing and planned.

Ongoing clinical trials

Based on the substantial clinical data generated to date with tavapadon, we initiated our registration-directed Phase 3 program beginning in January 2020. This program includes two trials in early-stage Parkinson's, known as TEMPO-1 and TEMPO-2, one trial in late-stage Parkinson's, known as TEMPO-3, and an open-label extension trial, known as TEMPO-4. Informed by the results of the Phase 2 trials in early- and late-stage Parkinson's, our Phase 3 program has been designed to further characterize and evaluate tavapadon's risk-benefit profile in the context of existing standards of care for Parkinson's patients. Specifically, these trials will evaluate the utility of tavapadon across the disease spectrum of Parkinson's, from early-stage patients to late-stage patients experiencing dyskinesias and "off" time on L-dopa. Our Phase 3 program will include additional standard clinical pharmacology studies to support a potential future new drug application, or NDA, submission and product labeling. We had an end-of-Phase 2 meeting with the FDA in August 2019, during which we obtained feedback on our registration-directed Phase 3 program. Based on this feedback, we believe that we have an understanding of all of the essential elements required for a potential NDA submission for tavapadon.

Phase 3 early-stage parkinson's trials

As part of our registration-directed Phase 3 program, we are conducting two trials in early-stage Parkinson's patients. The diagram below summarizes the design of the two trials:

TEMPO-1: phase 3 fixed-dose early-stage parkinson's trial

Based on historical registrational fixed-dose trials of approved Parkinson's treatments, we designed TEMPO-1, a Phase 3 trial as a double-blind, randomized, placebo-controlled, parallel-group, fixed-dose, 27-week trial to evaluate the efficacy, safety and tolerability of tavapadon in early-stage Parkinson's patients. We expect to enroll 522 patients with 1:1:1 randomization between tavapadon 5 mg QD, tavapadon 15 mg QD and placebo. We incorporated a preset mandatory dose titration schedule across the first six weeks of treatment in an attempt to minimize patient discontinuations. Key inclusion criteria include patients with modified Hoehn and Yahr

stage one to two Parkinson's with baseline MDS-UPDRS Part III motor score of 10 or greater and Part II score of two or greater. No concomitant Parkinson's medications are allowed, except for use of MAO-B inhibitors if treatment was initiated at least 90 days before entering the trial and the dosage will remain stable for the duration of the trial.

The primary endpoint for both our fixed-dose early-stage Parkinson's trial and our flexible-dose early-stage Parkinson's trial discussed below will be the change from baseline of the combined MDS-UPDRS Parts II and III scores. There is a long history of using the MDS-UPDRS Part III score, either individually or in combination with Part II score, as the primary endpoint in registrational Parkinson's trials. To our knowledge, Part III scores have been used alone or in combination with Part II scores as the primary basis of approval for the three D2/D3- preferring agonists and one MAO-B inhibitor that are currently FDA approved as monotherapies for the treatment of early Parkinson's symptoms. During our end-of-Phase 2 meeting with the FDA, the FDA stated that they believe that the MDS-UPDRS Part II score without Part III is a more appropriate primary endpoint in clinical trials for early-stage Parkinson's patients, as all score changes in activities rated in Part II reflect a clinically relevant change in patients. The FDA explained that its interpretation of the primary endpoint results in our early-stage Phase 3 Parkinson's trials would depend on a detailed analysis of the results and of the respective contributions of Parts II and III to the final trial results. The FDA also indicated that a determination as to whether the trials contribute substantial evidence of effectiveness would be a review issue at the time of the submission of the NDA.

Accordingly, the target enrollment being utilized for our Phase 3 trials in early-stage Parkinson's is powered, based on results from the Phase 2 early-stage Parkinson's trial, to provide 90% confidence of detecting a statistically significant placebo-adjusted improvement from baseline of four points or greater in the Part II and III combined score and a statistically significant placebo-adjusted change from baseline of one point or greater in the Part II score alone. Since each item evaluated by the MDS-UPDRS Part II total score measures daily function, we believe that any measurable improvements over placebo would be considered clinically relevant. Patients without any meaningful functional deficit at baseline, represented by an MDS-UPDRS Part II score of zero or one, who are thus not able to show meaningful improvement on their Part II score with treatment, will be excluded from the trials. We also believe the extended 27-week period of treatment will increase the probability of a robust difference from placebo on both the primary endpoint of Part II and III combined scores and the individual Part II score.

Key secondary endpoints are the change from baseline in the MDS-UPDRS Part II score and a responder analysis on Patient Global Impression of Change, a patient-reported assessment of the overall benefit of treatment (referred to as the PGI-I in prior tavapadon trials). Additional exploratory endpoints include quality of life measures as well as safety measures such as the ESS and Questionnaire for Impulsive-Compulsive Disorders in Parkinson's. We have designed the trial with these endpoints to demonstrate the impact of tavapadon on motor control and activities of daily living, as well as its potentially differentiated side effect profile with respect to somnolence and impulse control. We initiated this trial in January 2020. In response to the onset of the COVID-19 global pandemic, we paused patient screening and enrollment of our Parkinson's trials in March 2020, and we remain particularly vigilant about patient safety given the elderly nature of this population. We resumed the program and re-initiated dosing in the second half of 2020 and we expect data from this trial in the second half of 2023.

TEMPO-2: phase 3 flexible-dose early-stage parkinson's trial

TEMPO-2, our second Phase 3 trial is designed as a double-blind, randomized, placebo-controlled, parallel-group, flexible-dose, 27-week trial to evaluate the efficacy, safety and tolerability of tavapadon in patients with early-stage Parkinson's. We plan to enroll 296 patients with 1:1 randomization between tavapadon, which will be flexibly titrated up to between 5 mg QD and 15 mg QD, and placebo. Following a fixed titration scheme to the

5 mg QD dose level, each patient's dose will be further increased to a target dose of 15 mg QD unless prevented by tolerability. Patients unable to achieve or tolerate 15 mg QD or 10 mg QD may remain at 10 mg QD or 5 mg QD, respectively, for the remainder of the treatment phase. Key inclusion criteria include patients with modified Hoehn and Yahr stage one to two Parkinson's with baseline MDS-UPDRS Part III motor score of 10 or greater and Part II motor score of two or greater. No concomitant Parkinson's medications are allowed except for MAO-B inhibitors if use was initiated at least 90 days before entering the trial and the dosage will remain stable for the duration of the trial.

As mentioned above, the primary endpoint is the change from baseline of combined MDS-UPDRS Parts II and III scores. Similar to the fixed-dose early-stage Parkinson's Phase 3 trial, the primary endpoint will be supported by secondary and exploratory efficacy endpoints as well as safety measures. The flexible dose design of this trial allows for more efficient powering that requires only two arms instead of three arms. The trial is powered with 90% confidence to detect a statistically significant difference of four points or more from placebo on the primary endpoint and a difference of one point or more from placebo on the Part II score alone. We initiated this trial in January 2020. In response to the onset of the COVID-19 global pandemic, we paused patient screening and enrollment of our Parkinson's trials in March 2020 and we remain particularly vigilant about patient safety given the elderly nature of this population. We resumed the program and re-initiated dosing in the second half of 2020 and we expect data from this trial in the second half of 2023.

TEMPO-3: phase 3 flexible-dose late-stage parkinson's trial

TEMPO-3, our third Phase 3 trial is designed as a double-blind, randomized, placebo-controlled, parallel-group, flexible-dose, 27-week trial to evaluate the efficacy, safety and tolerability of tavapadon as an adjunct therapy in patients with late-stage Parkinson's who are treated with L-dopa and experience motor fluctuations. We expect to enroll 368 patients with 1:1 randomization between tavapadon flexibly dosed up to between 5 and 15 mg QD and placebo. Following a fixed titration scheme to the 5 mg QD dose level, each patient's dose will be further increased to a target dose of 15 mg QD unless prevented by tolerability. Patients unable to achieve or tolerate 15 mg or 10 mg QD may remain at 10 mg or 5 mg QD, respectively, for the remainder of the treatment period. Key inclusion criteria include patients with modified Hoehn and Yahr stage two to three Parkinson's who maintain some level of responsiveness to L-dopa and are experiencing at least 2.5 hours of "off" time per day for two consecutive days at baseline.

The diagram below summarizes the design of this trial:

The primary endpoint is the change from baseline in total "on" time without troublesome dyskinesias. Based on the learnings from the Phase 2 trial in late-stage Parkinson's, we have designed this trial with the intention of rectifying key design components that may have contributed to the inability to achieve Pfizer's pre-specified efficacy hurdle for continuing the tavapadon program. For example, to minimize gastrointestinal and other side

effects and patient discontinuations, the protocol for this trial allows for 14 weeks of gradual titration and adjustment, rather than the three weeks allowed in the Phase 2 trial. This titration schedule is followed by 13 weeks at maximal dosing, as opposed to the seven weeks in the Phase 2 trial, to fully explore tavapadon's potential efficacy in these patients. The FDA has publicly stated that the primary endpoint of "on" time without troublesome dyskinesias is the most clinically relevant regulatory endpoint to assess therapeutic benefit in this patient population. The trial is powered to demonstrate a one-hour improvement over placebo in the primary endpoint with 90% confidence. An interim analysis by an independent Interim Analysis Review Committee is planned for when 67% of target enrollment is achieved to assess the adequacy of the overall sample size relative to achieving trial objectives and to allow for potential sample size adjustment (up to a pre-specified maximum of 528 patients) if needed. We initiated this trial in the second half of 2020, with data expected in the first half of 2023.

Tempo-4: open-label extension trial

Patients who complete any of the three Phase 3 trials will have the option to be rolled into TEMPO-4, a 58-week open-label safety extension trial, which will also be open to patients who did not participate in any of the Phase 3 trials. This trial is designed to provide sufficient safety data to support potential registration, including enough patients with completed six-month and 12-month treatment durations to meet the requirements for long-term safety evaluation of chronic use products at the time of an NDA submission. Based on our enrollment estimates for the Phase 3 program and the safety database required to support an NDA filing, we expect the open-label extension trial will remain ongoing at the time of NDA submission. In addition to supporting the NDA package, this open-label extension trial will allow us to collect additional long-term data on efficacy and side-effect profile to further inform how physicians might use tavapadon in the treatment paradigm.

CVL-871

In June 2021, we announced that the FDA has granted Fast Track Designation for CVL-871 for the treatment of dementia-related apathy. CVL-871 is a selective partial agonist of the dopamine D1/D5 receptor subtypes specifically designed to achieve a modest level of partial agonism, which we believe may be useful in modulating the complex neural networks that govern cognition, motivation and behavior. Dopamine acting on D1/D5 receptor subtypes in the cortex and midbrain plays a key role in the finely-tuned and dynamic neural network that modulates cognitive function, reward-processing and decision-making. In patients with Parkinson's, we have observed that improving motor symptoms requires higher levels of partial agonism to offset the large losses in dopaminergic neurons in the motor cortex. In contrast, dementia patients require a more finely-tuned modulation of the neural networks that govern cognition, motivation and behavior to normalize the dynamic range. As such, we have designed CVL-871 to have a lower level of partial agonism than tavapadon. The hypothesis for using D1/D5 receptor subtype partial agonism to treat dementia-related apathy is informed by clinical trials of other compounds where increases in dopamine activity resulted in a statistically significant improvement on apathy scales. We believe CVL-871 may possess an optimal profile to target this new indication due to the degree to which it activates relevant dopamine circuits within the brain and its favorable clinical tolerability profile observed to date. We began screening in an exploratory Phase 2a dose-ranging trial in dementia-related apathy in the second quarter of 2021 with data expected in the second half of 2022.

Apathy background

Apathy is among the most common neuropsychiatric co-morbidities associated with dementia, afflicting almost 50% of the over 50 million dementia patients globally. Apathy represents a constellation of symptoms, such as social disengagement, diminished initiative and interest and loss of emotion, that result in impaired decision making, lack of empathy, affection or concern, loss of interest in personal wellbeing, relationships or external

issues, inability to initiate and maintain normal activities, and interference with complex and basic daily functions, including motivation to eat, dress, maintain personal hygiene, and take medications. The presence of apathy has been shown to be related to decreased quality of life, increased morbidity and mortality, along with early institutionalization and greater resource utilization resulting from increased caregiver burden. In addition, apathy is associated with an increased risk developing dementia and disease progression. Therefore, the management of apathy is an important component in caring for patients with dementia.

While clinicians, patients and caregivers have been challenged by this symptom, there are no currently approved therapies for dementia-related apathy. The FDA has demonstrated interest in development of a therapy for this indication and we are interacting with the agency to define the regulatory requirements and clinical development plan to achieve this novel indication. Pharmacologic treatment of patients is comprised primarily of acetylcholinesterase inhibitors, selective serotonin re-uptake inhibitors, or SSRIs, and psychostimulants such as methylphenidate. Acetylcholinesterase inhibitors, such as donepezil and rivastigmine, which are typically prescribed for Alzheimer's patients to improve cognition, have shown no proven effects on apathy in clinical trials. Though patients are sometimes prescribed SSRIs and antidepressants, use of these medications for apathy treatment in dementia is not supported by clinical evidence and the latest evidence suggests they may actually contribute to worsening symptoms.

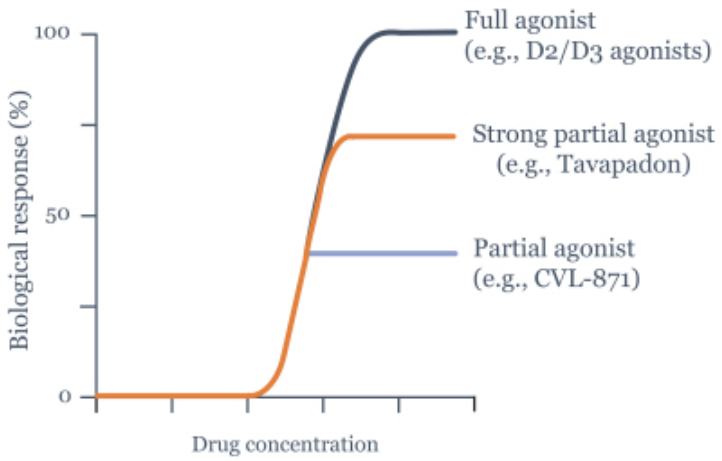
Conscious goal-directed behavior is mediated by the mesolimbic dopamine pathway. D1 receptors in non-motor brain regions are believed to modulate cognition, reward and decision-making. The hypothesis for using D1/D5 receptor subtype agonism in this indication is informed by clinical trials of other dopamine-potentiating compounds where increases in dopamine activity resulted in a statistically significant improvement on apathy scales. For example, in a 60-patient clinical trial evaluating methylphenidate, a stimulant associated with increased dopamine levels, neuropsychiatric inventory apathy scores were improved by 1.8 points versus placebo at week six (p=0.002). These results imply a 63% reduction from the baseline score for methylphenidate versus a 33% reduction for placebo. The principal investigator of this trial indicated that these effects appear large enough to be of significance to clinical practice. Based on additional discussions with clinicians, we believe an improvement of this magnitude would be clinically meaningful. Methylphenidate is a Schedule II controlled substance, stimulant medication used for the treatment of ADHD that has well-established side effects, including serious impacts on cardiovascular function, appetite and sleep.

Our solution—CVL-871

CVL-871 is a selective partial agonist of the dopamine D1/D5 receptor subtypes that we are developing for the treatment of dementia-related apathy. Key differentiating features of CVL-871 include:

1. **Mechanism of action—D1/D5 receptor subtype selectivity:** CVL-871 has been designed to selectively target dopamine D1/D5 receptor subtypes in order to treat motivational impairment without driving the somnolent, hallucinatory or impulse control effects mechanistically associated with the activation of D2/D3 receptor subtypes.

2. **Receptor pharmacology—partial agonist:** CVL-871 is an orally bioavailable, brain-penetrant small molecule with a 24-hour half-life. Both CVL-871 and tavapadon are designed as partial agonists to the D1/D5 receptors to a lesser extent than the natural ligand dopamine. CVL-871 has a reduced level of activation compared to tavapadon, which we believe facilitates optimal activation of D1/D5 in brain regions that control motivation and reward. These neural networks require more finely-tuned modulation to normalize the dynamic range, and the reduced partial agonism of CVL-871 is designed to restore, but not exceed, the optimal level of stimulation that is thought to be most associated with cognition and apathy. CVL-871's reduced partial agonism is illustrated below, as compared to tavapadon and a full agonist.



3. **Clinical and preclinical evaluation:** CVL-871 has been tested in a total of 58 subjects, including healthy volunteers in a Phase 1 single and MAD trial and Parkinson's patients in a seven-day Phase 1 trial. These trials have demonstrated evidence of CNS activity and provided clinical data that support the targeted lower partial agonism of CVL-871 relative to tavapadon. Preclinical studies showed activity in models of motor function as well as cortical function linked to increased D1 activation. Preclinical safety and toxicology studies of up to 26 weeks in duration have been completed and data to date supports the dosing duration expected in our Phase 2a trial.

We believe CVL-871 could possess the optimal profile amongst D1/D5 agonists to target hypothesized dopaminergic deficits in D1-mediated neural circuits related to motivation and reward processing, and clinical research suggests increased dopamine receptor activation may have a role in the treatment of dementia-related apathy.

Clinical trials

Two Phase 1 trials of CVL-871 have been completed in a total of 75 subjects, including both healthy volunteers and Parkinson's patients. In these trials, CVL-871 was observed to be generally well tolerated. Evidence of moderate improvement in motor symptoms, a measure of biological activity, was also observed, along with a PK profile that supports the potential for once-daily dosing. Consistent with CVL-871's lower partial agonism, these studies showed a difference compared to tavapadon, including improved tolerability in healthy volunteers and a more modest magnitude of motor benefit in patients with Parkinson's. Based on these findings, we are conducting an exploratory Phase 2a trial of CVL-871 in dementia-related apathy with data expected in the second half of 2022.

Phase 1 single and multiple ascending dose trial

In March 2015, Pfizer completed Trial B7821001, a placebo-controlled Phase 1 trial designed to evaluate the safety, tolerability and food effect of CVL-871 in healthy volunteers after both single and multiple doses.

The SAD portion of the trial had two cohorts. In Cohort 1, eight subjects were enrolled and participated in several periods where they received placebo or CVL-871 as a single dose of up to 1 mg. In Cohort 2, eight subjects were enrolled and participated in two periods where they received a single 0.4 mg dose of CVL-871 or placebo in the fed or the fasted state. One subject from each cohort withdrew from the trial due to nausea or vomiting.

In the MAD portion of the trial, 40 subjects were enrolled. In each of four cohorts, eight subjects received a daily oral dose of CVL-871 and two subjects received placebo. For doses beyond 0.5 mg, a predetermined titration schedule of up to six days was used to improve tolerability. One subject paused dosing for two days due to a rash, which resolved without treatment, and subsequently resumed dosing and completed the trial. One additional subject withdrew from the trial due to nausea.

Results from this trial established that CVL-871 has suitable PK for once-daily oral dosing and generally low PK variability and demonstrated a modest effect of food on drug absorption. Both single doses of up to 1 mg and multiple doses of up to 3 mg QD, with a seven-day titration period, were generally well tolerated in this trial. The most frequently reported AEs in the MAD phase were nausea (nine subjects), headache (seven subjects), dizziness (six subjects), vomiting (five subjects), abnormal dreams (three subjects on CVL-871 and one subject on placebo) and dizziness postural (three subjects). All reported AEs were either mild or moderate in severity and consistent with expectations for a dopaminergic agent in healthy volunteers.

Phase 1 multiple dose trial in parkinson's

In May 2016, Pfizer completed Trial B7821002, a placebo-controlled Phase 1 trial designed to examine the safety, tolerability, PK and PD of CVL-871 in patients with Parkinson's. This proof-of-principle trial was conducted in Parkinson's patients, a population previously studied to evaluate D1/D5 receptor subtype selectivity. The results from this trial provided evidence for our translational hypotheses on the relationship between CVL-871's lower level of partial agonism and motor symptom control, which is informing the development of CVL-871 in indications such as apathy that require lower levels of activation.

A total of 19 patients entered the treatment period, with 10 patients randomized to receive CVL-871 and nine patients randomized to receive placebo. Eligible patients had a Parkinson's diagnosis and were on a stable treatment regimen that included at least 300 mg/day of L-dopa. CVL-871 was titrated for three days and then kept stable at 3 mg QD for the last four days. All patients generally remained on their stable L-dopa dose throughout the trial, except that L-dopa was withheld beginning at 8:00 PM on the day prior to final assessments. A number of safety and PK measures were collected along with MDS-UPDRS Part III and several other exploratory efficacy measures.

CVL-871 was observed to be generally well tolerated and, as expected for a dopaminergic agent, was better tolerated in this population than in the healthy volunteers in the Phase 1 SAD and MAD trial. This difference in tolerability is expected because healthy volunteers do not have a preexisting dopamine deficit as compared to Parkinson's patients. There were no AEs experienced by more than two patients in either the CVL-871 or placebo groups. The most commonly reported AEs were nausea (two patients for CVL-871 and two patients for placebo), dry mouth (two patients for CVL-871 and one patient for placebo) and vomiting (one patient for CVL-871 and two patients for placebo). There were generally no consistent differences in clinically significant laboratory, vital sign or ECG abnormalities between the CVL-871 and placebo groups.

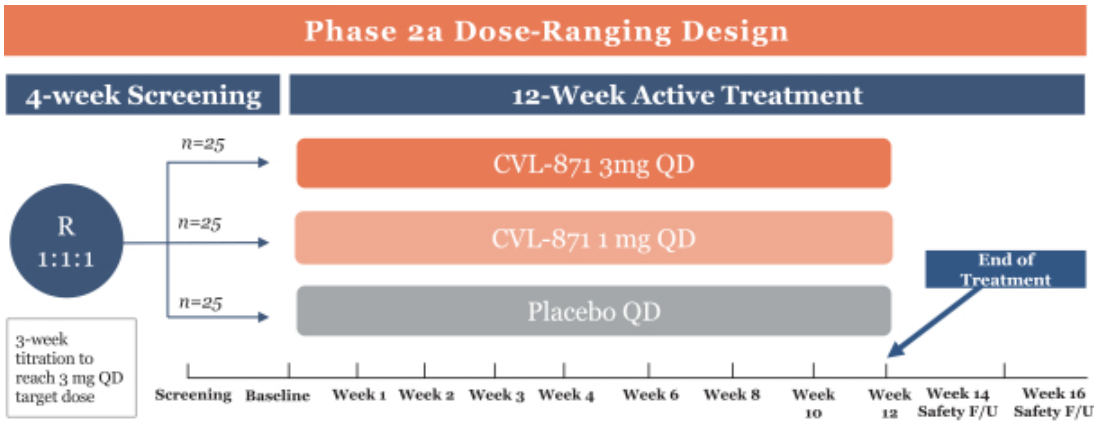
The primary efficacy endpoint was the change from baseline in MDS-UPDRS Part III motor score at Tmax on day seven. The placebo-adjusted mean change from baseline was -4.49 and did not meet the pre-specified decision criterion of significant improvement (>-4.8). We believe that, although the pre-specified decision criterion was not met, the results of this trial provide further support for the potential of a D1/D5 partial agonist as a therapy in Parkinson's disease. However, given CVL-871's reduced level of agonism, we believe its design is suited to treat indications such as apathy and motivation where mild changes in dopamine tone are sufficient to drive therapeutic benefit, as opposed to indications such as Parkinson's where there are more significant deficits in dopamine activity.

Preclinical studies

CVL-871 has been studied in multiple preclinical studies, including a rodent memory task model that showed an improvement in cognitive performance. Preclinical safety and toxicology studies for up to 26 weeks in rats and 13 weeks in primates have been completed, which support dosing in humans for up to 13 weeks in clinical trials. Preclinical safety and pharmacology studies showed modest effects on lowering blood pressure, which is routinely observed with dopaminergic agents. Additional toxicology studies are ongoing and planned, but preclinical safety studies to date support the dose levels to be evaluated in our planned exploratory Phase 2a trial.

Ongoing exploratory phase 2a clinical trial

We are conducting an exploratory Phase 2a, multi-center, randomized, double-blind, placebo-controlled, parallel-group, 12-week, dose-ranging trial. The objective of the trial is to evaluate the safety, tolerability, and PD of two fixed doses of CVL-871 in male and female subjects aged 50 to 85 years who have clinically significant apathy and a diagnosis of mild to moderate dementia (inclusive of possible/probable Alzheimer's disease dementia, possible/probable dementia with Lewy bodies, frontotemporal dementia or vascular dementia). The trial will include a four-week screening period, a 12-week treatment period, and a four-week safety follow-up period. Approximately 75 subjects will be enrolled and randomized in a 1:1:1 ratio to three treatment groups: 1 mg QD of CVL-871, 3 mg QD of CVL-871 or placebo, as shown in the figure below.



Several clinical assessments will be utilized to measure change in apathy severity during treatment, and these assessments will be evaluated as potential primary endpoint measures for late-stage trials. These include the Neuropsychiatric Inventory (NPI) apathy domain, the Neuropsychiatric Inventory-Clinician (NPI-C) apathy domain, the Dementia Apathy Interview and Rating (DAIR), and the Apathy Evaluation Scale-Clinician (AES-C). The NPI will also be used to assess changes in other neuropsychiatric symptoms. In addition, several measures will be utilized to assess changes in cognition, function (e.g. activities of basic living, and cognitive, functional, and behavioral performance), and caregiver burden. We began screening patients for this trial in the second quarter of 2021 with data expected in the second half of 2022.

CVL-936

We are developing CVL-936 for the treatment of SUD, with an initial focus on OUD. In order to maximize potential for activity, CVL-936, a selective dopamine D3-preferring, D2/D3 receptor subtype antagonist, was designed to block D3 signaling within the brain while also simultaneously reducing (but not fully inhibiting) signaling at the D2 receptor subtype. CVL-936 has shown encouraging activity in translationally relevant

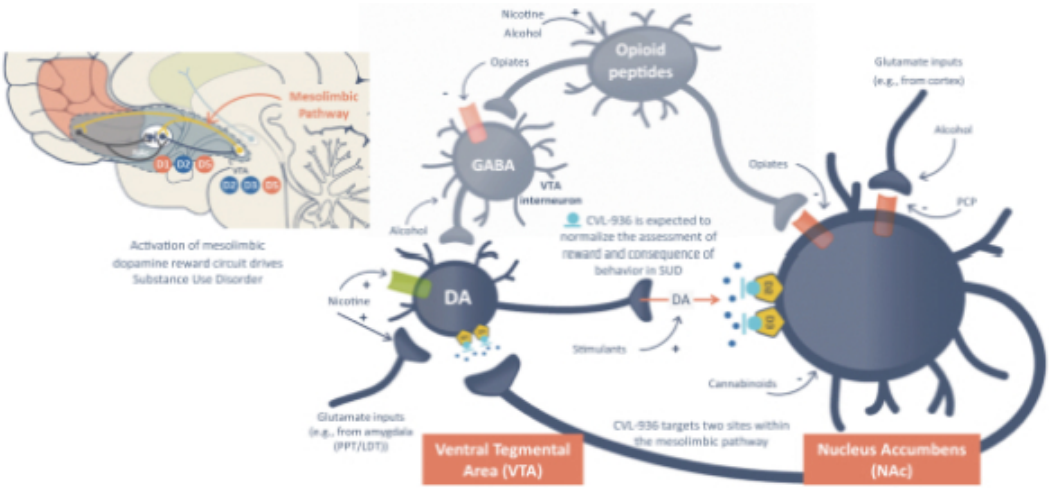
preclinical models of both cessation and relapse using nicotine and opioid-induced cues. Based on its profile, we expect CVL-936 will allow for dosing to levels that may result in near complete and sustained blockade of D3 signaling within the brain, which may be useful in treating SUD. We have received a notice of award for cooperative grant funding from NIDA to support the development of this compound in OUD. We initiated a Phase 1 SAD trial in healthy volunteers in January 2020. We concluded dosing of Cohort 1 of the Phase 1 SAD trial after receiving sufficient clinical data for the intended purposes for this trial. We intend to conduct a multiple dose canine EEG study prior to additional Phase 1 SAD and MAD evaluations.

Substance use disorder background

SUD covers a spectrum of different substances of abuse, including alcohol, nicotine, opioids and illicit substances. OUD is a leading public health issue, with approximately two million OUD patients in the United States. The mortality rate is expected to be between six to 20 times greater for opioid addicts as compared to the general population. Six-month and five-year relapse rates for OUD are estimated to be approximately 50% and 90%, respectively. The Society of Actuaries estimates that between 2015 and 2018, the opioid crisis cost the United States approximately $631 billion.

OUD is diagnosed through the DSM-V criteria, and most OUD patients seeking treatment are classified as moderate to severe. Treatment of OUD includes medically-supervised withdrawal, commonly known as detox, long-term medication-assisted treatment and psychosocial support. Currently approved treatments for long-term opioid abstinence include buprenorphine, naloxone, naltrexone and methadone, and most individuals remain on a combination of medications and psychosocial support indefinitely to manage their disorder. Despite many available therapies, compliance is often poor, patient relapse is common and there remains a clear unmet medical need for more effective treatments for OUD.

Though specific causal links to addictive behavior in humans are not fully understood, excessive signaling via D3 receptors may contribute to intense reward-seeking behavior. Commonly abused drugs have been shown to increase dopamine levels in the nucleus accumbens, where the D3 receptor is preferentially expressed, and postmortem studies have shown D3 mRNA levels were increased six-fold in the nucleus accumbens of cocaine-overdose fatalities compared to age-matched control subjects. Based on this evidence, together with other clinical data and preclinical activity of D3-preferring antagonists, including CVL-936, in relevant preclinical models, the D3 receptor appears to be central in the neurobiology of drug abuse, and we believe D3-preferring antagonists could have therapeutic value for the treatment of addiction. In response to the opioid crisis, the National Institute on Drug Addiction currently lists D3 antagonism as one of 10 priority mechanisms for rapid development. The role of D3 antagonism in reward circuits and its potential impact on SUD is further illustrated below.



Currently available atypical antipsychotics, which are D2-preferring antagonists of both D2 and D3 receptors, have shown some promise in treating addiction among schizophrenia patients with comorbid SUD. However, the substantial motor-related and metabolic side effects of these antipsychotics have limited their use to schizophrenia patients. Published clinical data of a “pure” D3 antagonist in a Phase 1b trial of nicotine addiction demonstrated marginal and short-lived effects on both a Stroop test with nicotine-associated cues and reported cigarette cravings. Despite this compound achieving a PET receptor occupancy of 89% at Tmax, these levels were not sustained over the course of the day. These data illustrated that sustained D3 antagonism may be necessary to effectively treat SUD, and therefore clinical development of this compound was discontinued. Our hypothesis is that consistently greater than 90% D3 receptor occupancy combined with meaningful D2 receptor occupancy is necessary for significant and sustained effect. We believe that compounds showing high D3 receptor occupancy of [3]90% and partial D2 receptor occupancy may be superior to pure D3 antagonists in SUD treatment.

Our solution—CVL-936

CVL-936 is a dopamine D3-preferring, D2/D3 receptor subtype antagonist that we are developing for the treatment of SUD, with an initial focus on OUD. Key differentiating features of CVL-936 include:

1. **Mechanism of action—D2/D3 receptor subtype selectivity:** As described above, combining full D3 and partial D2 antagonism appears to drive the PD effect in preclinical models. CVL-936 was designed as a potent dopamine D3 antagonist and a weaker dopamine D2 antagonist. CVL-936 is >48 fold selective for both D3 and D2 versus other dopamine receptor subtypes.

2. **Receptor pharmacology—antagonist:** CVL-936 is an orally bioavailable and brain-penetrant small molecule. CVL-936 was selected for its receptor-binding profile, which is projected to allow dosing to levels that could potentially block nearly all D3-mediated signaling in the brain, with the goal of supporting SUD patients who wish to stop substance abuse by eliminating the euphoric input from D3 receptor signaling. CVL-936 is also projected to antagonize D2 receptors and reduce, but not fully block, signaling of dopamine at these receptors at clinically relevant doses. This combination of D2/D3 antagonism was evaluated in preclinical models of cessation and relapse that have demonstrated clinically-translatable outcomes for currently approved SUD treatments.

3. **Preclinical evaluation**: D2 antagonism is typically associated with side effects, including extrapyramidal symptoms and catalepsy, that can be observed in preclinical models. Among other key optimization parameters, CVL-936 was designed and selected because it has not demonstrated significant D2-antagonist-mediated side effects in preclinical studies to date. In preclinical studies, CVL-936 showed potential for preventing reinstatement of drug-seeking behavior. The preclinical and *in vitro* data collected to date support investigating human doses of CVL-936 expected to demonstrate activity.

The well-characterized association between dopamine receptor modulation and reward suggests that CVL-936 has the potential to reduce aberrant reward processing and restore a balance between valuation of risk and reward with the expectation of reducing substance abuse. As such, we believe that CVL-936 has the potential to be used chronically to maintain abstinence and prevent reinforcement of maladaptive behaviors.

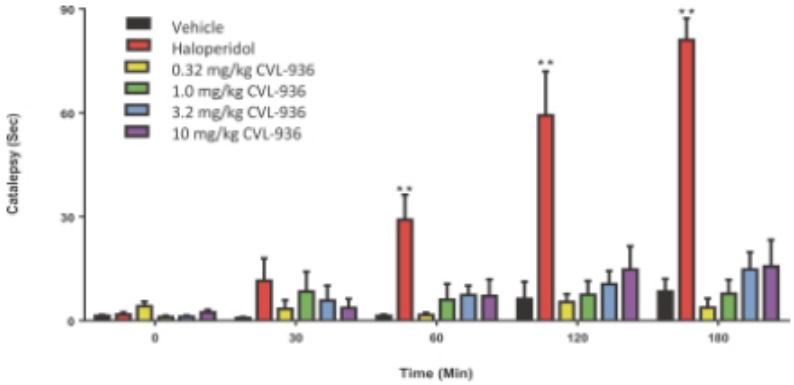
For the patient who is challenged with SUD, the overwhelming drive to re-experience the euphoria associated with a drug of abuse is a substantial hurdle that consistently drives poor judgment and the inability to resist cravings. Re-exposure to drugs of abuse reinforce maladaptive behaviors for drug-seeking that can ultimately lead to self-harm and/or death. Currently, the first-line treatment for OUD is cognitive behavioral therapy followed by mu opioid receptor partial agonists and antagonists. Therapeutic options for decoupling reward from maladaptive behavior would represent a novel functional approach to the treatment of SUDs. Additionally, we believe CVL-936 may have therapeutic potential across multiple substance use indications beyond OUD, including nicotine cessation, alcohol use disorder and binge eating.

Preclinical studies

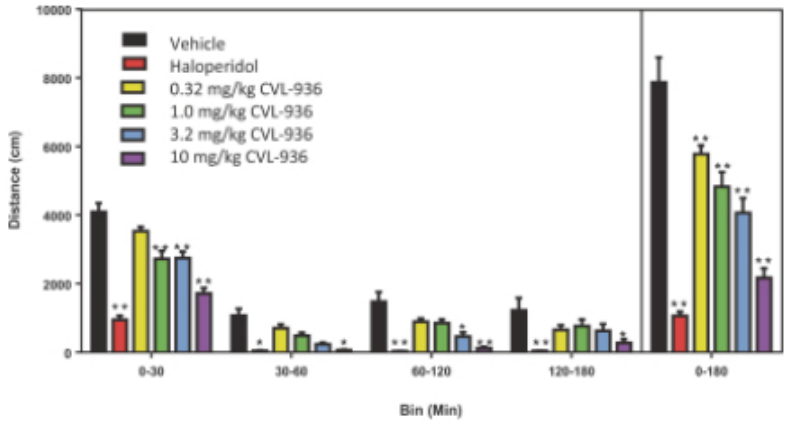
CVL-936 was evaluated in rats for the reduction of fentanyl-seeking under three reinstatement conditions: combined drug-associated cue plus drug prime, cue alone and combined drug-associated cue plus yohimbine, a pharmacological stressor. Following administration of CVL-936 30 minutes prior to the test session, CVL-936 dose-dependently attenuated cue- and prime-induced reinstatement of fentanyl-seeking behavior with a significant reduction observed at the 3.2 mg/kg dose compared to vehicle. In the fentanyl-associated cues alone paradigm, CVL-936 also attenuated cue-induced fentanyl-seeking behavior in a dose-dependent manner. Finally, when a cue was combined with a stressor, CVL-936 showed a dose-dependently attenuated reinstatement of stressor-induced fentanyl-seeking behavior with a significant decrease achieved at the 3.2 mg/kg dose compared with vehicle. CVL-936 showed similar dose-dependent attenuation of nicotine-seeking behavior in rats when primed, cued and treated with a pharmacological stressor.

D2 antagonists are commonly used as anti-psychotics, but are often associated with motor-related side effects. When tested in rats, CVL-936 demonstrated a favorable tolerability profile relative to haloperidol, a potent D2 antagonist. Specifically, as illustrated below, CVL-936 showed a reduced D2-antagonist mediated cataleptic effect compared to haloperidol at all doses tested and a reduced impact on spontaneous locomotion. As such, we believe CVL-936 is differentiated compared to existing D2 antagonists.

D2-antagonist mediated catalepsy in rats
CVL-936 vs. Haloperidol vs. Vehicle



D2-antagonist mediated locomotion in rats
CVL-936 vs. Haloperidol vs. Vehicle



In preclinical toxicology studies, CVL-936 showed no side effects that we believe would preclude studies in humans. Toxicology studies of up to one month have been completed in rats and canines, and the results support dosing in humans. Preclinical safety and pharmacology studies showed effects of increased heart rate and blood pressure, which were reversible and can be monitored clinically. Convulsions have also been observed in a single canine at exposures significantly higher than the doses expected to be evaluated in our planned clinical trials. Subsequent evaluation in a single dose canine study that employed EEG demonstrated no signals of pre-seizure activity. We intend to conduct an additional multiple dose canine EEG study prior to additional Phase 1 SAD and MAD evaluations.

Phase 1 single ascending dose trial

In January 2020, we initiated our first-in-human, double-blind, SAD, Phase 1 trial to investigate the safety, tolerability, PK profile and preliminary PD of CVL-936 in healthy volunteers between 18 and 50 years old. In response to the COVID-19 global pandemic, we have concluded dosing of Cohort 1 of the Phase 1 SAD trial after receiving sufficient clinical data for the intended purposes for this trial.

The primary objectives of this trial are to evaluate the safety and tolerability of single ascending doses of CVL-936 as assessed by treatment-emergent AEs, ECG results including continuous ECG monitoring, vital signs measurements, clinical laboratory tests including plasma prolactin levels, physical and neurological examinations, suicidality assessed using the C-SSRS and extrapyramidal symptoms based on the SAS, AIMS and BARS assessments.

In Cohort 1 of this trial, three single doses of CVL-936 (0.5 mg, 1.5 mg and 5 mg) and matching placebo were administered in a crossover design. During the trial, a total of 10 subjects were randomly assigned to receive treatment, of whom six received CVL-936 and nine received placebo.

Based on metabolite to parent ratios observed in Cohort 1, we determined that the metabolite PK stopping criteria would be met at a projected CVL-936 dose of 25 mg. Therefore, the goal of obtaining data to support the primary objectives of this trial were achieved and we elected to stop the trial prior to the initiation of Cohort 2.

In Cohort 1, single doses of CVL-936 up to 5 mg were generally well tolerated in healthy subjects. No safety concerns were noted in ECG findings or vital sign measurements. There was no indication of an effect of CVL-936 on extrapyramidal symptoms. One subject had an adverse event of clinically relevant neutropenia following treatment with the 5 mg dose of CVL-936, but, based on the subject's history, we and the investigator did not consider the neutropenia to be related to treatment with CVL-936. No other clinically relevant findings in clinical laboratory assessments occurred during the trial.

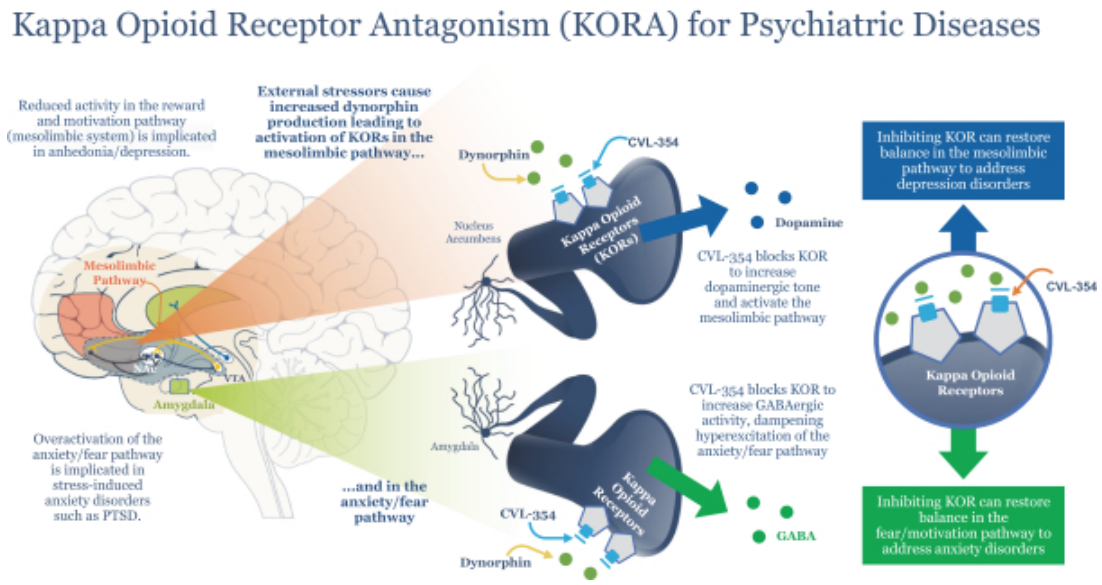
CVL-936 was characterized by rapid absorption and the increase in CVL-936 exposures was approximately dose proportional across the dose range studied. CVL-936 administration resulted in a dose-dependent increase in serum prolactin, which returned to baseline around eight hours post-dose. The increases in prolactin levels were not accompanied by any adverse effects. There was no evidence of an effect of CVL-936 on either mood or drug abuse potential.

We are evaluating the data observed in Cohort 1 and formulating our plans with respect to the development of this product candidate. We intend to conduct a multiple dose canine EEG study prior to additional Phase 1 SAD and MAD evaluations.

Preclinical assets

CVL-354

CVL-354 is an antagonist of the kappa opioid receptor, or KOR, that we plan to evaluate for the treatment of MDD and SUD. KORs are G-protein coupled receptors that are expressed throughout the CNS, but particularly in circuits linked to motivation and anxiety. As illustrated in the graphic below, KOR activation is associated with neural networks linked to stress, depression and anxiety. In the mesolimbic pathway, stressors lead to increased expression of the endogenous KOR activator, dynorphin, which results in reduced dopaminergic tone, an effect that is implicated in anhedonia and depression and that we believe can be reversed via KOR antagonism. In the fear and anxiety pathway, hyperactivity of the amygdala has been demonstrated in anxiety disorders. Activation of KOR in this circuit leads to loss of GABAergic tone; GABA is the main inhibitory neurotransmitter that dampens down neuronal hyperexcitation through hyperpolarization. We believe that KOR antagonism has the potential to increase GABAergic tone and therefore decrease excitation to address anxiety. In SUD specifically, our goal is to reduce the physical symptoms and anxiety associated with withdrawal and thereby help patients recovering from addiction to maintain abstinence.



CVL-354 is a high potency KOR antagonist, or KORA, and has 30-fold selectivity for KOR over the mu opioid receptor, or MOR. Notably, CVL-354 has no agonist activity at the MOR. Furthermore, CVL-354 has shown robust activity in preclinical animal models. Treatment with spiradoline, a KOR agonist, causes significantly decreased reward-seeking behavior in rodents, representing a demotivated state. Treatment with CVL-354 dose-dependently reversed this effect, re-establishing motivation. In addition, murine data generated in collaborations with the National Institute on Drug Abuse demonstrated statistically significant reductions in both the physical signs of acute opioid and nicotine withdrawal and in the anxiety precipitated from nicotine withdrawal. Our preclinical safety package to date demonstrated approximately 20-fold safety margins over predicted efficacious exposures, and we believe the data support dosing for up to 90 days in humans. We submitted an IND for CVL-354 in the second quarter of 2021 and plan to initiate a Phase 1 trial once the IND becomes effective.

CVL-047

We are developing CVL-047, our selective PDE4 inhibitor (PDE4D-sparing), for the treatment of MDD and schizophrenia, and we plan to submit an IND in the fourth quarter of 2021. PDE4 is the main enzyme for the metabolism of cyclic adenosine monophosphate, or cAMP, an important second messenger in the CNS. Non-selective PDE4 inhibitors, including rolipram, have been reported to have shown antidepressant, antipsychotic, pro-cognitive and anti-inflammatory activity. Notably, rolipram, a brain-penetrant non-selective PDE4 inhibitor, demonstrated antidepressant activity comparable to tricyclic antidepressants, including desipramine and imipramine, in small trials conducted by third parties. However, gastrointestinal side effects such as nausea and emesis have been dose-limiting in all PDE4 inhibitors tested in clinical trials to date.

In addition to depression, we believe PDE4 inhibition has the potential to treat psychosis in schizophrenia. CVL-047 has demonstrated antipsychotic activity in several preclinical assays, including the pre-pulse inhibition and conditioned avoidance response models.

There are four subtypes of the PDE4 receptor family. The gastrointestinal side effects that have hindered development for non-selective PDE4 inhibitors are widely believed to be more specifically linked to inhibition of the PDE4D subtype. CVL-047 is designed to be more selective for PDE4A, PDE4B and PDE4C over PDE4D and

has demonstrated promising overall preclinical properties. This has resulted in a reduced emetic response to treatment in non-human primate models, suggesting the potential for CVL-047 to deliver the benefits of PDE4 inhibition while minimizing the gastrointestinal side effects linked to PDE4D inhibition. Our initial focus will be on the advancement of CVL-047 in MDD and schizophrenia. We plan to submit an IND for CVL-047 in the fourth quarter of 2021.

M4 full/partial agonist

We also plan to expand our M4 franchise with additional product candidates with pharmacology tailored to specific indications. Based on early preclinical evidence and strong biological rationale, we are evaluating highly-selective M4 full and partial agonists for potential use in schizophrenia. We are currently in the process of identifying a lead candidate for this program.

LRRK2 inhibitor

Mutations within the LRRK2 gene are some of the most highly validated genetic risk factors for Parkinson's, with variants being associated with both familial and sporadic disease. The most common Parkinson's risk mutation in the LRRK2 gene is the G2019S variant, which is estimated to explain 3-6% of familial and 1-2% of sporadic Parkinson's worldwide. Knockdown of the LRRK2 gene has been shown to reduce both pathological forms of alpha-synuclein and the loss of dopaminergic neurons in preclinical models, suggesting that LRRK2 inhibitors may benefit all Parkinson's patients, not just those carrying LRRK2 mutations. We have developed a highly potent and selective LRRK2 kinase inhibitor that we believe has the potential to address disease progression in Parkinson's. We are currently in the process of identifying a lead candidate for this program.

Early pipeline target and lead identification strategy

Our approach for target identification focuses on neuroscience targets with the highest levels of biological validation, as demonstrated through human pharmacological activity, our understanding of human disease biology and causal genetic association to disease. Through prioritizing a combination of both target tractability and target validation, we believe that we can more efficiently focus our early discovery efforts and resources on high probability of success opportunities that are the most likely to achieve clinical proof-of-concept, and ultimately, drug approval. Within our labs, we will leverage human genome sequencing to identify causal relationships among single nucleotide polymorphs in idiopathic disease populations to identify novel associations between genetic pathways and disease. To date, we have successfully identified new targets that demonstrate gene dosage effects on disease phenotypes, including a pharmaceutically tractable gene that can both accelerate and reduce alpha-synuclein accumulation. Based on these data, we believe that we have the opportunity to identify compounds for use in modifying Parkinson's through modulation of alpha-synuclein levels to potentially prevent or slow the advancement of the disease. Additionally, based upon human genetics, prior clinical trials and pharmacology studies, we have identified two novel targets that have the potential to address pruritis and pain.

Our model for lead identification follows a philosophy of looking broadly to identify the most tractable chemical matter as a starting point for creating future clinical development compounds, and ultimately, approved drugs. The largest pharmaceutical companies manage internal chemical compound libraries of two to three million structures from an estimated 10^{60} total possible chemical structures. These internal chemical libraries are skewed towards classes of protein targets that have been the focus of earlier programs, creating a chemical structure bias in the libraries that are represented in each individual company's compound library. Our technology-enabled approach for lead identification of chemical matter leverages new technologies to not only screen a much larger selection of chemical structures, but also to sample it in an unbiased manner. For

example, current DNA-encoded libraries, or DELs, range from 50 to 100 billion chemical structures and are built randomly without bias. Each compound within a DEL is ligated to a unique DNA sequence that serves as a “barcode” for identifying the chemical structure of compounds of interest after a successful binding structure has been identified. This DNA barcode approach also allows for pooled screening of massive compound libraries, ultimately leading to what we believe is a more efficient process to identify structural epitopes of chemical leads that are designed to advance into more intensive screening assays in a shorter timeframe than single compound screening approaches.

In addition to existing wet lab technologies, we are also coupling our DEL approaches with artificial intelligence, or AI, assisted drug design. AI-based *in silico* drug design has made dramatic progress over the past five years in areas such as deep learning and generative adversarial network methods that have created an entirely virtual approach to designing potent and selective small molecules based upon predicted crystal structure of protein targets and potential small molecule epitope interactions. These AI-based drug design systems are trained on chemical binding and drug-target interactions to rapidly generate unique chemical matter for synthesis and testing. Reiterative refinement can generate novel chemical leads. Through a combination of unique starting material identified via DEL screening and refined design via AI, unique chemical leads can be efficiently generated, providing us with an advantage in compound optimization with the greatest likelihood of creating novel intellectual property. By combining these approaches for the identification of lead chemical structures, we can focus our research investment on higher value data generation for lead optimization.

Our internal research laboratories will include capabilities aimed at discovering receptor-selective molecules with carefully designed pharmacological activity. We will leverage electrophysiological and PD characterization to develop molecules that may be able to normalize neurocircuitry in neuroscience disease and minimize potential for side effects. We will evaluate chemical leads in house using both physiological and behavioral approaches to characterize their neural activity at the level of the intact CNS in model organisms.

Based on current plans for our internal laboratory space, we expect to grow to a steady state of six active internal programs in the lead optimization space, generating two to three IND-ready lead molecules per year in order to sustain an ongoing portfolio of differentiated high-quality assets. This expected level of productivity does not include internalizing programs from acquisitions and collaborations that may also increase our preclinical productivity.

Manufacturing and supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently source all of our preclinical and clinical supply through third-party contract manufacturing organizations, or CMOs.

For clinical supply, we use CMOs who act in accordance with the FDA’s GLP and current good manufacturing practices, or cGMP, for the manufacture of drug substance and product. We expect to rely on third parties for our manufacturing processes and the production of all clinical supply drug substance and drug product. We use additional contract manufacturers to fill, label, package, store and distribute investigational drug products. It is our intent to identify and qualify additional manufacturers to provide active pharmaceutical ingredients, or APIs, and fill-and-finish services prior to submission of an NDA to the FDA for any product candidates that complete clinical development.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe our product candidates,

approach, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies as well as public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with approved treatment options, including off-label therapies, and new therapies that may become available in the future.

Our competitors may have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Schizophrenia

We are developing CVL-231 for the treatment of schizophrenia. While there remains significant unmet need in schizophrenia, we may face competition from second-generation atypical antipsychotic treatments that work primarily by inhibiting D2 receptors as their primary mechanism of action. These drugs include: Abilify and Abilify Maintena, marketed by Otsuka Holdings; Invega Trinza and Invega Sustenna, marketed by Johnson & Johnson; Aristada and Lybalvi, marketed by Alkermes; Zyprexa, marketed by Eli Lilly; Vraylar, marketed by Allergan; Caplyta, marketed by Intra-Cellular Therapies; and Latuda, marketed by Sumitomo Dainippon Pharma.

Additionally, we are aware of several product candidates in clinical development that are designed to modulate dopamine, serotonin and/or muscarinic receptors, including product candidates being developed by ACADIA Pharmaceuticals, Sunovion Pharmaceuticals, Minerva Neurosciences, Neurocrine Biosciences and Karuna Therapeutics.

Epilepsy

We are developing darigabat for the treatment of epilepsy. Darigabat may face competition from a variety of currently marketed therapies such as generic anticonvulsants, AEDs, sodium channel modulators and BZDs, as well as surgical options such as deep brain stimulation in patients who have failed polypharmacy. Additionally, there are next-generation therapies in development harnessing the previously mentioned mechanisms of action, such as NBI-921352 (formerly known as XEN901) being developed by Neurocrine Biosciences. Furthermore, there are multiple compounds that have been recently approved or are in late-stage development for focal epilepsy, including cenobamate, which was developed by SK Life Sciences and was approved by the FDA in November 2019.

We may also face competition from other companies developing next-generation $GABA_A$ receptor modulators such as Sage Therapeutics and Marinus Pharmaceuticals, among others, as well as several companies, such as VistaGen Therapeutics, developing molecules targeting the NMDA receptor as both antagonists and agonists. There are also several therapies that are either marketed or in development targeting rarer forms of epilepsy such as Lennox-Gastaut syndrome and Dravet Syndrome that could have efficacy in broader epileptic populations, including fenfluramine from Zogenix and cannabinoid-based therapies from GW Pharmaceuticals.

Parkinson's disease

We are developing tavapadon for the treatment of early- and late-stage Parkinson's. We may face competition from currently available treatments for both stages of disease, such as L-dopa, D2/D3-preferring agonists and MAO-B inhibitors as monotherapy or in combination, as well as deep brain stimulation devices by Medtronic Inc. and St. Jude Medical Inc., among others, for the later stages of disease. Additionally, we are aware of several potential therapeutics being developed by other pharmaceutical and biotechnology companies, including Denali, Prothena, Roche, Voyager Therapeutics, Prevail Therapeutics, Sage Therapeutics, Neurocrine Biosciences, Eli Lilly, AstraZeneca, and IRLAB Therapeutics, that are in various stages of clinical development. These companies are employing a variety of therapeutic modalities, including gene therapy and gene editing, in addition to small molecule chemistry, to address Parkinson's.

Substance use disorder

We are developing CVL-936 for the treatment of SUD, with an initial focus on OUD. In the treatment of OUD, we may face competition from manufacturers of oral buprenorphine products, including Indivior, which markets Suboxone and Subutex brands, and Braeburn, which markets Brixadi. We may also face competition from manufacturers of naloxone, naltrexone and methadone, including Emergent BioSolutions, which markets Narcan, BioDelivery Sciences, which markets Bunavail, and Alkermes, which markets Vivitrol. Other products are marketed or in development by companies such as Eli Lilly and GlaxoSmithKline.

Pfizer license agreement

In August 2018, we entered into the Pfizer License Agreement pursuant to which we were granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how, to develop, manufacture and commercialize certain compounds and products, which currently constitute the product candidates included in the table in the section entitled "*–Our Pipeline*", in the field of treatment, prevention, diagnosis, control and maintenance of all diseases and disorders in humans, subject to the terms and conditions of the Pfizer License Agreement. The license excludes the field of treatment, prevention, diagnosis, control and maintenance of inflammatory bowel diseases and disorders in humans by compounds or products exerting a therapeutic effect on the LRRK2 target, which is retained by Pfizer. Under the terms of the Pfizer License Agreement, Pfizer is granted a non-exclusive, sublicensable, royalty-free, worldwide license under intellectual property we develop during the term of the agreement for all purposes in the LRRK2 field retained by Pfizer. Additionally, Pfizer has an exclusive right of first negotiation in the event that we seek to enter into any significant transaction with a third party with respect to a product either globally or in certain designated countries. Significant transactions include exclusive licenses, assignments, sales, exclusive co-promotion arrangements, and other transfers of all commercial rights to a product globally or in certain designated countries, as well as exclusive distribution agreements globally or in certain designated countries.

Under the Pfizer License Agreement, we are solely responsible for the development, manufacture, regulatory approval and commercialization of compounds and products in the field. We are required to use commercially reasonable efforts to develop and seek regulatory approval for a product that contains or incorporates one of certain scheduled compounds to exert a therapeutic effect on certain targets, in each of the following countries: United Kingdom, Germany, France, Italy, Spain, China, Japan and the United States, each a major market country. We are also required to use commercially reasonable efforts to commercialize each such product, if approved, in each major market country in which regulatory approval for such product has been obtained. The Pfizer License Agreement requires Pfizer to transfer certain know-how and data, regulatory filings and materials, inventory, and other materials, records and documents, and provide certain other transitional

support and assistance which has been and is expected to be immaterial, to us to facilitate our development, manufacture and commercialization of compounds and products in the field.

As partial consideration for the licensed assets, we issued Pfizer 3,833,333.33 shares of Old Cerevel Series A-2 Preferred Stock with an estimated fair value of $100.4 million or $26.20 per share. We also reimbursed Pfizer for $11.0 million of direct expenses related to the Pfizer License Agreement, bringing the total initial consideration to $111.4 million.

Under the terms of the Pfizer License Agreement, we are also required to make regulatory approval milestone payments to Pfizer, ranging from $7.5 million to $40.0 million on a compound-by-compound basis, upon the first regulatory approval in the United States for the first product containing or comprised of a given compound, with the amount of the payments determined by which designated group the compound falls into and with each such group generally characterized by the compounds' stage of development. Each such regulatory approval milestone is payable only once per compound. If all of our product candidates included in the table in the section entitled "—*Our Pipeline*" are approved in the United States, the total aggregate amount of such regulatory approval milestones payable to Pfizer would be approximately $220.0 million.

In addition, we are required to pay Pfizer commercial milestone payments up to an aggregate of $170.0 million per product when aggregate net sales of products under the Pfizer License Agreement in a calendar year first reach various thresholds ranging from $500.0 million to $2.0 billion. Each commercial milestone payment is payable only once upon first achievement of the applicable commercial milestone. If all of our product candidates included in the table in the section entitled "—*Our Pipeline*" achieves all of the commercial milestones, the total aggregate amount of such commercial milestones payable to Pfizer would total approximately $1.7 billion.

We are also required to pay Pfizer tiered royalties on the aggregate net sales during each calendar year, determined on a product-by-product basis with respect to products under the Pfizer License Agreement, at percentages ranging from the low-single digits to mid-teens, with the royalty rate determined by which designated group the applicable compound for such product falls into and with each such group generally characterized by the compounds' stage of development, and subject to certain royalty deductions for the expiration of patent, regulatory and data exclusivity, generic competition and third-party royalty payments as set forth in the Pfizer License Agreement. The royalty term expires, on a product-by-product and country-by-country basis, on the later of (1) expiration of all regulatory or data exclusivity for such product in such country, (2) the date upon which the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the Pfizer License Agreement, a valid claim of the licensed patents and (3) 12 years following the first commercial sale of such product in such country.

Pfizer can terminate the Pfizer License Agreement in its entirety upon our material breach, subject to specified notice and cure provisions. However, if such material breach is with respect to one or more, but not all, products, targets or countries, Pfizer's right to terminate is only with respect to such products, targets or countries. Either party may terminate the Pfizer License Agreement in its entirety upon event of a bankruptcy, insolvency or other similar proceeding of the other party or a force majeure event that prohibits the other party from performing for a period of time. Absent early termination, the term of the Pfizer License Agreement will continue on a country-by-country basis and product-by-product basis, until the expiration of the royalty term for the country and the product. Upon Pfizer's termination of the Pfizer License Agreement for our material breach or either party's termination for bankruptcy, insolvency or other similar proceeding or force majeure, we would grant Pfizer an exclusive, sublicensable, royalty-free, worldwide, perpetual license under certain intellectual property we develop during the term of the Pfizer License Agreement. In addition, we would negotiate a transition plan with Pfizer that would address, among other things, the transfer of know-how and

data, regulatory approvals and filings and materials, inventory and other materials, records and documents, and the provision of certain other transitional support and assistance for the terminated products, targets or countries.

Intellectual property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that we do not consider appropriate for patent protection.

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our platform technologies and product candidates will receive protection from or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Patents

Shortly after our formation in July 2018, we entered into the Pfizer License Agreement, pursuant to which we acquired exclusive worldwide rights under Pfizer patents, patent applications and know-how to develop, manufacture and commercialize our current product candidates.

We have exclusive licenses under the Pfizer License Agreement to patent rights in the United States and numerous foreign jurisdictions relating to our product candidates. As of May 20, 2021, the patent rights in-licensed under the Pfizer License Agreement include:

- For our dopamine D1 agonists, our portfolio includes eight patent families directed to various dopamine D1 agonists, compositions of matter and methods of treating dopamine D1-associated disorders, including schizophrenia, schizoaffective disorder, cognitive impairment, Parkinson’s disease, Alzheimer’s disease and dementia. Across these eight patent families, the portfolio includes 18 granted patents in the United States and 71 patents granted in foreign jurisdictions, including Canada, Japan, China or validated in various member states of the European Patent Office. Additionally, seven patent applications have been allowed or are pending in the United States and foreign jurisdictions. A subset of the patents and patent applications in our dopamine D1 agonist portfolio relate to either or both tavapadon and CVL-871. For tavapadon, the applicable patents and pending patent applications are directed to tavapadon, compositions of matter and certain methods of treatment, including methods of treating Parkinson’s disease and apathy in Alzheimer’s disease, and, excluding any patent term adjustments or extensions, have a statutory expiration date in 2034. For CVL-871, the applicable patents and pending patent applications are directed to CVL-871, compositions of matter and certain methods of treatment, including methods of treating Alzheimer’s disease, dementia and cognitive impairment, and, excluding any patent term adjustments or extensions, have a statutory expiration date in 2034.

- For our $GABA_A$ receptor modulators, our portfolio includes three patent families directed to various $GABA_A$ receptor modulators, compositions of matter and methods of treating $GABA_A$ receptor-associated diseases or disorders, including pain, epilepsy and anxiety. Across these three families, the portfolio includes three granted patents in the United States and 42 patents granted in foreign jurisdictions, including Canada, China, Japan or validated in various member states of the European Patent Office. Additionally, one patent application is pending in a foreign jurisdiction. A subset of the patents and patent applications in our $GABA_A$ receptor modulator portfolio relate to darigabat. For darigabat, the applicable patents and pending patent applications are directed to darigabat, compositions of matter and methods of treating various conditions, including pain, epilepsy and anxiety, and, excluding any patent term extensions, have a statutory expiration date in 2033.
- For our muscarinic M4 positive allosteric modulators, our portfolio includes two patent families directed to various M4 PAMs, compositions of matter and methods of treating M4 receptor subtype associated diseases or disorders, including Alzheimer's disease, schizophrenia, pain, addiction and sleep disorders. Across these two families, the portfolio includes one granted patent in the U.S. and 19 granted patents in foreign jurisdictions. Additionally, two applications are pending in the U.S. and 30 applications are pending in foreign jurisdictions, including the PCT. A subset of the patent applications in our M4 positive allosteric modulator portfolio relate to CVL-231. For CVL-231, these pending patent applications are directed to CVL-231, compositions of matter and methods of treating schizophrenia, and, excluding any patent term adjustments or extensions, have a statutory expiration date in 2037.
- For our dopamine D3 ligands our portfolio includes one patent family directed to various dopamine D3 ligands, compositions of matter and methods of treating diseases associated with dopamine D3 receptors, including Parkinson's disease, schizophrenia, dementia, psychosis, depression, mania, anxiety, dyskinesias, substance addiction, renal insufficiency and impulse control disorder. This patent family relates to CVL-936. This family includes one granted patent in the U.S. and 13 granted patents in foreign jurisdictions, including Australia, Canada, Russia and validations in various member states of the European Patent Office. Additionally, one application is pending in the U.S. and 7 applications are allowed or pending in foreign jurisdictions. Excluding any patent term adjustments or extensions, any patents that have or may issue from this family have a statutory expiration date in 2037.
- For our KOR antagonists, our portfolio includes one patent family directed to various KOR antagonists, compositions of matter and methods of modulating KOR and treating neurological disorders or psychiatric disorders, such as substance abuse disorders, depressive disorders, anxiety disorders, trauma and stressor related disorders, or feeding and eating related disorders. This family includes one granted patent in the U.S., one granted patent in a foreign jurisdiction and 11 pending applications in foreign jurisdictions. Excluding any patent term adjustments or extensions, the granted patent and any applications that may issue from this family have a statutory expiration date in 2037.
- For our muscarinic M4 agonists, our portfolio includes one patent family directed to various M4 agonists, compositions of matter and methods of treating M4 muscarinic receptor-associated diseases or disorders, including Alzheimer's disease, schizophrenia, pain, addiction, Parkinson's disease, PD-LID and sleep disorders. This family includes one pending U.S. application, as well as five pending applications in each of Canada, China, the European Patent Office, Japan and Taiwan. Excluding any patent term adjustments or extensions, any patents that may issue from this family will have a statutory expiration date in 2039.
- For our PDE4 inhibitors, our portfolio includes five patent families directed to various PDE4 inhibitors, compositions of matter and methods of treating schizophrenia, depression, anxiety, Parkinson's disease, Alzheimer's disease, multiple sclerosis, chronic obstructive pulmonary disease, inflammation, stroke, asthma, cerebral vascular disease and allergic conjunctivitis and, excluding any patent term adjustments or

extensions, have statutory expiration dates in 2034, 2035, 2036 and 2037. The patent families include eight granted patents in the United States and 73 patents granted in foreign jurisdictions, including Canada, China, Japan, or validated in various member states of the European Patent Office. Additionally, one patent application is pending in the U.S. and 22 patent applications have been allowed or are pending in foreign jurisdictions.

- For our LRRK2 inhibitors, our portfolio includes five patent families directed to various LRRK2 inhibitors, compositions of matter and methods of treating Parkinson's disease, Alzheimer's disease and other neurodegeneration disorders and, excluding any patent term adjustments or extensions, have statutory expiration dates in 2033, 2034, 2036 and 2038. The patent families include three granted patents in the United States and 17 patents granted in foreign jurisdictions, including Canada, Japan, or validated in various member states of the European Patent Office. Additionally, two patent applications are pending in the U.S. and 31 patent applications are pending in foreign jurisdictions.

See the section entitled "*—Pfizer License Agreement*" for additional information on our rights under the Pfizer License Agreement.

Trade secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also generally provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Trademarks

As of May 20, 2021, our registered trademark portfolio contained 40 registered trademarks in foreign jurisdictions, including, but not limited to, Argentina, Brazil, China, Colombia, Japan, the Russian Federation, Switzerland, Turkey and the United Kingdom. In addition, we have three allowed trademark applications in the U.S. Further, there are 19 pending trademark applications in foreign jurisdictions, including, but not limited to, Canada, China, the European Union, Mexico, South Korea and Venezuela.

Government regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

Review and approval of drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities. In addition, an applicant may need to recall a product.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical, or preclinical, laboratory tests, animal studies and formulation studies in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an IRB representing each clinical site before each clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA and payment of user fees;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, including REMS, and post-approval studies required by the FDA.

Preclinical studies

Before an applicant begins testing a compound in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or API and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. Some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted.

The IND and IRB processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of the investigational drug. In an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments. In addition, the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. The FDA also may impose a clinical hold or partial clinical hold after commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review of the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Human clinical trials in support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the

requirement that all research subjects, or their legal representative, provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1*. The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine maximal dosage.
- *Phase 2*. The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3*. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Post-approval studies, often referred to as Phase 4 studies, may be conducted after initial regulatory approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, within 15 calendar days after the sponsor determines that the information qualifies for reporting, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the applicant must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Review of an NDA by the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission

of most NDAs is additionally subject to a significant application user fee as well as annual prescription drug product program fees. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt, before accepting the NDA for filing, to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Applications for drugs containing new molecular entities are meant to be reviewed within 10 months from the date of filing, and applications for “priority review” products containing new molecular entities are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

During its review of an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA, including drug component manufacturing (such as APIs), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an NDA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential AEs, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast track, breakthrough therapy, and priority review

The FDA has a number of programs intended to facilitate and expedite development and review of new drugs if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. Three of these programs are referred to as Fast Track designation, breakthrough therapy designation, and priority review designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition.

For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate an NDA review for a priority review if it is for a product that treats a serious or life- threatening disease or condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly.

The accelerated approval pathway is contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, could result in the FDA's withdrawal of the approval and require the withdrawal of the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities and select clinical trial sites, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If a complete response letter is issued, the applicant may resubmit the NDA to address all of the deficiencies identified in the letter, withdraw the application, or request a hearing. If the applicant resubmits the NDA, only when the deficiencies have been addressed to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety or effectiveness after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

Post-approval requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, many changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are annual prescription drug product program fee requirements for certain marketed products.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and

impose reporting and documentation requirements upon the NDA holder and any third-party manufacturers that the NDA holder may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or voluntary product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Hatch-Waxman amendments

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product, known as a reference

listed drug, or RLD. ANDAs are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject’s bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Non-patent exclusivity

Under the Hatch-Waxman Amendments, the FDA may not approve (or in some cases accept) an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, which states the proposed generic drug will not infringe one or more of the already approved product’s listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for non-NCE drugs if the NDA or a supplement to the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication, but it generally would not protect the original, unmodified product from generic competition. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; it only prevents FDA from approving such ANDAs.

Hatch-Waxman patent certification and the 30-month stay

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also

known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. If the drug has NCE exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires seven and a half years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

Patent term restoration and extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent term restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date, provided the sponsor acted with diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question and within 60 days of drug approval. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and approval of medicinal products in the european union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical trial approval

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the national competent authority, or NCA, of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the relevant independent ethics committee, or EC, has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC and corresponding national implementing laws of the EU Member States and further detailed in applicable guidance documents. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or the Clinical Trials Regulation, was adopted in the EU. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. It is currently expected that the new Clinical Trials Regulation (EU) No. 536/2014 will come into effect on January 31, 2022.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the “EU portal”; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by an elected Reference Member State, with support of the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States Concerned). Part II is assessed separately by each Member State Concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

Marketing authorization

To obtain a marketing authorization for a product in the EEA, an applicant must submit a MAA either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EEA Member States (decentralized procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EEA.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of HIV or AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are a

significant therapeutic, scientific or technical innovation and whose authorization would be in the interest of public health at EU level, the centralized procedure is optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure, the maximum timeframe for the evaluation of a MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 67 days from the date of the CHMP Opinion, the European Commission will adopt its final decision on the marketing authorization application.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the United Kingdom medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required. For additional information related to the United Kingdom's decision to leave the EU, please refer to the discussion below under the section entitled "*—Brexit and the Regulatory Framework in the United Kingdom*."

The decentralized marketing authorization procedure allows an applicant to apply for simultaneous authorization in more than one EEA country of medicinal products that have not yet been authorized in any EEA country and that do not fall within the mandatory scope of the centralized. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The Reference Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the Concerned Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a Concerned Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EEA Member States of the marketing authorization of a medicinal product by the competent authorities of another EEA Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EEA Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EEA Member State.

Pediatric development

Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the EEA, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted (i) a product-specific waiver, (ii) a class waiver or (iii) a deferral for one or more of the measures included in the PIP. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Regulatory data protection in the European Union

In the EEA, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator’s data contained in the dossier of the reference product when applying for a generic or biosimilar (abbreviated) marketing authorization, for a period of eight years from the date of which the reference product was first authorized in the EEA. During an additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted and authorized, and the innovator’s data may be referenced, but no generic or biosimilar medicinal product can be placed on the EEA market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on a MAA with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of authorization and renewals

A marketing authorization has an initial validity of five years. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant EEA Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authorities of the relevant Member States decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the EEA market (in the case of the centralized procedure) or on the market of the authorizing EEA Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Regulatory requirements after a marketing authorization has been obtained

Where an authorization for a medicinal product in the EEA is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the European Union with the intention to import the APIs into the European Union.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83/EC, as amended, and EU Member State laws.

Brexit and the regulatory framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as "Brexit." Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Pursuant to Article 50 of the Lisbon Treaty, the United Kingdom ceased being a Member State of the EU on January 31, 2020, however there was an initial transition period during which EU medicinal product laws continued to apply in the United Kingdom. This transition period ended on December 31, 2020. Since the regulatory framework in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom, now that United Kingdom legislation has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long term. The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products evolves over time.

European data collection regulation

In the event we decide to conduct clinical trials in the European Union, we may be subject to additional privacy restrictions. The collection and use of personal health information in the European Union is governed by the provisions of the Data Protection Directive, and as of May 25, 2018, the GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive (which governs the collection and use of personal health data in the European Union), the GDPR, and the related national data protection laws of the European Union Member

States may result in fines and other administrative penalties. The GDPR introduced new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Further, it is unclear at this time what effect Brexit will have on our ability to comply with the GDPR.

Healthcare and privacy laws and regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching hospitals and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare and privacy laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal civil and criminal false claims laws, including the civil FCA, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent; knowingly making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- HIPAA, which created additional federal civil and criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or

services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the HHS, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value. Many of these laws differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers;
- many state laws that govern the privacy of personal information in specified circumstances, for example, in California, the California Consumer Protection Act, or the CCPA, which went into effect on January 1, 2020, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information collection practices may be subject to the CCPA and possible changes to the CCPA may broaden its scope; and
- some state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers, marketing expenditures, and drug pricing information. Certain state and local laws require the registration of pharmaceutical sales and medical representatives. State and foreign laws, including for example the GDPR, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and FCA that may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information (e.g., the California Consumer Privacy Act), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pharmaceutical insurance coverage and healthcare reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment

programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Even if we do receive a favorable coverage determination for our products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Facilities

Our principal executive offices are located in Cambridge, Massachusetts and consist of approximately 61,000 square feet of leased space. The space serves as the location of our corporate headquarters and is comprised of office and laboratory space. The lease expires in 2030, subject to our option to extend the lease for two five-year terms.

We believe that our facilities are adequate for our current and anticipated near-term needs and that suitable additional or substitute space would be available if needed.

Legal proceedings

From time to time, we may be party to litigation arising in the ordinary course of business. We are currently not subject to any material legal proceedings and, to the best of our knowledge, no material legal proceedings are currently pending or threatened.

Employees

As of March 31, 2021, we had 122 full-time employees, including approximately 39 employees with M.D. and/or Ph.D. degrees and approximately 79 employees directly engaged in research and development, with the rest providing administrative, business and operations support. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be good.

We have, since our inception, worked to create a high-performing, inclusive and diverse workforce, which is a core element of our operating culture. We have deliberately sought to secure top talent with a diversity of thought, experiences and backgrounds who are committed to making a difference in the lives of patients with neuroscience diseases. We believe that, by embracing differences, we have a unique advantage in challenging the status quo to apply innovative thinking to long-existing medical challenges. As of December 31, 2020, our workforce was self-reportedly approximately 48% women and approximately 30% Asian, Hispanic, Latino, Black or African American, and our senior leadership was 75% women or minorities, reflecting the workforce we strive to create throughout the company.

Human capital

We believe that our single most important asset that differentiates us now and into the future is our employees. Our human capital resource objectives include finding and attracting the best talent and inspiring them to bring their best to Cerevel each and every day. We strive to achieve these objectives through competitive compensation programs and cutting-edge benefits that are intended to meet employees where they are. Our culture underpins all that we do and is anchored in our core values of trust, courage, respect, curiosity and compassion. We strive to be inclusive and diverse in thought, action and in the people who join us. To ensure that this is knitted into the fiber of our organization, we are implementing initiatives across our entire workforce through company-wide workshops, targeted hiring and internship objectives, supplier and vendor diversity programs and inclusivity plans for ongoing and new clinical studies, the achievement of which are an element in our annual incentive plan goals for 2021. We also regularly conduct surveys to gauge employee engagement and to create an ongoing open dialogue with our employees. We are also committed to professional development at every level of our organization through real-time work experiences as well as other learning opportunities and training programs.

Corporate information

Cerevel Therapeutics, Inc. was formed as a Delaware corporation in 2018. ARYA was incorporated as a blank check company on February 20, 2020 as a Cayman Islands exempted company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses.

On June 4, 2020, ARYA consummated its initial public offering, or the IPO, of 14,950,000 units, which included the exercise in full of the underwriters' option to purchase an additional 1,950,000 units at the IPO price to cover over-allotments. Each unit consisted of one Class A ordinary share and one-third of one redeemable warrant, which we refer to as the Public Warrants, each whole Public Warrant entitling the holder thereof to purchase one Class A ordinary share at an exercise price of $11.50 per share, subject to adjustment.

Simultaneous with the consummation of the IPO and the issuance and sale of the units, ARYA consummated the private placement of 499,000 private placement units at a price of $10.00 per private placement unit, generating total proceeds of $4,990,000. The private placement warrants included in the private placement units purchased by the Sponsor, or the Private Placement Warrants, are substantially similar to the Public Warrants, except that if held by the Sponsor or its permitted transferees, they (i) may be exercised for cash or on a cashless basis and (ii) are not subject to being called for redemption (except in certain circumstances when the Public Warrants are called for redemption and a certain price per share of common stock threshold is met).

On October 27, 2020, or the Closing Date, pursuant to the Business Combination Agreement, dated as of July 29, 2020, by and among ARYA, Cassidy Merger Sub 1, Inc., a Delaware corporation, and Cerevel Therapeutics, Inc., a Delaware corporation, as amended on October 2, 2020 by Amendment No. 1 to Business Combination Agreement, or the Business Combination Agreement, ARYA consummated the Business Combination. In connection with the Business Combination, ARYA's Class A ordinary shares and Class B ordinary shares automatically converted, on a one-for-one basis, into shares of our common stock.

Our principal corporate office is located at 222 Jacobs Street, Suite 200, Cambridge, MA 02141, and our telephone number is (844) 304-2048. Our website address is www.cerevel.com. The information contained in or accessible from our website is not incorporated by reference in this prospectus or in any other filings we make with the SEC. We have included our website address in this prospectus solely as an inactive textual reference.

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our Current Reports on Form 8-K, our proxy statements on Schedule 14A, and amendments to those reports and statements filed or furnished pursuant to Section 13(a), 14 or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

The SEC also maintains a website that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC. The SEC's Internet website address is http://www.sec.gov.

Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and notes thereto included elsewhere in this prospectus. Certain of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the material and other risks that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements."

Overview

Introduction

We are a clinical-stage biopharmaceutical company pursuing a targeted approach to neuroscience that combines a deep understanding of disease-related biology and neurocircuitry of the brain with advanced chemistry and CNS target receptor selective pharmacology to discover and design new therapies. We seek to transform the lives of patients through the development of new therapies for neuroscience diseases, including schizophrenia, epilepsy and Parkinson's disease. Our "ready-made" pipeline of 11 small molecule programs, which includes five clinical-stage product candidates, was developed through over a decade of research and investment by Pfizer and was supported by an initial capital commitment from an affiliate of Bain Capital and a keystone equity position from Pfizer. We are advancing our broad and diverse pipeline with six clinical trials underway or expected to start by the end of 2021 and up to seven clinical data readouts expected by the end of 2023. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with the proven expertise of large pharmaceutical company experience and capabilities in drug discovery and development.

On October 27, 2020, ARYA completed the acquisition of Cerevel Therapeutics, Inc., or Old Cerevel, a private company, pursuant to the Business Combination Agreement. ARYA was incorporated as a Cayman Islands exempted company on February 20, 2020 and was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. Cerevel Therapeutics, Inc. was incorporated in Delaware on July 23, 2018 under the name Perception Holdco, Inc. which was subsequently changed to Cerevel Therapeutics, Inc. on October 23, 2018.

Our principal operations commenced on September 24, 2018, or the Formation Transaction Date, when Old Cerevel acquired licensed technology to a portfolio of pre-commercial neuroscience assets from Pfizer in exchange for the issuance of Series A-2 Preferred Stock of Old Cerevel and obtained a $350.0 million equity commitment, or the Equity Commitment, from Bain Investor, an affiliate of Bain Capital, to develop the in-licensed assets in exchange for the issuance of Series A-1 Preferred Stock and Series A Common Stock of Old Cerevel, which we refer to collectively as the Formation Transaction. Bain Investor also received the option to purchase up to an additional 10.0 million shares at $10.00 per share, subject to Pfizer's participation rights, or the Share Purchase Option. On the Formation Transaction Date, we received an initial investment of $115.0 million in equity funding from Bain Investor to begin operations. During 2019 we received an additional investment of $60.1 million in equity funding from Bain Investor. Bain Investor contributed an additional $25.0 million in equity financing in July 2020, or the Additional Financing Shares.

Upon the closing of the transactions contemplated by the Business Combination Agreement, which we refer to as the Business Combination or the Business Combination Transaction, Old Cerevel became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc. Upon completion of the Business Combination Transaction, and pursuant to the terms of the Business Combination Agreement, the existing shareholders of Old Cerevel exchanged their interests for shares of common stock of Cerevel Therapeutics Holdings, Inc., or New Cerevel.

We accounted for the Business Combination Transaction as a reverse recapitalization which is the equivalent of Old Cerevel issuing stock for the net assets of ARYA, with ARYA treated as the acquired company for accounting purposes. The net assets of ARYA were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Cerevel. The shares and corresponding capital amounts and loss per share related to Old Cerevel's outstanding redeemable convertible preferred stock, redeemable convertible common stock, and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the exchange ratio established in the Business Combination Agreement (1.00 share of Old Cerevel for 2.854 shares of New Cerevel), or the Exchange Ratio.

For additional information on our operations, please read Note 1, *Nature of Operations*, to our consolidated financial statements included elsewhere in this prospectus. For additional information on the Business Combination Transaction and the Additional Financing Shares, please read Note 3, *Business Combination*, to our audited consolidated financial statements included elsewhere in this prospectus.

Business environment

The biopharmaceutical industry is extremely competitive. We are subject to risks and uncertainties common to clinical-stage companies in the biopharmaceutical industry. These risks include, but are not limited to, the introduction of new products, therapies, standards of care or technological innovations, our ability to obtain and maintain adequate protection for our licensed technology, data or other intellectual property and proprietary rights and compliance with extensive government regulation and oversight. We are also dependent upon the services of key personnel, including our Chief Executive Officer, executive team and other highly skilled employees. Demand for experienced personnel in the pharmaceutical and biotechnology industries is high and competition for talent is intense. Please read the section entitled "*Risk Factors*" for additional information.

We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies as well as public and private research institutions. Many of our competitors are working to develop or have commercialized products similar to those we are developing and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. Our competitors may also have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products. Other smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Risks and liquidity

Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. We will not generate revenue from product sales unless and until we successfully complete clinical development, are able to obtain regulatory approval for and successfully commercialize the product candidates we are developing or may develop. We currently do not have any product candidates approved for commercial sale. In addition, we operate in an environment of rapid change in technology. We are also dependent upon the services of our employees, consultants, third-party CROs, CMOs and other third-party organizations.

Our product candidates, currently under development or that we may develop, will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities. There can be no assurance that our research and development activities will be successfully completed, that adequate protection for our licensed or developed technology will be obtained and maintained, that products developed will obtain necessary regulatory approval or that any approved products will be commercially viable.

Until such time, if ever, as we can generate substantial product revenue, we will need substantial additional funding to support our continuing operations and pursue our growth strategy, and we may finance our operations through a combination of additional private or public equity offerings, debt financings, collaborations, strategic alliances, marketing, distribution or licensing arrangements with third parties or through other sources of financing. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangement with collaborators on terms unfavorable to us or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

We have incurred significant operating losses since our inception and expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. We believe that our available cash resources as of March 31, 2021, of $343.3 million, will enable us to fund our operating expense and capital expenditure requirements through at least twelve months from the issuance date of our financial statements included in this prospectus.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- advance our clinical-stage product candidates CVL-231, darigabat, tavapadon, CVL-871 and CVL-936 through clinical development, including as we advance these candidates into later-stage clinical trials;
- advance our preclinical stage product candidates into clinical development including CVL-354 and CVL-047;

- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increase personnel to support our operations;
- meet the requirements and demands of being a public company;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Pfizer License Agreement and any future in-license or collaboration agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties.

Impact of the COVID-19 pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

We are closely monitoring the impact of the pandemic of COVID-19 on all aspects of our business, including how it will impact our operations and the operations of our suppliers, vendors and business partners. We have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address this pandemic; however, the spread of COVID-19 has caused us to modify our business practices, including implementing a temporary work-from-home policy for all employees who are able to perform their duties remotely and temporarily restricting all non-essential travel and discouraged employee attendance at industry events and in-person work-related meetings. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of COVID-19.

More specifically, the onset of the COVID-19 pandemic caused brief pauses in patient screening and enrollment in our Phase 3 trials of tavapadon for the treatment of Parkinson's (which we subsequently resumed in the second half of 2020), and we remain particularly vigilant about patient safety given the elderly nature of this population. While we have taken measures to revise clinical trial protocols, the ultimate extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, including vaccination campaigns, among others.

In addition, recurrences or additional waves of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience prolonged business shutdowns or other disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could

have a material adverse impact on our business, results of operations and financial condition. The estimates of the impact on our business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

We have not incurred any significant impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our consolidated financial statements.

Our agreements with licensors and stockholders

Pfizer license agreement

In August 2018, we entered into the Pfizer License Agreement pursuant to which we were granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how to develop, manufacture and commercialize certain compounds and products, which currently constitute the entirety of our asset portfolio, subject to the terms and conditions of the Pfizer License Agreement.

Under the Pfizer License Agreement, we are solely responsible for the development, manufacture, regulatory approval and commercialization of compounds and products in the field and we will pay Pfizer tiered royalties on the aggregate net sales during each calendar year, determined on a product-by-product basis, with respect to products under the Pfizer License Agreement, and we may pay potential milestone payments to Pfizer, based on the successful achievement of certain regulatory and commercial milestones. To date, no regulatory or commercial approval milestone payments or royalty payments were made or became due under this agreement.

For additional information on our Pfizer License Agreement, please read Note 6, *Pfizer License Agreement,* to our audited consolidated financial statements included in this prospectus.

Components of operating results

Revenues

We have not generated any revenues since our inception and do not expect to generate any revenues from the sale of products in the near future, if at all. If our development efforts for our current product candidates or additional product candidates that we may develop in the future are successful and can be commercialized, we may generate revenue in the future from product sales. Additionally, we may enter into collaboration and license agreements from time to time that provide for certain payments due to us. Accordingly, we may generate revenue from payments from such collaboration or license agreements in the future.

Research and development

We support our drug discovery and development efforts through the commitment of significant resources to our preclinical and clinical development activities. Our research and development expense includes:

- employee-related expenses, consisting of salaries, benefits and equity-based compensation for personnel engaged in our research and development activities;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including costs incurred under agreements with clinical research organizations, or CROs, investigative clinical trial sites and consultants and other third-party organizations that conduct research and development activities on our behalf;

- costs associated with preclinical studies and clinical trials, including research materials;
- materials and supply costs associated with the manufacture of drug substance and drug product for preclinical testing and clinical trials;
- costs related to regulatory compliance requirements; and
- certain indirect costs incurred in support of overall research and development activities, including facilities, depreciation and technology expenses.

We expense research and development expenses as incurred. Payments we make for research and development services prior to the services being rendered are recorded as prepaid assets in our consolidated balance sheets and are expensed as the services are provided. We estimate and accrue the value of goods and services received from CROs, CMOs and other third parties each reporting period based on estimates of the level of services performed and progress in the period when we have not received an invoice from such organizations. When evaluating the adequacy of accrued liabilities, we analyze progress of the studies or clinical trials, including the phase of completion of events, invoices received and contracted costs. We reassess and adjust our accruals as actual costs become known or as additional information becomes available. Our historical accrued estimates have not been materially different from actual costs.

Our external research and development expenses for our clinical stage product candidates are tracked on a program-by-program basis and consist primarily of fees, reimbursed materials and other costs paid to consultants, contractors, CROs and CMOs. External research and developments costs that directly support our discovery activities and preclinical programs are classified within other research and development programs. Program costs for the periods presented do not reflect an allocation of expenses associated with personnel costs, equity-based compensation expense, activities that benefit multiple programs or indirect costs incurred in support of overall research and development, such as technology and facilities-related costs.

We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities both in the near-term and beyond as we continue to invest in activities to develop our product candidates and preclinical programs and as certain product candidates advance into later stages of development. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, scope and duration of later-stage clinical trials. Furthermore, the process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we cannot accurately estimate or know the nature, timing and costs that will be necessary to complete the preclinical and clinical development for any of our product candidates or when and to what extent we may generate revenue from the commercialization and sale of any of our product candidates or achieve profitability.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;

- the duration of patient follow-up; and
- the efficacy and safety profile of our product candidates.

Changes in any of these assumptions could significantly impact the cost and timing associated with the development of our product candidates. Additionally, future competition and commercial and regulatory factors beyond our control may also impact our clinical development programs and plans.

General and administrative

We expense general and administrative costs as incurred. General and administrative expenses consist primarily of salaries, benefits, equity-based compensation and outsourced labor for personnel in executive, finance, human resources, legal and other corporate administrative functions. General and administrative expenses also include legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, insurance costs, facilities and depreciation expenses.

We estimate and accrue for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from our service providers. We reassess and adjust our accruals as actual costs become known or as additional information becomes available.

We expect that our general and administrative expenses will increase both in the near-term and beyond as we continue to build general corporate infrastructure to support organization; however, we expect that the rate at which these expenses grow will moderate throughout 2021.

Interest income, net

Interest income, net primarily consists of interest earned on our cash, cash equivalents and restricted cash.

Other income (expense), net

Other income (expense), net consists of amounts for other miscellaneous income and expense unrelated to our core operations.

For the three months ending March 31, 2021, other income (expense), net primarily consisted of gains (losses) on the fair value remeasurement of the private placement warrants.

The private placement warrants were free-standing financial instruments that were reclassified from equity to other long-term liabilities on March 31, 2021. We revalue our private placement warrants each reporting period with increases or decreases in the fair value of these warrants recognized as an adjustment to other income (expense), net in our consolidated statements of operations and comprehensive loss. Changes in the fair value of our private placement warrants result from changes to one or multiple inputs, including adjustments to the discount rate, expected volatility and dividend yield as well as changes in the fair value of our common stock and public warrants.

Prior to the Business Combination Transaction, other income (expense), net primarily consisted of gains (losses) on the fair value remeasurement of the Equity Commitment and Share Purchase Option. The Equity Commitment and Share Purchase Option were free-standing financial instruments that were recorded at their fair value on the Formation Transaction Date. We revalued these instruments each reporting period and recorded increases or decreases in their respective fair value as an adjustment to other income (expense), net in our consolidated statements of operations and comprehensive loss through their termination upon the completion of the Business Combination Transaction.

Changes in the fair value of these financial instruments resulted from changes to one or multiple inputs, including adjustments to the discount rates and expected volatility and dividend yield as well as changes in the amount and timing of the anticipated future funding required to settle these instruments and the fair value of our preferred and common stock that were expected to be exchanged to complete that additional funding. Discount rates in our valuation models represent a measure of the credit risk associated with settling the financial instruments. The expected dividend yield was assumed to be zero as we have never paid dividends, nor do we have current plans to do so in the future. Significant judgment was employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period.

Income tax benefit (provision), net

To date, we have not recorded any significant amounts related to income tax expense, we have not recognized any reserves related to uncertain tax positions, nor have we recorded any income tax benefits for net operating losses incurred to date or for our research and development tax credits.

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of March 31, 2021, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

We file income tax returns in the U.S. federal tax jurisdiction and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our initial tax return period for U.S. federal income taxes was the 2018 period. We currently remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for the 2019 and 2018 tax years. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of our income tax benefit (provision), net. To date, no amounts are being presented as an uncertain tax position.

Results of operations

Comparison of the three months ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

(In thousands)	For the three months ended March 31, 2021	2020	Change
Operating expenses:			
Research and development	$ 36,561	$ 26,959	36%
General and administrative	14,010	10,743	30%
Total operating expenses	50,571	37,702	34%
Loss from operations	(50,571)	(37,702)	34%
Interest income, net	15	204	(93%)
Other income (expense), net	(425)	(15,710)	(97%)
Loss before income taxes	(50,981)	(53,208)	(4%)
Income tax benefit (provision), net	—	—	—%
Net loss	$(50,981)	$(53,208)	(4%)

Research and development

The following table summarizes the components of research and development expense for the three months ended March 31, 2021 and 2020:

(In thousands)	For the three months ended March 31, 2021	2020	Change
Tavapadon	$10,871	$ 9,184	18%
CVL-231	7,115	3,606	97%
Darigabat	5,065	3,327	52%
CVL-871	1,167	399	192%
CVL-936	20	1,038	(98%)
Other research and development programs	2,146	1,073	100%
Unallocated	1,752	2,204	(21%)
Personnel costs	6,628	5,218	27%
Equity-based compensation	1,797	910	97%
Total research and development	$36,561	$26,959	36%

For the three months ended March 31, 2021, compared to the same period in 2020, the increase in research and development expense was primarily due to costs associated with the continued advancement of our tavapadon, CVL-231, darigabat and CVL-871 programs as well as increased investment in our preclinical and discovery research efforts. The increase in research and development expense for the three-month comparative periods also reflects an increase in personnel costs, including equity-based compensation, as we continue to develop our organizational infrastructure to advance our pipeline. These increases were partially offset by reduction in

costs for the development of CVL-936 as we concluded dosing of Cohort 1 of the Phase 1 SAD trial in the first quarter of 2020 after receiving sufficient clinical data for the intended purposes for this trial.

General and administrative

	For the three months ended March 31,		
(In thousands)	**2021**	**2020**	**Change**
General and administrative	$14,010	$10,743	30%

For the three months ended March 31, 2021, compared to the same period in 2020, the increase in general and administrative expense was primarily due to increased public company costs and a $2.2 million net charge associated with the departure of certain executives. Cost savings from a reduction in outsourced labor were offset by increased personnel costs as we continued to grow our organization.

Interest income, net

	For the three months ended March 31,		
(In thousands)	**2021**	**2020**	**Change**
Interest income, net	$ 15	$ 204	(93)%

Interest income, net primarily consists of interest earned on our cash, cash equivalents and restricted cash. The decrease in interest income, net, reflects a reduction in market interest rates.

Other income (expense), net

The following table summarizes other income (expense), net for the three months ended March 31, 2021 and 2020:

	For the three months ended March 31,		
(In thousands)	**2021**	**2020**	**Change**
Loss on fair value remeasurement of Equity Commitment	$ —	$ (15,760)	**
Gain on fair value remeasurement of Share Purchase Option	—	50	**
Loss on fair value remeasurement of private placement warrants	(424)	—	**
Other, net	(1)	—	**
Other income (expense), net	$ (425)	$ (15,710)	**

** – Not meaningful

The Equity Commitment and Share Purchase Option were free-standing financial instruments that were recorded at fair value on the Formation Transaction Date. We revalued these financial instruments each reporting period until their termination upon the completion of our Business Combination Transaction in 2020.

For additional information on our Equity Commitment and Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included in our Annual Report.

Comparison of the year ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019	Change
Operating expenses:			
Research and development	$ 103,303	$ 50,294	105%
General and administrative	45,813	33,169	38%
Total operating expenses	149,116	83,463	79%
Loss from operations	(149,116)	(83,463)	79%
Interest income, net	224	1,552	(86%)
Other income (expense), net	(3,274)	(46,433)	(93%)
Loss before income taxes	(152,166)	(128,344)	19%
Income tax benefit (provision), net	24	(45)	(153%)
Net loss	$ (152,142)	$ (128,389)	19%

Research and development

The following table summarizes the components of research and development expense for the years ended December 31, 2020 and 2019:

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019	Change
Tavapadon	$ 31,678	$ 16,973	87%
Darigabat	10,984	8,174	34%
CVL-231	16,360	2,646	518%
CVL-936	2,110	2,201	(4%)
CVL-871	1,003	—	100%
Other research and development programs	6,304	1,224	415%
Unallocated	8,608	3,587	140%
Personnel costs	23,017	12,887	79%
Equity-based compensation	3,239	2,602	24%
Total research and development	$ 103,303	$ 50,294	105%

For 2020 compared to 2019, the increase in research and development expense was primarily due to an increase in program costs related to advancing our pipeline and increased personnel costs, including equity-based compensation, as well as an increase in unallocated costs as we grew our organization. The increase in unallocated costs is primarily related to an increase in professional services and other indirect research and development costs reflecting our increased investment in technology, increased consulting and professional fees for cross-program support activities and other overhead expenses.

General and administrative

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019	Change
General and administrative	$ 45,813	$ 33,169	38%

For 2020 compared to 2019, the increase in general and administrative expense was primarily due to increased personnel costs, including equity-based compensation, higher facility-related costs as we grew our organization, as well as certain non-recurring charges recognized in connection with our Business Combination Transaction.

The increase in facility-related costs is primarily associated with the lease for our headquarters in Cambridge, Massachusetts. General and administrative expense for 2020 includes a $3.0 million charge recognized in October 2020 related to the payment of remaining management fees due pursuant to the Management Agreement with affiliate entities of Bain Investor upon the completion of the Business Combination Transaction.

General and administrative expense for 2020 also includes a $2.5 million charge related to the write-off of deferred financing costs directly associated with our previously anticipated IPO and other financing activities that were abandoned in June 2020 upon signing of the term sheet for our Business Combination Transaction.

Interest income, net

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019	Change
Interest income, net	$ 224	$ 1,552	(86%)

Interest income, net primarily consists of interest earned on our cash, cash equivalents and restricted cash. The decrease in interest income, net, reflects a reduction in market interest rates and lower average comparative cash, cash equivalents and restricted cash balances.

Other income (expense), net

The following table summarizes other income (expense), net for the years ended December 31, 2020 and 2019:

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019	Change
Loss on fair value remeasurement of Equity Commitment	$ (3,530)	$ (51,562)	(93%)
Gain on fair value remeasurement of Share Purchase Option	260	5,120	(95%)
Other, net	(4)	9	(144%)
Other income (expense), net	$ (3,274)	$ (46,433)	(93%)

For 2020 compared to 2019, other income (expense), net, primarily reflects the net changes related to the fair value remeasurement of the Equity Commitment and the Share Purchase Option.

For 2020, the change in fair value remeasurement of Equity Commitment reflects a $5.5 million loss recognized on the partial settlement of the Equity Commitment liability in July 2020 upon the Bain Investor contributing an

additional $25.0 million in exchange for the issuance of convertible preferred and convertible common stock as well as a net gain of $2.0 million related to the fair value remeasurement of the Equity Commitment through its termination.

For 2019, the change in the fair value remeasurement of Equity Commitment reflects the loss recognized upon the partial settlement of the Equity Commitment liability upon the issuance of Series A-1 Preferred Stock and Series A Common Stock in December 2019 as well as changes in fair value remeasurement of Equity Commitment and Share Purchase Option also reflect changes in the probability of exercise and timing of future expected funding required in settlement of the Equity Commitment and Share Purchase Option and increases in the fair value of our preferred and common stock expected to be exchanged for that additional funding.

For additional information on our Equity Commitment and Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included elsewhere in this prospectus.

Liquidity and capital resources

Sources of liquidity and capital

We have incurred significant operating losses since our inception and we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. Our net losses totaled $51.0 million and $152.1 million for the three months ended March 31, 2021 and the year ended December 31, 2020, respectively, and as of March 31, 2021, we had an accumulated deficit of $441.9 million. We have not yet generated revenues.

Prior to the Business Combination, our operations were funded primarily from the issuance of convertible preferred stock, convertible common stock and common stock, as described above in Note 1, *Nature of Operations,* to our consolidated financial statements included elsewhere in this prospectus. Upon the closing of the Business Combination Transaction in October 2020, we received net proceeds totaling approximately $439.5 million.

Our cash and cash equivalents totaled $343.3 million as of March 31, 2021. Until required for use in our business, we typically invest our cash in investments that are highly liquid, readily convertible to cash with original maturities of 90 days or less at the date of purchase. We attempt to minimize the risks related to our cash and cash equivalents by maintaining balances in accounts only with accredited financial institutions and, consequently, we do not believe we are subject to unusual credit risk beyond the normal credit risk associated with ordinary commercial banking relationships.

Future funding requirements

Our primary use of cash is to fund operating expenses, primarily related to our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We have incurred significant operating expenses since our inception, and we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. In the future, we will require additional capital to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities.

Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;

- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments under the Pfizer License Agreement and the Funding Agreements;
- the royalty payments due under the Pfizer License Agreement and the Funding Agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the total amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and preclinical studies.

Our expectations with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to us and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate certain of our research, product development or future commercialization efforts, obtain funds through arrangements with collaborators on terms unfavorable to us, or pursue other merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

For additional information on risks associated with our substantial capital requirements, please read the section entitled “*Risk Factors*” included elsewhere in this prospectus.

Warrants

ARYA issued public warrants and private placement warrants (collectively, the warrants) in its IPO in June 2020. The warrants became exercisable beginning on June 9, 2021. Warrants may only be exercised for a whole number of shares. No fractional shares will be issued upon exercise of the warrants. Each whole warrant entitles the holder to purchase one share of common stock at an exercise price of $11.50 per share.

We will use our commercially reasonable efforts to maintain the effectiveness of our registration statement and a current prospectus relating to those common shares issuable upon exercise of the warrants until the warrants expire or are redeemed, as specified in the warrant agreement. If our common stock at the time of any exercise of a warrant is not listed on a national securities exchange, we may, at our option, require holders of the warrants who exercise their warrants to do so on a “cashless basis.” We are not required to file or maintain in effect a registration statement. In no event will we be required to net cash settle any warrant.

Except as described in the warrant agreement, the private placement warrants have terms and provisions that are identical to those of the public warrants. If the private placement warrants are held by holders other than the Sponsor or its permitted transferees, the private placement warrants will be redeemable by us and exercisable by the holders on the same basis as the public warrants.

We may call the warrants for redemption:

- in whole and not in part;
- upon not less than 30 days’ prior written notice of redemption to each warrant holder; and
- if, and only if, the closing price of our common stock equals or exceeds $18.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of the redemption is given to the warrant holder.

If and when the warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. If we call the public warrants for redemption, as described above, we will have the option to require any holder that wishes to exercise the public warrants to do so on a “cashless basis,” as described in the warrant agreement.

Commencing ninety days after the warrants become exercisable, we may redeem the outstanding warrants:

- in whole and not in part;
- at $0.10 per warrant upon a minimum of 30 days’ prior written notice of redemption, provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares determined by reference to the table included in the warrant agreement, based on the redemption date and the “fair market value” of our shares of common stock, except as otherwise described below;
- if, and only if, the closing price of the shares of common stock equals or exceeds $10.00 per share (as adjusted for share subdivisions, share dividends, reorganizations, reclassifications, recapitalizations and the like) on the trading day before we send the notice of redemption to the warrant holders;
- if, and only if, the private placement warrants are also concurrently called for redemption on the same terms as the outstanding public warrants, as described above; and
- if, and only if, there is an effective registration statement covering the issuance of common stock issuable upon exercise of the warrants and a current prospectus relating thereto available throughout the 30-day period after written notice of redemption is given.

The warrants will expire five years after the completion of the Business Combination Transaction, or earlier upon redemption or liquidation.

Working capital

Comparison of the periods ended March 31, 2021 and December 31, 2020

The following table summarizes our total working capital, defined as current assets less current liabilities as of March 31, 2021 and December 31, 2020:

	As of		
(In thousands)	**March 31, 2021**	**December 31, 2020**	**Change**
Current assets	$ 349,811	$ 390,560	(10)%
Current liabilities	(34,151)	(29,548)	16%
Total working capital	$ 315,660	$ 361,012	(13)%

The change in working capital at March 31, 2021 from December 31, 2020, reflects a net decrease in total current assets of $40.7 million and a net increase in total current liabilities of $4.6 million.

The net decrease in total current assets was primarily driven by a net decrease in our cash and cash equivalents primarily due to $36.4 million of net cash flows used in operations and $4.7 million of cash used for the purchase of property and equipment.

The net increase in current liabilities was primarily driven by an increase in accounts payable and increases in accrued expenses and other current liabilities related to increased external research and development services partially offset a decrease in the accrual for employee compensation and personnel costs.

Comparison of the year ended December 31, 2020 and 2019

The following table summarizes our total working capital, defined as current assets less current liabilities as of December 31, 2020 and 2019:

	As of December 31,		
(In thousands)	**2020**	**2019**	**Change**
Current assets	$390,560	$ 87,077	349%
Current liabilities	(29,548)	(14,876)	99%
Total working capital	$361,012	$ 72,201	400%

The change in working capital at December 31, 2020, from December 31, 2019, reflects net a net increase in total current assets of $303.5 million partially off-set by a net increase in total current liabilities of $14.7 million.

The net increase in total current assets was primarily driven by a net increase in our cash and cash equivalents following the completion of the Business Combination Transaction, partially offset by $117.8 million of net cash flows used in operations and $18.9 million of cash used for the purchase of property and equipment.

The net increase in current liabilities was primarily driven by an increase in accounts payable and increases in accrued expenses and other current liabilities related to compensation, external research and development services and construction-in-progress accruals related to the build-out of our Cambridge, Massachusetts headquarters.

Cash flows

Comparison of the three months ended March 31, 2021 and 2020

The following table summarizes our sources and uses of cash for the years ended March 31, 2021 and 2020:

	For the three months ended March 31,		
(In thousands)	**2021**	**2020**	**Change**
Net cash flows used in operating activities	$(36,418)	$ (29,454)	24%
Net cash flows used in investing activities	(4,660)	(2,556)	82%
Net cash flows provided by financing activities	742	—	**
Net decrease in cash, cash equivalents and restricted cash	$(40,336)	$ (32,010)	26%

Cash flows used in operating activities

Net cash flows used in operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided by financing activities will continue to be our primary source of funds to finance operating needs and capital expenditures for the foreseeable future.

Net cash flows used in operating activities is derived by adjusting our net loss for:

- non-cash operating items such as depreciation and amortization, non-cash rent expense, equity-based compensation, impairments and write-offs of deferred charges;
- changes in operating assets and liabilities reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- changes in the fair value remeasurement of the Equity Commitment, Share Purchase Option and the private placement warrants.

For the three months ended March 31, 2021, cash used in operating activities primarily reflects our net loss for the period of $51.0 million, adjusted for net non-cash charges totaling $6.4 million and a net change of $8.1 million in our net operating assets and liabilities. Our non-cash charges primarily consisted of $6.1 million of equity-based compensation expense. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses and other liabilities related to increased external research and development services partially offset by a decrease in the accrual for employee compensation and personnel costs and an increase in operating lease liabilities resulting from landlord reimbursement for tenant improvements.

For the three months ended March 31, 2020, net cash used in operating activities primarily reflected our net loss for the period of $53.2 million, adjusted by non-cash charges totaling $19.3 million and a net change of $4.5 million in relation to our net operating assets and liabilities. Our non-cash charges primarily consisted of net losses totaling $15.7 million recognized related to the Equity Commitment and Share Purchase Option, $3.0 million of equity-based compensation expense and $0.5 million of non-cash rent expense. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses and other current liabilities, and a decrease in prepaid expenses and other current assets.

Cash flows used in investing activities

For the three months ended March 31, 2021, cash used in investing activities reflected $4.7 million used for purchases of property and equipment, primarily related to the build-out of our Cambridge, Massachusetts headquarters.

For the three months ended March 31, 2020, cash used in investing activities reflected $2.6 million used for purchases of property and equipment, primarily related to the build-out of our Cambridge, Massachusetts headquarters.

Cash flows provided by financing activities

For the three months ended March 31, 2021, net cash provided by financing activities totaled $0.7 million, reflecting proceeds received from stock option exercises.

Comparison of the year ended December 31, 2020 and 2019

The following table summarizes our sources and uses of cash for the years ended December 31, 2020 and 2019:

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019	Change
Net cash flows used in operating activities	$ (117,802)	$ (70,720)	67%
Net cash flows used in investing activities	(18,892)	(1,099)	1,619%
Net cash flows provided by financing activities	440,835	60,058	634%
Net increase (decrease) in cash and cash equivalents	$ 304,141	$ (11,761)	(2,686%)

Cash flows used in operating activities

Net cash flows used in operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided by financing activities will continue to be our primary source of funds to finance operating needs and capital expenditures for the foreseeable future.

Net cash flows used in operating activities is derived by adjusting our net loss for:

- non-cash operating items such as depreciation and amortization, non-cash rent expense, equity-based compensation, impairments and write-offs of deferred charges;
- changes in operating assets and liabilities reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- changes in the fair value remeasurement of the Equity Commitment and the Share Purchase Option.

For 2020, cash used in operating activities primarily reflects our net loss for the period of $152.1 million, adjusted for net non-cash charges totaling $16.6 million and a net change of $17.7 million in our net operating assets and liabilities. Our non-cash charges primarily consisted of $10.5 million of equity-based compensation expense, net losses totaling $3.3 million recognized in relation to the Equity Commitment and Share Purchase Option and a $2.5 million charge related to the write-off of deferred financing costs directly associated with our previously anticipated IPO and other financing activities that were abandoned in June 2020 upon signing of the term sheet for our Business Combination Transaction. The net change in our operating assets and liabilities was

primarily due to an increase in account payable and accrued expenses and other liabilities associated with compensation, external research and development services and an increase in operating lease liabilities resulting from landlord reimbursement for tenant improvements.

For 2019, net cash used in operating activities primarily reflected our net loss for the period of $128.4 million, adjusted by non-cash charges totaling $57.3 million and a net change of $0.3 million in relation to our net operating assets and liabilities. Our non-cash charges primarily consisted of net losses totaling $46.4 million recognized related to the Equity Commitment and Share Purchase Option, $8.3 million of equity-based compensation expense and $2.4 million of non-cash rent expense. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses and other current liabilities, partially offset by an increase in prepaid expenses, other current assets and other assets.

Cash flows used in investing activities

For 2020, cash used in investing activities reflected $18.9 million used for purchases of property and equipment, primarily related to the build-out of our Cambridge, Massachusetts headquarters.

For 2019, cash used in investing activities reflected $1.1 million used for purchases of property and equipment.

Cash flows provided by financing activities

For 2020, net cash provided by financing activities totaled $440.8 million, which primarily consisted of net proceeds from the completion of the Business Combination Transaction.

For 2019, net cash provided by financing activities totaled $60.1 million, which primarily consisted of net proceeds from the issuance of Series A-1 Preferred Stock and Series A Common Stock.

Contractual obligations and other commitments

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, contracts and other purchase obligations. We did not have any debt obligations as of March 31, 2021 or December 31, 2020.

Our most significant contracts relate to agreements with CROs for clinical trials and preclinical studies, CMOs and other service providers for operating purposes, which we enter into in the normal course of business. These contracts are generally cancelable at any time by us following a certain period after notice and therefore, we believe that our non-cancelable obligations under these agreements are not material. In addition, we have obligations with respect to potential future royalties payable, contingent development, regulatory and commercial milestone payments and amounts related to uncertain tax positions. The timing and amount of such obligations are unknown or uncertain as of March 31, 2021. For additional information on potential royalties and milestone payments payable to Pfizer, see *“Our Agreements with Licensors and Stockholders—Pfizer License Agreement*.”

As of March 31, 2021, our remaining obligations associated with expenditures expected to be incurred related to the build out of our corporate headquarters totaled $3.5 million. Other than the Funding Agreements, described in Note 14, *Subsequent Events*, to our accompanying unaudited condensed consolidated financial statements, there have been no other material changes to our contractual obligations and commitments since December 31, 2020.

Contract research and manufacturing organizations

As of March 31, 2021, and December 31, 2020, we recorded accrued expenses of approximately $14.5 million and $7.1 million, respectively, in our consolidated balance sheets for expenditures incurred by CROs and CMOs.

Tax related obligations

To date, we have not recognized any reserves related to uncertain tax positions. As of March 31, 2021, and December 31, 2020, we had no accrued interest or penalties related to uncertain tax positions.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements and do not have holdings in any variable interest entities.

Critical accounting policies and estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP.

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Other significant accounting policies are outlined in Note 4, *Summary of Significant Accounting Policies,* to our audited consolidated financial statements included elsewhere in this prospectus.

Fair value measurements

Certain of our assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in our consolidated balance sheets for cash, cash equivalents and restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Our cash, cash equivalents and restricted cash are comprised of funds held in an exchange traded money market fund, are measured at fair value on a recurring basis using quoted market prices for that fund and are classified as Level 1. As of December 31, 2020, we held $387.8 million in money market funds (Level 1), inclusive of restricted cash balances, with no unrealized gains or losses. As of December 31, 2019, we held $83.7 million in money market funds (Level 1), inclusive of restricted cash balances, with no unrealized gains or losses.

As of December 31, 2019, the Equity Commitment and Share Purchase Option approximated their fair value based on Level 3 inputs. In October 2020, the Equity Commitment and Share Purchase Option were terminated upon completion of the Business Combination Transaction. Immediately prior to the closing of the Business Combination Transaction, the closing of this transaction was considered certain to occur which reduced the fair value of the remaining Equity Commitment and Share Purchase Option to zero and as a result, we recognized a gain of $7.8 million and $0.9 million in relation to these instruments, respectively.

We do not have any other material financial or non-financial assets or liabilities that require material estimation that should be recognized or disclosed at fair value on a recurring basis at March 31, 2021 or December 31, 2020.

Fair value of equity commitment and share purchase option

The Equity Commitment and Share Purchase Option were free-standing financial instruments that may have required us to transfer equity upon settlement or exercise, respectively, and were recorded at fair value on the Formation Transaction Date. The fair value of each financial instrument on the Formation Transaction Date was allocated to the Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series A Common Stock.

We utilized a hybrid methodology that combines both an income approach and a market approach, which incorporated a probability weighted expected return (PWERM) related to pre-IPO funding, to estimate the fair value of our Equity Commitment and Share Purchase Option during 2019 and throughout 2020, until the Equity Commitment and Share Purchase Option were terminated upon completion of the Business Combination Transaction. Under this methodology, these financial instruments were valued based upon a probability weighted-average of two separate models prepared following an income approach and a market approach. The fair value of the funding obligation under each model was estimated as the net present value of the anticipated future funding, reduced by the value of the additional shares of preferred and common stock that would be exchanged for future funding.

We revalued these financial instruments each reporting period, until the Equity Commitment and Share Purchase Option were terminated, utilizing models that are sensitive to changes in the unobservable inputs such as changes in the estimated future funding dates or fair value of our stock. Changes in the fair value of these instruments resulted from changes to one or multiple inputs, including adjustments to the discount rates and expected volatility and dividend yield as well as changes in the amount and timing of the anticipated future funding required in settlement of the Equity Commitment and Share Purchase Option and the fair value of our

preferred and common shares expected to be exchanged for that additional funding. Discount rates in our valuation models represented a measure of the credit risk associated with settling the financial instruments. The expected dividend yield was assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on our common stock. Significant judgment was employed in determining these assumptions as of the Formation Transaction Date and for each subsequent period.

Changes in fair value of the Equity Commitment and Share Purchase Option were recognized as a component of other income (expense), net in our consolidated statements of operations and comprehensive loss. We classified the fair value of the remaining Equity Commitment and the fair value of the Share Purchase Option as an asset or liability within our consolidated balance sheets. Immediately prior to the closing of the Business Combination Transaction, or Closing, these financial instruments were adjusted to their final fair value of zero and were terminated upon Closing.

Equity-based compensation

We determine the fair value of each award issued under our equity-based compensation plan on the date of grant. We recognize compensation expense for service-based awards on a straight-line basis over the requisite service period which generally approximates the vesting term. For service-based awards with performance or market conditions, we recognize compensation expense on a straight-line basis over the requisite service period for each separate vesting portion of the award, with the amount of compensation expense recognized at any date at least equaling the portion of the grant-date fair value of the award that is vested at that date. Equity-based compensation expense for awards with performance conditions are recognized to the extent we determine that the condition is considered probable to be met. We reassess the probability of achieving these performance conditions each reporting period until the date such conditions are settled. Cumulative adjustments are recorded each period to reflect the estimated outcome of the performance condition.

We elected to account prospectively for forfeitures as they occur rather than apply an estimated forfeiture rate to equity-based compensation expense. We classify equity-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified, as applicable.

Determination of the fair value—preferred and common stock

Prior to the completion of the Business Combination Transaction, given the absence of an active market for our common stock, we were required to estimate the fair value of our common stock at the time of each grant of an equity-based award. We have utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of our common stock. Each valuation methodology includes estimates and assumptions that require judgment. These estimates and assumptions included a number of objective and subjective factors in determining the value of our common stock at each grant date, including the following factors:

- prices paid for our convertible preferred stock and common stock, and the rights, preferences, and privileges associated with our convertible preferred stock and common stock;
- the progress of our research and development efforts, including the status of preclinical studies and planned clinical trials for our investigational medicines;
- our stage of development and projected growth;
- the fact that the grants of equity-based awards involved illiquid securities in a private company;

- the likelihood of achieving a liquidity event for the common stock underlying the equity-based awards, such as an initial public offering, or IPO, given prevailing market conditions;
- the analysis of IPOs and the market performance of similar companies in the biotechnology and pharmaceutical industries;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors; and
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry.

We used a hybrid methodology that combines both an income approach and a market approach to estimate the business enterprise value and our total equity value to calculate the fair value of our preferred stock and common stock during 2019 and throughout 2020, until completion of the Business Combination Transaction. A probability-weighted discounted cash flow analysis was first prepared reflecting multiple scenarios for future outcomes associated with the acquired product candidates in order to estimate the cash flows associated with estimated liquidity events (i.e., an IPO). We also used a PWERM to determine the fair value of pre-IPO funding scenarios. We then used a market approach to estimate the value as of each potential date of liquidity, resulting in an estimate of the total equity value, including the value of planned future funding. The value of the preferred stock and common stock was then estimated using an option pricing method, allocating total equity value based on an assumed future liquidity date, the liquidation preference of the preferred stock and the assumed funding in each scenario. Each of these scenarios was probability-weighted based on the expected outcomes to arrive at a final estimated fair value per share of the common stock.

Subsequent to the closing of the Business Combination Transaction, our board of directors determines the fair value of each share of common stock underlying stock-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant.

We believe our methodologies are reasonable based upon our internal peer company analyses and further supported by transactions involving our preferred stock. If different assumptions had been made, equity-based compensation expense, consolidated net loss and consolidated net loss per share could have been significantly different.

For financial reporting purposes, we performed common stock valuations, with the assistance of a third-party specialist, at various dates, which resulted in valuations of Old Cerevel common stock, unadjusted by the Exchange Ratio, of $9.15 per share as of March 31, 2019, $9.45 per share as of June 30, 2019, $11.25 per share as of September 30, 2019, $10.00 per share as of October 31, 2019, $16.35 per share as of December 31, 2019, $14.60 per share as of March 31, 2020, $26.80 per share as of June 30, 2020, $26.75 per share as of September 30, 2020 and $28.54 immediately prior to the completion of the Business Combination Transaction. Subsequent to the closing of the Business Combination Transaction, our board of directors determines the fair value of each share of common stock underlying stock-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant.

Determination of fair value—stock option awards

Subsequent to the closing of the Business Combination Transaction, we estimate the fair value of our stock option awards using the Black Scholes method utilizing the “simplified method,” for determining the expected life of the award, which is based on the mid-point between the vesting date and the end of the contractual term as all options granted after becoming a public entity will be granted “at-the-money.” We determine the volatility for options granted based on an analysis of reported data for a peer group of companies. The expected volatility of granted options has been determined using a weighted-average of the historical volatility

measures of this peer group of companies. We will continue to apply this method until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The risk-free interest rate utilized in our calculations is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on our common stock.

Prior to the closing of the Business Combination Transaction, we estimated the fair value of the stock option awards on the date of grant using the option pricing method, which is a variant of an income approach. The option pricing method was used given that a portion of the option awards have an exercise price that is considered to be “deeply out of the money,” The option pricing method incorporated the probability of the performance and market conditions being met and adjustments to the estimated life and value of the options to reflect the necessary growth in the common share value for such shares to become exercisable.

As there was no public market for our common stock prior to the closing of the Business Combination Transaction, we determined the volatility for options granted based on an analysis of reported data for a peer group of companies. The expected volatility of granted options were determined using a weighted-average of the historical volatility measures of this peer group of companies. The expected life of options for these awards were determined by probability-weighting the calculated expected life of the option at each month the option was eligible to be at- or in-the-money to estimate the overall adjusted expected life. We did not utilize the “simplified method” to determine expected life as this method is not valid for options that are “deeply out of the money.” The risk-free interest rate utilized in our calculations is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and does not have current plans to pay any dividends on our common stock.

Our option awards granted prior to the Business Combination Transaction, reflect multiple strike prices. In order to motivate our employees, a premium in exercise price was applied to 25% of each option award. Following the closing of the Business Combination Transaction, the strike price of our option awards reflects the closing price of our common stock as reported by Nasdaq on the date of grant.

Vesting terms

Stock options granted to employees generally vest 25% on the first anniversary of the applicable vesting start date of each grant with the remainder vesting in 36 equal monthly installments thereafter, subject to continued employment. Stock options granted to our non-employee directors vesting in 36 monthly installments through the third anniversary of the grant date.

Restricted stock unit awards granted generally vest in three equal annual installments beginning on the first anniversary of the date of grant.

Conversion of equity awards

Pursuant to the terms of our Business Combination Agreement, the shareholders of Old Cerevel exchanged their shares of common stock in Old Cerevel for shares of Cerevel Therapeutics Holdings, Inc., based upon the Exchange Ratio. Awards under the company’s previously existing equity incentive plans, including the 2020 Old Cerevel Equity Incentive Plan and the 2018 Old Cerevel Equity Incentive Plan, were also exchanged for awards issued under a new equity incentive plan adopted by Cerevel Therapeutics Holdings, Inc. at the same Exchange Ratio.

For additional information on the Business Combination and our equity-based incentive plans, please read Note 3, *Business Combination* and Note 12, *Equity-Based Compensation,* to our audited consolidated financial statements included elsewhere in this prospectus.

Accrued research and development

We have entered into various agreements with CROs, CMOs and other service providers. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, our estimated accruals have not differed materially from actual costs incurred.

Emerging growth company and smaller reporting company status

We are an “emerging growth company” as defined in the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take, have taken, and intend to take, advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earliest of (i) December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter.

Recent accounting pronouncements

For a discussion of new accounting standards and their expected impact on our consolidated financial statements or disclosures, please read Note 3, *Recent Accounting Guidance*, to our unaudited condensed consolidated financial statements and Note 5, *Recent Accounting Guidance*, to our audited consolidated financial statements, included elsewhere in this prospectus.

Quantitative and qualitative disclosures about market risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We had cash and cash equivalents of $343.3 million and $383.6 million as of March 31, 2021 and December 31, 2020, respectively, which consisted of bank deposits and highly liquid money market funds. Furthermore, we had no outstanding debt as of March 31, 2021 or December 31, 2020.

Interest rate sensitivity

Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Foreign currency exchange risk

We currently do not have significant exposure to foreign currencies as we hold no foreign exchange contracts, option contracts, or other foreign hedging arrangements. Further, our operating activities are predominately denominated in U.S. dollars.

We do not believe that inflation, interest rate changes or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Certain relationships and related person transactions

Other than compensation and employment-related arrangements, including those described under the section entitled "*Executive and Director Compensation*" in this prospectus and the transactions described below, since our inception, there has not been and there is not currently proposed, any transaction or series of similar transactions to which:

- we were, or will be, a participant;
- the amount involved exceeded, or will exceed, $120,000; and
- in which any of our directors or executive officers, or any holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

Amended and restated registration and shareholder rights agreement

On the Closing Date, Sponsor, Perceptive PIPE Investor, Jake Bauer, Chad Robins, Todd Wider, Bain Investor and Pfizer entered into an Amended and Restated Registration and Shareholder Rights Agreement, as amended by that certain Waiver, dated as of January 20, 2021, or the Registration and Shareholder Rights Agreement, pursuant to which, among other things, Sponsor, Perceptive PIPE Investor, Bain Investor and Pfizer agreed not to effect any sale or distribution of any of our equity securities held by any of them during the lock-up period described therein and were granted certain registration rights and certain preemptive rights with respect to their respective shares of common stock, and Bain Investor and Pfizer agreed to cast their votes such that our board of directors would be constituted as set forth in the Business Combination Agreement and the Registration and Shareholder Rights Agreement and would have certain rights to nominate directors to serve on our board of directors, in each case, on the terms and subject to the conditions therein.

In particular, the Registration and Shareholder Rights Agreement provides for the following registration rights:

- *Demand registration rights*. We are required, upon the written request of Bain Investor, Pfizer, Sponsor or Perceptive PIPE Investor, or the Sponsor Holders, to file a registration statement and use reasonable best efforts to effect the registration of all or part of their registrable securities. We are not obligated to effect any demand registration if a demand registration or piggyback registration was declared effective or an underwritten shelf takedown was consummated within the preceding 90-day period.
- *Shelf registration rights*. We are required, upon the written request of any Sponsor Holder, to file a shelf registration statement pursuant to Rule 415 under the Securities Act and use reasonable best efforts to effect the registration of all or a portion of their registrable securities, provided that Sponsor and Perceptive PIPE Investor were deemed to have given such a request as of the date of the Registration and Shareholder Rights Agreement, Messrs. Bauer, Robins and Wider are entitled to include their registrable securities on a shelf registration statement filed in connection with such request and we could satisfy such request by including such registrable securities on the registration statement that was to be filed in respect of the PIPE financing. Promptly upon receipt of a shelf registration request, we must deliver a written notice to all other Sponsor Holders and offer each such Sponsor Holder the opportunity to include its registrable securities in such shelf registration statement. At any time that we have an effective shelf registration statement with respect to a Sponsor Holder's registrable securities, such Sponsor Holder may make a written request to effect a public offering, including pursuant to an underwritten shelf takedown, provided that we are not obliged to effect any underwritten shelf takedown if a demand registration or piggyback registration was declared effective or an underwritten shelf takedown was consummated within the preceding 90-day period.

- *Piggyback registration rights*. If we propose to file a registration statement to register any of our equity securities under the Securities Act or to conduct a public offering, either for our own account or for the account of any other person, subject to certain exceptions, the Sponsor Holders are entitled to include their registrable securities in such registration statement.
- *Expenses and indemnification*. All fees, costs and expenses of underwritten registrations will be borne by us and underwriting discounts and selling commissions will be borne by the holders of the shares being registered. The Registration and Shareholder Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and holders of registrable securities are obligated to indemnify us for material misstatements or omissions attributable to them.
- *Registrable securities*. Our securities cease to be registrable securities when a registration statement with respect to the sale of such securities has become effective under the Securities Act and such securities have been disposed of in accordance with such registration statement, such securities have been transferred pursuant to Rule 144 of the Securities Act or such securities have ceased to be outstanding.
- *Lock-up*. Each Sponsor Holder, we and our directors and officers will, if requested, deliver a customary lock-up agreement in connection with any underwritten public offering, subject to certain customary exceptions.

Moreover, under the Registration and Shareholder Rights Agreement, each of Bain Investor and Pfizer agreed to cast all votes to which such entities are entitled such that our board of directors shall consist of 11 directors, divided into three classes (Class I, II and III) with Class I consisting of three directors and Class II and III each consisting of four directors. For as long as Bain Investor holds an amount of our equity securities that is equal to 50% or more of the amount of securities it held at the Closing, it shall be entitled to nominate four directors, with such right (i) decreasing to three directors at such time when Bain Investor holds 35% or more but less than 50% of the amount of securities it held at the Closing; (ii) decreasing to two directors at such time when Bain Investor holds 20% or more but less than 35% of the amount of securities it held at the Closing; (iii) decreasing to one director at such time when Bain Investor holds 5% or more but less than 20% of the amount of securities it held at the Closing; and (iv) terminating at such time when Bain Investor holds less than 5% of the amount of securities it held at the Closing. For as long as Pfizer holds an amount of our equity securities that is equal to 50% or more of the amount of securities it held at the Closing, it shall be entitled to nominate two directors, with such right (i) decreasing to one director at such time when Pfizer holds 20% or more but less than 50% of the amount of securities it held at the Closing; and (ii) terminating at such time when Pfizer holds less than 20% of the amount of securities it held at the Closing. Additionally, for as long as Bain Investor holds an amount of our equity securities that is equal to 60% or more of the amount of securities it held at the Closing, it shall be entitled, with the prior written consent of Pfizer (which consent may not be unreasonably withheld, conditioned or delayed), to nominate two unaffiliated directors to our board of directors. Finally, for as long as Pfizer holds at least 20% of the amount of securities it held at the Closing, Pfizer has the right to designate one non-voting observer to attend each meeting of our board of directors or its committees. As of the date of this prospectus, Dr. Coles was nominated to serve on our board of directors as our chief executive officer; Ms. Baron and Dr. Birnbaum were nominated to serve on our board of directors by Pfizer; Mr. Gordon, Dr. Koppel, Dr. McKernan and Ms. Sulzberger were nominated to serve on our board of directors by Bain Investor; Drs. Dekkers and Riedel were nominated to serve on our board of directors as unaffiliated directors by Bain Investor, with the prior written consent of Pfizer; and Mr. Giordano was nominated to serve on our board of directors as the director mutually agreed by us and the Sponsor pursuant to the Business Combination Agreement.

In addition, under the Registration and Shareholder Rights Agreement, in the event that we propose to issue any capital stock, subject to certain customary exceptions, or New Securities, each Sponsor Holder has the right to purchase, in lieu of the person to whom we proposed to issue such New Securities, its pro rata proportion of such New Securities. Such preemptive rights will terminate on the earlier to occur of the seventh anniversary of the Closing and (i) in the case of Bain Investor, the date on which Bain Investor beneficially owns less than 50% of the amount of securities it held at the Closing, (ii) in the case of Pfizer, the date on which Pfizer beneficially owns less than 50% of the amount of securities it held at the Closing or Bain Investor beneficially owns less than 50% of the amount of securities it held at the Closing and (iii) in the case of Sponsor and Perceptive PIPE Investor, the date on which Sponsor and Perceptive PIPE Investor beneficially own less than 80% of the amount of securities they held at the Closing or Bain Investor beneficially owns less than 50% of the amount of securities it held at the Closing.

Finally, pursuant to the Registration and Shareholder Rights Agreement, to the fullest extent permitted by law, the doctrine of corporate opportunity and any analogous doctrine will not apply to (i) any Sponsor Holder, (ii) any member of our board of directors, non-voting observer or any officer who is not our or any of our subsidiaries' full-time employee or (iii) any affiliate, partner, advisory board member, director, officer, manager, member or shareholder of any Sponsor Holder who is not our or any of our subsidiaries' full-time employee (any such person listed in (i), (ii) or (iii) being referred to herein as an External Party). Therefore, we will renounce any interest or expectancy in, or being offered an opportunity to participate in, business opportunities that are from time to time presented to any External Party.

Funding agreements

In April 2021, Cerevel Inc. entered into the NovaQuest Funding Agreement with NovaQuest and the Bain Funding Agreement with Bain, pursuant to which NovaQuest and Bain will provide funding to Cerevel Inc. to support its development of tavapadon for the treatment of Parkinson's disease.

Bain is an affiliate of Bain Investor, a holder of more than 5% of our outstanding common stock, and is thus considered a related party. The Funding Agreements were reviewed and approved by both a special committee of our board of directors comprised solely of independent and uninterested directors and our audit committee.

Pursuant to the Funding Agreements, Cerevel Inc. will receive up to $62.5 million in funding from each of NovaQuest and Bain, for a combined total of up to $125 million in funding, of which approximately $31.3 million (25% of the Total Funding Commitment) was received within 10 business days of the Effective Date, and $37.5 million (30% of the Total Funding Commitment), approximately $31.3 million (25% of the Total Funding Commitment) and $25.0 million (20% of the Total Funding Commitment) will be received on the first, second and third anniversaries of the Effective Date, respectively, subject to certain customary funding conditions.

In return, Cerevel Inc. agreed to pay to NovaQuest and Bain (i) upon approval of tavapadon by the FDA, a combined $187.5 million (1.5x of the Total Funding Commitment), or the Approval Milestone Payment, with 50% of the Approval Milestone Payment due within 30 days of FDA approval and 12.5% of the Approval Milestone Payment due on each of the first four anniversaries of FDA approval, (ii) upon first reaching certain cumulative U.S. net sales thresholds, certain sales milestone payments and (iii) combined tiered, mid-single digit to low-double digit royalties on annual net sales of tavapadon in the U.S.

At the time that NovaQuest and Bain collectively receive an aggregate of approximately $531.3 million (4.25x of the Total Funding Commitment), Cerevel Inc.'s payment obligations under the Funding Agreements will be fully satisfied. Cerevel Inc. has the option to satisfy its payment obligations to NovaQuest and Bain upon the earlier of FDA approval or May 1, 2025 by paying an amount equal to the Total Funding Commitment multiplied by a certain factor (which will initially be 3.00x and will increase over time to a maximum of 4.25x), less amounts previously paid to NovaQuest and Bain.

During the term of the Funding Agreements, Cerevel Inc. will use commercially reasonable efforts to develop and commercialize tavapadon in the United States, except that, upon the occurrence of certain significant safety, efficacy and regulatory technical failures of the program, or each, a Technical Failure, Cerevel Inc. will have the right to terminate the development of tavapadon and, upon such termination, will not be obligated to make any payments to NovaQuest and Bain. If Cerevel Inc. suspends or terminates the development of tavapadon or fails to perform certain diligence obligations for any reason other than a Technical Failure, Cerevel Inc. will pay NovaQuest and Bain a combined amount equal to the total amount funded by NovaQuest and Bain up to the date of termination, plus 12% interest compounded annually.

Cerevel Inc. has granted NovaQuest and Bain a security interest in the assets material to the development and commercialization of tavapadon in the U.S., provided that Cerevel Inc. will be permitted to incur certain indebtedness and NovaQuest and Bain will agree to customary subordination in connection therewith. The Funding Agreements also include customary representations and warranties and covenants.

Certain relationships and related person transactions—ARYA

Class B ordinary shares

On March 2, 2020, the Sponsor paid $25,000 to cover certain offering costs of ARYA in consideration of 3,593,750 ARYA Class B ordinary shares. On June 4, 2020, ARYA effected a share capitalization resulting in the Sponsor and each of Messrs. Bauer, Robins and Wider, or the Initial Shareholders, holding 3,737,500 of ARYA's Class B ordinary shares.

The Sponsor agreed to forfeit up to 487,500 Class B ordinary shares to the extent that the over-allotment option was not exercised in full by the underwriters in the IPO. The forfeiture would have been adjusted to the extent that the over-allotment option was not exercised in full by the underwriters in the IPO so that the Class B ordinary shares would represent 20.0% of ARYA's issued and outstanding ordinary shares (excluding the private placement shares and assuming the Initial Shareholders did not purchase any units in the IPO) after the IPO. On June 9, 2020, the underwriters in the IPO exercised their over-allotment option; thus, these Class B ordinary shares were no longer subject to forfeiture.

The Initial Shareholders agreed, subject to limited exceptions, not to transfer, assign or sell any of their Class B ordinary shares until the earlier to occur of: (i) one year after the completion of an initial business combination and (ii) subsequent to the initial business combination, (x) if the closing price of ARYA's Class A ordinary shares equals or exceeds $12.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the initial business combination, or (y) the date on which ARYA completes a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of the Public Shareholders having the right to exchange their ordinary shares for cash, securities or other property. This restriction was amended and restated upon the signing of the Registration and Shareholder Rights Agreement.

In connection with the Business Combination, the Class B ordinary shares were converted on a one-for-one basis into shares of our common stock.

Private placement units

Simultaneously with the closing of the IPO, the Sponsor purchased an aggregate of 499,000 ARYA private placement units at a price of $10.00 per private placement unit in a private placement, generating gross proceeds of approximately $5.0 million. Each private placement unit consisted of one ARYA Class A ordinary share and one-third of one private placement warrant, with each whole private placement warrant exercisable for one ARYA Class A common share at a price of $11.50 per share. Pursuant to the Business Combination, the

private placement warrants automatically converted into warrants to purchase our common stock, with each whole private placement warrant exercisable for one share of our common stock at a price of $11.50 per share.

Related party loans

On March 2, 2020, the Sponsor agreed to loan ARYA an aggregate of up to $300,000 to cover expenses related to the IPO pursuant to a promissory note, or the Note. This loan was non-interest bearing and payable on the earlier of December 31, 2020 or the completion of the IPO. The Sponsor paid an aggregate of approximately $250,000 to cover for expenses on ARYA's behalf under the Note. On June 8, 2020, ARYA repaid the Note in full.

Administrative services agreement

Effective June 4, 2020, ARYA entered into an agreement to pay monthly expenses of $10,000 for office space, administrative services and support services to the Sponsor. The agreement was to terminate upon the earlier of the completion of a business combination or the liquidation of ARYA. ARYA incurred approximately $39,000 in general and administrative expenses for the period from February 20, 2020 (inception) through September 30, 2020 pursuant to this agreement. ARYA ceased paying the administrative support fees upon completion of the Business Combination.

ARYA registration and shareholder rights agreement

ARYA previously entered into a registration and shareholder rights agreement pursuant to which the Initial Shareholders and their permitted transferees were entitled to certain registration rights with respect to ARYA's private placement units, private placement warrants, the private placement shares, the securities issuable upon conversion of working capital loans (if any) and ARYA's Class A ordinary shares issuable upon exercise of the foregoing and upon conversion of ARYA's Class B ordinary shares. This agreement was amended and restated upon the signing of the Registration and Shareholder Rights Agreement.

PIPE financing

At the Closing, Perceptive Life Sciences Master Fund Ltd purchased $30,000,000 of our common stock in a private placement. The funds from such private placement were used as part of the consideration to our equityholders in connection with the Business Combination.

Certain relationships and related person transactions—Cerevel

Pfizer license agreement

On August 13, 2018, Cerevel entered into the Pfizer License Agreement with Pfizer, a holder of 5% or more of its capital stock, pursuant to which Cerevel was granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how, to develop, manufacture and commercialize certain compounds and products, which currently constitute the entirety of its asset portfolio, subject to the terms and conditions of the Pfizer License Agreement. See the section entitled "*Business—Pfizer License Agreement*" in this prospectus for additional details on the Pfizer License Agreement.

As partial consideration for the licensed assets, Cerevel issued to Pfizer 3,833,333.33 shares of its Series A-2 Preferred Stock with an estimated fair value of $100.4 million, or $26.20 per share. See the section entitled "*—Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series A Common Stock Financing*" below. Cerevel also reimbursed $11.0 million of direct expenses related to the Pfizer License Agreement, bringing the total initial consideration to $111.4 million.

Series A-1 preferred stock, series A-2 preferred stock and series a common stock financing

On August 13, 2018, in connection with the Pfizer License Agreement, Cerevel entered into the Stock Purchase Agreement pursuant to which Cerevel sold (i) Bain Investor an aggregate of (x) 6,900,000 shares of Series A-1 Preferred Stock at a purchase price of $10.00 per share and (y) 4,600,000 shares of Series A Common Stock at a purchase price of $10.00 per share, and (ii) Pfizer 3,833,333.33 shares of Series A-2 Preferred Stock in consideration for the transactions contemplated by the Pfizer License Agreement (see the section entitled "*—Pfizer License Agreement*" above). In July 2019, Cerevel issued and sold an aggregate of 3,450 shares of its Series A-1 Preferred Stock and 2,300 shares of its Series A Common Stock to Bain Investor at a purchase price of $10.00 per share, for aggregate consideration of $57,500. In December 2019, Cerevel issued and sold an aggregate of 4,204,075 shares of Series A-1 Preferred Stock and 1,795,925 shares of Series A Common Stock to Bain Investor at a purchase price of $10.00 per share, for aggregate consideration of $60.0 million. In July 2020, Cerevel issued and sold an aggregate of 1,750,000 shares of Series A-1 Preferred Stock and 750,000 shares of Series A Common Stock to Bain Investor at a purchase price of $10.00 per share, for aggregate consideration of $25.0 million.

Upon the closing of the Business Combination, Pfizer's 3,833,333.33 shares of Series A-2 Preferred Stock were converted into 26,149,211 shares of our common stock after giving effect to the anti-dilution protections and the Exchange Ratio established by the Business Combination and Bain Investors' Series A-1 Preferred Stock and Series A-1 Common Stock were converted into 52,461,943 shares of our common stock after giving effect to the exchange feature that was redeemed related to the July Additional Financing Shares and the Exchange Ratio established in the Business Combination.

Stock purchase agreement

The Stock Purchase Agreement that Cerevel entered into in connection with its initial financing provided, among other things, that:

- if Cerevel has not received $350.0 million in aggregate gross cash proceeds in exchange for equity interests, which such amount includes the proceeds received in the initial financing, subsequent financings and from this transaction and is referred to as the Financing Threshold, by September 24, 2022, Bain Investor shall be required to purchase that amount of shares of its common stock such that the Financing Threshold is met;
- at any time prior to the Financing Threshold having been met, its cash balance is equal to or less than $10.0 million, Bain Investor shall be required to purchase an amount of additional shares of its Series A-1 Preferred Stock and Series A Common Stock that allows Cerevel to maintain a reasonable level of cash to fund its operations in accordance with the previously agreed development plan for at least six months; and
- until the time the Financing Threshold is met, Bain Investor has the right to purchase up to that amount of shares of Series A-1 Preferred Stock and Series A Common Stock at a purchase price of $10.00 per share that results in the Financing Threshold having been met.

Pursuant to the Business Combination Agreement, Cerevel, Bain Investor and Pfizer terminated the Stock Purchase Agreement at the Closing.

Stockholders' agreement

In connection with its initial financing, Cerevel entered into a stockholders' agreement with Bain Investor and Pfizer, or the Stockholders' Agreement. The Stockholders' Agreement, among other things, provided for the appointment of Cerevel directors by Bain Investor and Pfizer and certain waivers of the doctrine of corporate opportunity. Pursuant to the Business Combination Agreement, Cerevel, Bain Investor and Pfizer terminated the Stockholders' Agreement at the Closing.

Registration rights agreement

In connection with its initial financing, Cerevel entered into a registration rights agreement with Bain Investor and Pfizer, or the Registration Rights Agreement. The Registration Rights Agreement provided certain registration rights to Bain Investor and Pfizer. Pursuant to the Business Combination Agreement, Cerevel, Bain Investor and Pfizer terminated the Registration Rights Agreement at the Closing.

Management agreement

In connection with its initial financing, Cerevel entered into a management agreement, or the Management Agreement, with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP, which are entities related to Bain Investor. The Management Agreement, among other things:

- obligated Cerevel to pay such entities a non-refundable quarterly fee of $250,000; and
- obligated Cerevel to pay such entities, in the aggregate, a $5.0 million fee upon the completion of a qualified public offering or change of control transaction, less any quarterly fees previously paid to such entities.

Cerevel paid the remaining approximately $3.0 million of management fees payable under the Management Agreement upon the closing of the Business Combination. No additional fees were payable pursuant to the Management Agreement following the closing of the Business Combination. Following the closing of the Business Combination, Cerevel entered into a new management agreement with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP providing for the expense reimbursement and indemnification of such entities.

Consulting agreement

Prior to his joining Cerevel as its Chief Human Resources Officer, Cerevel was party to a consulting agreement with Kenneth DiPietro pursuant to which Cerevel paid Mr. DiPietro approximately $250,000 in fees for services and expense reimbursement and granted him 5,000 options to purchase its common stock in consideration for human resources planning services. Such consulting agreement terminated automatically once Mr. DiPietro joined Cerevel as an employee in April 2019.

Policies and procedures for related person transactions

Our written related person transaction policy sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

A “Related Person Transaction” is a transaction, arrangement or relationship in which we or any of our subsidiaries was, is or will be a participant, the amount of which involved exceeds $120,000, and in which any related person had, has or will have a direct or indirect material interest. A “Related Person” means:

- any person who is, or at any time during the applicable period was, one of our officers or one of our directors;
- any person who is known by us to be the beneficial owner of more than 5% of our voting stock;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than 5% of its voting stock, and any person (other than a tenant or employee) sharing the household of such director, officer or beneficial owner of more than 5% of its voting stock; and

- any firm, corporation or other entity in which any of the foregoing persons is a partner or principal or in a similar position or in which such person has a 10% or greater beneficial ownership interest.

We have policies and procedures designed to minimize potential conflicts of interest arising from any dealings we may have with our affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time. Specifically, pursuant to its charter, our audit committee has the responsibility to review related person transactions.

Executive officers and directors

The following sets forth certain information, as of the date of this prospectus, concerning our executive officers and directors.

Name	Age	Position
N. Anthony Coles, M.D.	61	Chairperson, Chief Executive Officer and Class I Director
Scott Akamine, J.D.	37	Chief Legal Officer
Mark Bodenrader	48	Chief Accounting Officer
Abraham Ceesay, M.B.A.	43	President
Kenneth DiPietro	62	Chief Human Resources Officer
John Renger, Ph.D.	52	Chief Scientific Officer
Raymond Sanchez, M.D.	60	Chief Medical Officer
Kathleen Tregoning, M.A.	50	Chief Corporate Affairs Officer
Kathy Yi, M.B.A.	50	Chief Financial Officer
Deborah Baron, M.B.A.	52	Class II Director
Morris Birnbaum, M.D., Ph.D.	69	Class I Director
Marijn Dekkers, Ph.D.	63	Class III Director
Doug Giordano, M.B.A.	58	Class II Director
Christopher Gordon, M.B.A.	48	Class I Director
Adam Koppel, M.D., Ph.D.	51	Class II Director
Ruth McKernan, Ph.D., CBE, FMedSci	63	Class II Director
Deval Patrick, J.D.	64	Class III Director
Norbert Riedel, Ph.D.	63	Class III Director
Gabrielle Sulzberger, J.D., M.B.A.	61	Class III Director

Executive officers

N. Anthony Coles, M.D. has served as our Chief Executive Officer since September 2019 and has served as the Chairperson of our board of directors since December 2018. From October 2014 to September 2019, Dr. Coles co-founded and served as the chairperson and chief executive officer of Yumanity Therapeutics, Inc., where he continues to serve as executive chair. Yumanity Therapeutics is a clinical-stage biopharmaceutical company targeting neurodegenerative diseases caused by protein misfolding. From October 2013 to October 2014, Dr. Coles served as the chairperson and chief executive officer of TRATE Enterprises, LLC, a privately-held company. Previously, Dr. Coles served as president, chief executive officer and chairperson of the board of Onyx Pharmaceuticals, Inc., from 2012 until its sale to Amgen in 2013, having served as its president, chief executive officer and a member of its board of directors from 2008 until 2012. Prior to joining Onyx Pharmaceuticals, Inc., Dr. Coles was president, chief executive officer and a member of the board of directors of NPS Pharmaceuticals,

Inc. Before joining NPS Pharmaceuticals, Inc. in 2005, Dr. Coles was senior vice president of commercial operations at Vertex Pharmaceuticals Incorporated, and earlier, held several executive positions at Bristol-Myers Squibb Company and positions of increasing responsibility at Merck & Co., Inc. In addition to having previously served as a director of Onyx and NPS, Dr. Coles was formerly a director of CRISPR Therapeutics AG, Laboratory Corporation of America Holdings and Campus Crest Communities, Inc. Dr. Coles currently serves on the board of directors of Regeneron Pharmaceuticals, Inc. Dr. Coles also currently serves on the board of directors of McKesson Corporation but will not stand for re-election at its next annual shareholders meeting in July 2021. Dr. Coles earned a B.A. at Johns Hopkins University, a medical degree from Duke University, and a master's degree in public health from Harvard University. He completed his cardiology and internal medicine training at Massachusetts General Hospital and was a research fellow at Harvard Medical School. We believe Dr. Coles is qualified to serve on our board of directors because of his extensive executive experience in our industry and his service as our Chief Executive Officer.

Scott Akamine, J.D., has served as our Chief Legal Officer since May 2021. Previously, he served as general counsel and corporate secretary of AEON Biopharma, Inc., a privately-held biopharmaceutical company, overseeing legal and certain administrative functions, including business development, corporate governance, intellectual property and compliance. Prior to AEON, Scott was the associate general counsel and interim general counsel at CoreLogic, Inc. and general counsel and corporate secretary at Incipio, LLC. He also held legal roles of escalating responsibility at Allergan, Inc. until the company was acquired by Actavis plc. Mr. Akamine began his legal career as a corporate attorney at Latham & Watkins. Mr. Akamine earned his B.A. from Chapman University and his J.D. from Pepperdine University School of Law.

Mark Bodenrader has served as our Vice President of Finance and Chief Accounting Officer since September 2019. Previously, from February 2007 to September 2019, Mr. Bodenrader held various roles of increasing responsibility at Biogen Inc., a publicly traded biotechnology company, most recently as corporate controller. Previously, he was head of internal audit at Heritage Property Investment Trust. From 2003 to 2004, Mr. Bodenrader served as manager, assurance and business advisory services at Grant Thornton LLP, after serving as assistant controller at Cabot Industrial Trust from 1998 to 2002. Mr. Bodenrader began his career in public accounting at Arthur Andersen, LLP. Mr. Bodenrader earned a B.S. in Finance and Accounting from Merrimack College, and is a Certified Public Accountant.

Abraham Ceesay, M.B.A. has served as our President since May 2021. From January 2019 until April 2021, Mr. Ceesay served as the chief executive officer at Tiburio Therapeutics, Inc., a biopharmaceutical company focused on the development of novel therapies for rare neuroendocrine tumors and endocrine diseases. Prior to joining Tiburio, from May 2016 to October 2018, Mr. Ceesay served as chief operating officer at scPharmaceuticals Inc., a publicly traded pharmaceutical company. Before joining scPharmaceuticals, from February 2014 to March 2016, Mr. Ceesay served as vice president, sales & marketing operations at Keryx Biopharmaceuticals, Inc., now Akebia Therapeutics, Inc., a publicly traded biopharmaceutical company focused on renal disease. Prior to Keryx, from July 2010 to February 2014, Mr. Ceesay served at Ironwood Pharmaceuticals, Inc., a publicly traded pharmaceutical company, most recently as vice president, marketing. From May 2002 to July 2010, he held positions of increasing responsibility at Sanofi Genzyme, the specialty care global business unit of Sanofi, a publicly traded multinational pharmaceutical company, most recently as director, cardiometabolic & renal global marketing. Mr. Ceesay currently serves as a member of the boards of directors of Food for Free, Life Science Cares and Camp Harbor View, each a non-profit organization. Mr. Ceesay holds a B.S. from Ithaca College and an M.B.A. from Suffolk University's Sawyer School of Management.

Kenneth DiPietro has served as our Chief Human Resources Officer since April 2019. Previously, Mr. DiPietro worked as the chief talent officer for Oak Hill Capital Partners from February 2018 to October 2018 and was also a senior advisor to several Polaris Ventures portfolio companies beginning in August 2017. Previously, he was a

director at InVivo Therapeutics Holdings Corp. after serving as executive vice president of human resources at Biogen Inc. from February 2012 to September 2017. Earlier in his career, Mr. DiPietro held senior human resources roles with Lenovo Group Limited, Microsoft Corporation, and Dell Technologies. Mr. DiPietro also served in a range of human resource and general management positions over 19 years at PepsiCo. Mr. DiPietro earned a B.S. in Industrial and Labor Relations from Cornell University. He sits on the Dean's Advisory Board at Cornell, the Peer Roundtable, the Boston Posse Advisory Board and advises a small number of technology startups focused on human resource management.

John Renger, Ph.D. has served as our Chief Scientific Officer since May 2019. Previously, Dr. Renger served as vice president of research and development and regulatory affairs at Imbrium Therapeutics L.P. from April 2018 to April 2019 and as head of clinical research and translational medicine at Purdue Pharma L.P. from August 2016 to April 2018. Previously, Dr. Renger held roles of increasing responsibility at Merck & Co. between October 2001 and August 2016, most recently serving as associate vice president. Dr. Renger was a postdoctoral fellow at the Massachusetts Institute of Technology Center for Learning and Memory and previously worked at the RIKEN Brain Science Institute in Japan. Dr. Renger earned his Ph.D. in biological sciences with a focus on neurogenetics at the University of Iowa where he also completed his B.S. in biology.

Raymond Sanchez, M.D., has served as our Chief Medical Officer since January 2019. Previously, from November 2007 to January 2019, Dr. Sanchez held various roles of increasing responsibility at Otsuka Pharmaceutical Development and Commercialization, Inc., most recently as senior vice president, global clinical development. From June 2018 to January 2019, Dr. Sanchez served as the chief medical officer of Avanir Pharmaceuticals. Dr. Sanchez is currently the executive co-chair of the International Society for CNS Drug Development and trustee, member of the board of directors for the Connecticut Mental Health Center Foundation, Yale School of Medicine, as well as several other not-for-profit organizations. Dr. Sanchez received a bachelor's degree from the Weinberg College of Arts and Sciences at Northwestern University and a medical degree from the Feinberg School of Medicine at Northwestern. He completed his residency training and fellowship in psychiatry at the Yale University Medical School, where he was also appointed as an instructor.

Kathleen Tregoning, M.A. has served as our Chief Corporate Affairs Officer since July 2020. Previously, from February 2017 to March 2020, Ms. Tregoning served as executive vice president for External Affairs at Sanofi S.A., a French multinational pharmaceutical company, where she was responsible for leading an integrated organization that brought together market access, communications, public policy, government affairs, patient advocacy and corporate social responsibility. Prior to joining Sanofi, Ms. Tregoning spent more than a decade at Biogen Inc., a multinational biotechnology company, first as vice president, Public Policy & Government Affairs, from 2006 to 2015, and then as senior vice president, Corporate Affairs, from December 2015 to February 2017. Previously, Ms. Tregoning served as a professional staff member in the United States Congress, where she held health policy roles with the Senate Budget Committee, the House Energy & Commerce Committee, and the House Ways & Means Committee. Ms. Tregoning began her career with Andersen Consulting, where she developed business strategies and processes for clients in a range of industries, and later served as an Assistant Deputy Mayor for Policy & Budget in the office of the Mayor of Los Angeles. Ms. Tregoning graduated from Stanford University with a B.A. in International Relations and holds an M.A. in Public Policy from the Kennedy School of Government at Harvard University.

Kathy Yi, M.B.A. has served as our Chief Financial Officer since June 2019. Ms. Yi has over 18 years of experience in corporate finance, including financial analysis in support of M&A transactions, licensing and other business development activities. Previously, Ms. Yi served as executive vice president, chief financial officer and secretary of Sangamo Therapeutics, Inc., from February 2017 to June 2019. Prior to Sangamo Therapeutics, Ms. Yi was head of finance at Novartis Pharmaceutical Corporation from February 2014 to February 2017. From 2007 to 2014, Ms. Yi held various financial management positions of increasing seniority at Life Technologies

Corp., a biotech company that was acquired by Thermo Fisher Scientific in 2014, including finance leader, corporate FP&A from 2012 to 2014, director of finance, M&A/corporate development from 2010 to 2012 and director of finance, global manufacturing operations from 2007 to 2010. From 2001 to 2007, Ms. Yi held increasing roles of responsibilities in corporate finance at Intel Corporation. Ms. Yi earned her B.S. in Chemical Engineering from the University of California at Berkeley and an M.B.A. from Columbia Business School.

Directors

Deborah Baron, M.B.A. has served as a member of our board of directors since January 2021. Ms. Baron is currently a senior vice president in Pfizer Inc.'s Worldwide Business Development Group, which she joined in 2002. In this role, Ms. Baron leads all Pfizer business development activities, covering a wide range of transaction types including venture investments, research/development/commercial collaborations, license agreements, mergers and acquisitions and divestitures. Prior to this role, Ms. Baron held positions of increasing responsibility at Pfizer, including leading business development activities in Pfizer's Primary Care and Emerging Markets businesses. Before joining Pfizer in 2002, Ms. Baron was an associate principal at McKinsey & Co, a management consulting firm, and was previously a manufacturing engineer at The Stanley Works, now Stanley Black & Decker, Inc., a manufacturer of industrial tools and household hardware and provider of security products. Ms. Baron received her B.S. in Mechanical Engineering from the Massachusetts Institute of Technology and an M.B.A. from the Sloan School of Management at the Massachusetts Institute of Technology. We believe Ms. Baron is qualified to serve on our board of directors because of her extensive executive experience in our industry.

Morris Birnbaum, M.D., Ph.D. has served as a member of our board of directors since September 2018. Since 2017, Dr. Birnbaum has served as the senior vice president and chief scientific officer of internal medicine at Pfizer Inc., where he previously served as senior vice president and chief scientific officer of CVMET from 2014 to 2017. Previously, Dr. Birnbaum served as a professor of medicine at the University of Pennsylvania from December 1994 to June 2014. Dr. Birnbaum was elected to membership in the American Society for Clinical Investigation and Association of American Physicians and is a fellow of the American Association for the Advancement of Science. Dr. Birnbaum completed his undergraduate, graduate and medical training at Brown University. He carried out clinical training in internal medicine at Barnes Hospital of Washington University School of Medicine and then performed postdoctoral studies at the University of California, San Francisco and Sloan-Kettering Cancer Institute. We believe Dr. Birnbaum is qualified to serve on our board of directors because of his scientific and industry experience in our field.

Marijn Dekkers, Ph.D. has served as a member of our board of directors since September 2018. Since May 2017, Dr. Dekkers has served as a founder and the chairman of Novalis LifeSciences LLC, an investment and advisory firm for the life science industry. From October 2010 to April 2016, Dr. Dekkers served as chief executive officer of Bayer AG in Leverkusen, Germany, and from 2002 to 2009, he was chief executive officer of Thermo Fisher Scientific. Dr. Dekkers currently serves on the board of directors of the Foundation for the National Institutes of Health, Georgetown University, Quanterix Corporation and Ginkgo Bioworks and previously served on the board of directors of Unilever, General Electric and Biogen. Dr. Dekkers received his Ph.D. and M.S. in chemical engineering from the University of Eindhoven and his bachelor's degree in chemistry from the Radboud University, both in the Netherlands. We believe Dr. Dekkers is qualified to serve on our board of directors because of his extensive executive experience in our industry.

Doug Giordano, M.B.A. has served as a member of our board of directors since September 2018. Mr. Giordano currently serves as a managing director at Perceptive Advisers and formerly served as a senior vice president in Pfizer Inc.'s Worldwide Business Development Group, which he joined in 2007. Previously, Mr. Giordano held positions of increasing responsibility within Pfizer's U.S. Pharmaceuticals commercial strategy and business

development team. Before his U.S. pharmaceuticals operating role, Mr. Giordano worked in a mergers and acquisitions role within Pfizer's Medical Technology Group. Prior to his role with the Medical Technology Group, Mr. Giordano held positions within Pfizer's U.S. Pharmaceutical Group in finance and global manufacturing. Prior to joining Pfizer, Mr. Giordano was a consultant at Booz, Allen & Hamilton. From April 2017 to March 2019, Mr. Giordano served on the board of directors of ICU Medical, Inc. He also previously served on the board of directors of ViiV Healthcare Limited from 2012 to 2019. Mr. Giordano earned a bachelor's degree in biomedical engineering from Duke University and an M.B.A. from Cornell University's Johnson School of Business. We believe Mr. Giordano is qualified to serve on our board of directors because of his industry experience in our field.

Christopher Gordon, M.B.A. has served as a member of our board of directors since September 2018. Mr. Gordon is a managing director at Bain Capital. He joined the firm in 1997 and has significant experience in private equity investing, with a specialized focus in the healthcare sector. He currently co-leads Bain Capital's North American Private Equity business and leads Bain Capital's North American healthcare team. Mr. Gordon is also a member of the investment committee for Bain Capital Life Sciences. Prior to joining Bain Capital, he was a consultant at Bain & Company. Mr. Gordon has been actively involved in and served on the Board of Directors of a wide spectrum of prominent healthcare companies in which Bain Capital has made investments. These include HCA Inc., Quintiles Transnational Corporation, Grupo Notre Dame Intermedica, Air Medical Group Holdings Inc., Acadia Healthcare Company Inc., Beacon Health Options, Physio Control Inc., QuVa Pharmaceuticals, Waystar Inc., Aveanna Healthcare Holdings, Inc. and Surgery Partners, Inc.. He is also a founding director of the Healthcare Private Equity Association. Mr. Gordon volunteers his time and support to a variety of charitable organizations and currently serves on the board of directors of Tenacity, Boston Medical Center Health Plan and Dana Farber Cancer Institute Board of Trustees. Mr. Gordon received a bachelor's degree in economics from Harvard College, graduating magna cum laude, and an M.B.A. from Harvard Business School, where he was a Baker Scholar. We believe Mr. Gordon is qualified to serve on our board of directors because of his experience as a director and public equity and growth private equity investor in pharmaceutical companies.

Adam Koppel, M.D., Ph.D. has served as a member of our board of directors since September 2018. Dr. Koppel is managing director of Bain Capital Life Sciences. He initially joined Bain Capital Public Equity in 2003, where he was a leader within the healthcare sector until 2014. From 2014 to 2016, Dr. Koppel was executive vice president of corporate development and chief strategy officer at Biogen, Inc. Prior to joining Bain Capital Public Equity in 2003, Dr. Koppel was an associate principal at McKinsey & Co in New Jersey where he served a variety of healthcare companies. Dr. Koppel sits on the board of directors of BCLS Acquisition Corp., Solid Biosciences, Inc., Dicerna Pharmaceuticals, Inc., Aptinyx Inc. and Foghorn Therapeutics, Inc. Dr. Koppel previously served on the board of directors of Trevena, Inc., PTC Therapeutics, Inc. and Viacyte, Inc. Dr. Koppel graduated magna cum laude from Harvard University with a bachelor's and master's degrees in history and science. He received an M.D. and Ph.D. in neuroscience from the University of Pennsylvania School of Medicine and an M.B.A. from The Wharton School at the University of Pennsylvania, where he was a Palmer Scholar. We believe Dr. Koppel is qualified to serve on our board of directors because of his background as an executive officer, director and public equity and growth private equity investor in pharmaceutical companies, as well as his scientific and medical background.

Ruth McKernan, Ph.D., CBE, FMedSci has served as a member of our board of directors since December 2020. Dr. McKernan has served as a venture partner at SV Health Investors, LLP, a global investment firm focused on the healthcare industry, since 2018. Previously, from 2015 to 2018, Dr. McKernan served as chief executive officer of Innovate UK, a non-departmental public body funded by a grant-in-aid from the UK government. From 2005 to 2015, Dr. McKernan held various roles of increasing responsibility at Pfizer Inc., a global

pharmaceutical company, most recently as chief scientific officer. Prior to joining Pfizer, she served in multiple senior positions over 18 years at Merck & Co., a publicly traded pharmaceutical company.

Dr. McKernan currently serves as chair of the board of directors of AstronauTx Ltd. and BioIndustry Association, a trade association for innovative life sciences in the UK, and as a trustee of Alzheimer's Research UK, and is a member of Cancer Research UK. Dr. McKernan earned her B.S. in Pharmacology and Biochemistry from King's College London, where she also obtained her Ph.D. in Neuroscience from the Institute of Psychiatry, Psychology and Neuroscience. Dr. McKernan was conferred with Honorary D.Sc. degrees from the University of Bradford and the University of Coventry. We believe Dr. McKernan is qualified to serve on our board of directors because of her scientific and industry experience in our field.

Deval Patrick, J.D. has served as a member of our board of directors since January 2021. Mr. Patrick is currently senior advisor to Bain Capital and co-chair of American Bridge 21st Century, a political action committee that supports progressive politics and grassroots groups. From April 2015 to December 2019, Mr. Patrick served as a managing director of Bain Capital, where he founded and led a growth equity fund focused on delivering competitive financial returns and positive social impact. Previously, from January 2007 to January 2015, Mr. Patrick served as governor of Massachusetts. Prior to his tenure in government, Mr. Patrick served as the executive vice president and general counsel at The Coca-Cola Company; as vice president and general counsel at Texaco Inc.; and as a partner in two Boston law firms. From 1994 to 1997, Mr. Patrick served as the Assistant Attorney General of the United States for Civil Rights in the Department of Justice. Since 2015, Mr. Patrick has served on the boards of directors of Global Blood Therapeutics, Inc., where he is a member of its audit and nominating and corporate governance committees, and of American Well Corporation, where he is a member of its audit committee. Mr. Patrick also currently serves on the boards of directors of Twilio Inc., where he is a member of its compensation committee, and a number of private companies. Mr. Patrick is a Rockefeller Fellow, a Crown Fellow of the Aspen Institute, and the author of two books. Mr. Patrick received a B.A. from Harvard College and a J.D. from Harvard Law School. We believe Mr. Patrick is qualified to serve on our board.

Norbert G. Riedel, Ph.D., has served as a member of our board of directors since December 2018. Since September 2015, Dr. Riedel has served as the chief executive officer of Aptinyx Inc., a biopharmaceutical company, where he also serves as a member of the board of directors and previously served as president from September 2015 to December 2020. Dr. Riedel previously served as chief executive officer and president of Naurex Inc., the predecessor to Aptinyx Inc., from January 2014 to August 2015. From 2001 to January 2013, he served as corporate vice president and chief scientific officer of Baxter International Inc., a diversified healthcare company, where from 1998 to 2001, he also served as president and general manager of the recombinant therapeutic proteins business unit and vice president of research and development of the bioscience business unit. From 1996 to 1998, Dr. Riedel served as head of worldwide biotechnology and worldwide core research functions at Hoechst-Marion Roussel, now Sanofi, a global pharmaceutical company. Dr. Riedel served on the board of directors of Ariad Pharmaceuticals, Inc., an oncology company, from May 2011 until the company was acquired in February 2017. Dr. Riedel also serves on the board of directors of Jazz Pharmaceuticals plc, Eton Pharmaceuticals, Inc. and the Illinois Biotechnology Innovation Organization and is also a member of the Austrian Academy of Sciences. Dr. Riedel is an Adjunct Professor at Boston University School of Medicine and an Adjunct Professor of Medicine at Northwestern University's Feinberg School of Medicine. Dr. Riedel previously served as an associate professor of medicine at Boston University School of Medicine and a visiting associate professor at the Massachusetts Institute of Technology. Dr. Riedel holds a diploma in biochemistry and a Ph.D. in biochemistry from the University of Frankfurt. We believe Dr. Riedel is qualified to serve on our board of directors because of his significant scientific, drug discovery and development and commercial expertise with over 20 years of experience in the biotechnology and pharmaceutical industries.

Gabrielle Sulzberger, J.D., M.B.A. has served as a member of our board of directors since June 2019. Ms. Sulzberger currently serves as a strategic advisor to Two Sigma Impact and previously served as a partner at Fontis Partners, a private equity fund. Ms. Sulzberger also currently serves as the chairperson of the board of True Food Kitchen, as a member of the board of directors of Eli Lilly and Company, Mastercard, Acorns Financial and Brixmor Property Group and as a board trustee of the Ford Foundation. Previously, Ms. Sulzberger served as the chairperson of the board of directors of Whole Foods Market and as a member of the board of directors of Teva Pharmaceuticals and Stage Stores. Ms. Sulzberger earned a bachelor's degree from Princeton University, a J.D. from Harvard Law School and an M.B.A. from Harvard Business School. We believe Ms. Sulzberger is qualified to serve on our board of directors because of her experience as a private equity investor as well as her experience as a director of a range of businesses and industries.

Director independence

The Nasdaq listing rules require that a majority of our board of directors be independent. An "independent director" is defined generally as a person other than an executive officer or employee of us or any other individual having a relationship which, in the opinion of our board of directors, would interfere with the exercise of independent judgement in carrying out the responsibilities of a director. Our board of directors has determined that each individual who serves on our board of directors, other than Dr. Coles, qualifies as an independent director under Nasdaq listing standards.

Committees of the board of directors

Our board of directors has four standing committees: an audit committee, a compensation committee, a nominating and corporate governance committee and a science and technology committee. Copies of each committee's charter are posted on our website at www.cerevel.com under the "Investors & Media" section. The information contained on or that can be accessed through our website is not incorporated by reference into this prospectus, and you should not consider such information to be part of this prospectus.

Audit committee

The members of our audit committee are Ms. Sulzberger, Mr. Giordano and Dr. Riedel, and Ms. Sulzberger serves as the chairperson of our audit committee. Under the Nasdaq listing rules and applicable SEC rules, we are required to have at least three members of the audit committee. The Nasdaq listing rules and Rule 10A-3 under the Exchange Act require that the audit committee of a listed company be composed solely of independent directors for audit committee purposes, and each member of our audit committee qualifies as an independent director for audit committee purposes under applicable rules. Each of Ms. Sulzberger, Mr. Giordano and Dr. Riedel is financially literate and each of Ms. Sulzberger, Mr. Giordano and Dr. Riedel qualifies as an "audit committee financial expert" as defined in applicable SEC rules.

Compensation committee

The members of our compensation committee are Dr. Dekkers, Dr. Koppel and Mr. Patrick, all of whom are independent directors, and Dr. Dekkers serves as the chairperson of the compensation committee.

Nominating and corporate governance committee

The members of our nominating and corporate governance committee are Mr. Gordon, Ms. Baron, Ms. Sulzberger and Mr. Giordano, all of whom are independent directors, and Mr. Gordon serves as the chairperson of the nominating and corporate governance committee.

Science and technology committee

The members of our science and technology committee are Dr. Riedel, Dr. Birnbaum, Dr. Koppel and Ms. McKernan, and Dr. Riedel serves as the chairperson of the science and technology committee.

Role of our board of directors in risk oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also has the responsibility to review with management the process by which risk assessment and management is undertaken, monitor compliance with legal and regulatory requirements, and review the adequacy and effectiveness of our internal controls over financial reporting. Our nominating and corporate governance committee is responsible for periodically evaluating our company's corporate governance policies and systems in light of the governance risks that our company faces and the adequacy of our company's policies and procedures designed to address such risks. Our compensation committee assesses and monitors whether any of our compensation policies and programs is reasonably likely to have a material adverse effect on our company.

Code of business conduct and ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our code of business conduct and ethics is available on our website at www.cerevel.com under the "Investors & Media" section.

We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of certain provisions as they relate to our directors and executive officers, at the same location on our website or in public filings. The information on our website is not intended to form a part of or be incorporated by reference into this prospectus.

Executive and director compensation

Executive compensation overview

Our approach to executive compensation directly supports the talent strategy we have employed to develop and grow a new organization that has experienced and will continue to experience significant growth in a short time period. With a pipeline of 11 small molecule programs, which includes five clinical-stage product candidates, six clinical trials underway or expected to start by the end of 2021 and up to seven clinical data readouts expected by the end of 2023, we believe our portfolio of product candidates is larger and more complex than that of most other development-stage biopharmaceutical companies, necessitating an elevated talent strategy and an executive compensation philosophy that will support our aspirations to maximize these opportunities for our stakeholders.

We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with the proven expertise of large pharmaceutical company drug discovery and development. Our people will be what differentiates us from our competitors through building deep and innovative capabilities and expertise. Constructing a leadership team to provide structure and direction will require retaining talent with proven leadership and results, extensive technical expertise, aggressive organizational expansion experience and the vision to take us to new heights. Attracting, recruiting and hiring talent who have the requisite skill set, background and track record to lead and manage a portfolio of our scale with the dexterity to operate in a start-up environment is a challenge.

Our named executive officers are identified in the 2020 Summary Compensation Table below. Their compensation primarily consists of (i) base salary, (ii) annual performance-based cash bonus plan awards and (iii) equity incentive awards. Our named executive officers are also eligible to participate in the same retirement and health and welfare benefit plans as our other full-time employees.

Our compensation committee will continue to annually review and assess our compensation programs to ensure they align with our compensation philosophy and guiding principles. Our compensation committee will continue to engage a seasoned compensation consultant to provide tailored market guidance and best practices.

Our named executive officers for 2020 are:

- N. Anthony Coles, M.D., our Chairperson and Chief Executive Officer;
- John Renger, Ph.D., our Chief Scientific Officer;
- Kathleen Tregoning, M.A., our Chief Corporate Affairs Officer; and
- Bryan Phillips, J.D., our former Chief Legal Officer

Our compensation philosophy is in part focused on assembling an experienced research and development team with a differentiated understanding of the complex neurocircuitry, receptor pharmacology and genetics that underlie neuroscience diseases to develop small molecules with target receptor selectivity and indication-appropriate pharmacology, which we believe are key to enhancing activity and improving tolerability in the treatment of these diseases. In 2020, Ms. Tregoning and Mr. Phillips joined us and received new hire equity grants that were intended to entice them to join Cerevel and/or leave respective prior employers and cover any pay forfeitures they experienced. These new hire equity grants caused their compensation, as calculated in accordance with SEC rules, to exceed the typical levels expected for their respective roles. For those reasons, Ms. Tregoning and Mr. Phillips are named executive officers for 2020. Other of our executive offers received their new hire equity grants in prior years and therefore, in accordance with SEC rules, these new hire equity grants were not factored into the determination of our 2020 named executive officers.

2020 summary compensation table

The following table presents information regarding the total compensation awarded to, earned by and paid to our named executive officers for services rendered to us in all capacities during the fiscal years ended December 31, 2020 and December 31, 2019.

Name and principal position	Year	Salary ($)	Bonus ($)(2)	Option awards ($)(3)	Non-equity incentive compensation ($)(4)	All other compensation ($)	Total ($)
N. Anthony Coles M.D.	2020	600,000	—	1,499,999	444,000	198,000(5)	2,741,999
Chairperson and Chief Executive Officer(1)	2019	398,630	—	9,817,097	229,212	291,000(6)	10,735,939
John Renger, Ph.D.	2020	450,000	—	900,000	266,400	228,675(7)	1,845,075
Chief Scientific Officer	2019	330,411	130,000	1,489,792	151,989	26,716(8)	2,128,908
Kathleen Tregoning, M.A.							
Chief Corporate Affairs Officer	2020	193,205	100,000	3,322,419	114,378(9)	—	3,730,002
Bryan Phillips, J.D.							
Former Chief Legal Officer(10)	2020	410,000	—	2,543,628	242,720	239,600(11)	3,435,948

(1) In addition to serving as our Chief Executive Officer, Dr. Coles serves as our Chairperson but receives no additional compensation for his service in this role.

(2) The amounts reflect signing bonuses paid to the applicable named executive officer at his or her time of hire. All other cash bonuses, which were based upon the achievement of performance goals under our annual performance-based cash bonus plan, are disclosed under the "*Non-Equity Incentive Compensation*" column.

(3) The amounts reflect the aggregate grant date fair value of stock option awards granted in 2020 and 2019, as computed in accordance with ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in *Note 12, Equity-Based Compensation*, to our audited consolidated financial statements included in this prospectus. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the named executive officers upon the exercise of the stock options or any sale of the underlying shares of common stock.

(4) The amounts reported reflect the annual performance-based cash bonus plan amounts awarded to our named executive officers for their service. See "*—Annual Performance-Based Cash Bonus*" below.

(5) The amount reported for Dr. Coles represents $198,000 for Dr. Coles' housing allowances.

(6) The amount reported for Dr. Coles represents $216,000 for Dr. Coles' housing allowances and $75,000 for legal fees he incurred in connection with the negotiation of his compensatory agreements.

(7) The amount reported for Dr. Renger represents $150,000 for Dr. Renger's relocation reimbursement, $17,100 for matching contributions under our 401(k) plan and $61,575 for tax-gross ups for relocation reimbursements.

(8) The amount reported for Dr. Renger represents $12,000 for living expense reimbursement, $7,875 for matching contributions made by us under our 401(k) plan, $4,590 for legal fees he incurred in connection with the negotiation of his compensatory agreements and $2,251 for tax-gross ups for living expense reimbursement.

(9) Ms. Tregoning's annual performance-based cash bonus plan award was prorated based on the number of days she was in active service during fiscal year 2020.

(10) Mr. Phillips resigned as Chief Legal Officer, effective on December 18, 2020, and provided transitional services through January 8, 2021.

(11) The amount reported for Mr. Phillips represents $203,133 for relocation reimbursement ($125,000 of which was repaid in connection with Mr. Phillips' resignation), $134,899 for tax-gross ups for relocation, $17,100 for matching contributions made by us under our 401(k) plan and $9,468 for legal fees he incurred in connection with the negotiation of his compensatory agreements.

Narrative disclosure to the summary compensation table

2020 base salaries

The employment agreement with each named executive officer, described below, establishes a base salary, which is subject to discretionary increases that factors into consideration market competitiveness, his or her

skill set, experience, performance, role and responsibilities and budget. As of December 31, 2020, the base salaries for Drs. Coles and Renger, Ms. Tregoning and Mr. Phillips were $600,000, $450,000, $410,000 and $410,000, respectively.

Annual performance-based cash bonus

Our annual performance-based cash bonus plan is designed to align, motivate and reward our executive team for strong company performance based on the attainment of certain pre-identified short-term business priorities. During the fiscal year ended December 31, 2020, the target annual bonuses for Drs. Coles and Renger, Ms. Tregoning and Mr. Phillips were equal to 50%, 40%, 40% and 40%, respectively, of their respective annual base salaries. Early in 2020, our board of directors determined a number of company performance goals for fiscal 2020 pertaining to (i) research and development progress of certain clinical assets, (ii) finance and (iii) people and culture, with a pre-determined assigned weight of 50%, 40% and 10%, respectively.

In 2021, our board of directors evaluated our 2020 performance against these earlier established performance goals. For research and development, we achieved 146% of target, and, for each of finance and people and culture, we achieved 150% of target. The overall result was an aggregate achievement of 148%, or the Company Multiplier. Each named executive officer's target bonus (prorated, if applicable) was then multiplied by such Company Multiplier to determine his or her bonus payment for 2020. The amounts earned under our annual performance-based cash bonus plan with respect to the fiscal year ended December 31, 2020 are reported under the "*Non-Equity Incentive Compensation*" column in the 2020 Summary Compensation Table above.

Equity incentive compensation

In order to appropriately balance the achievement of short-term results through our annual performance-based cash bonus plan, we also grant stock options to our executives to emphasize the importance of long-term value creation by aligning the long-term interests of our executives with that of our stakeholders. These stock options only increase in value when our enterprise value increases. The outstanding option awards generally vest over four years, with 25% vesting on the first anniversary of the vesting start date of each grant and in 36 equal monthly installments thereafter, generally subject to continued service. The stock options awarded to the named executive officers during the fiscal year ended December 31, 2020 are reflected in the Outstanding Equity Awards Table below.

Employment agreements with our named executive officers

We are party to employment agreements with each of our named executive officers. The material terms of these agreements with each named executive officer are described below.

N. Anthony Coles, M.D. On November 23, 2018, we entered into an employment agreement with Dr. Coles for the position of Executive Chairperson, Chairperson of our board of directors and his future appointment to Chief Executive Officer. In accordance with his employment agreement, as amended, on November 27, 2018, Dr. Coles was appointed to the position of Executive Chairperson and Chairperson of our board of directors with a base salary of $300,000. Dr. Coles' agreement also provided for him to become Chief Executive Officer no later than March 31, 2019; however, his agreement was subsequently amended to provide for his appointment to be effective as of September 3, 2019. In connection with taking on the Chief Executive Officer role, Dr. Coles' base salary increased to $600,000. Under his employment agreement, Dr. Coles is eligible to earn an annual target bonus equal to 50% of his base salary. His salary is subject to increase from time to time by our board of directors within its discretion. Dr. Coles was promised an equity award of stock options, a portion of which was

contingent upon him becoming Chief Executive Officer no later than March 31, 2019, which deadline was extended by subsequent amendments to September 4, 2019. Dr. Coles' employment agreement provides that his stock option awards that are subject to time-based vesting and outstanding as of the date of a sale event (as defined in his employment agreement) will be accelerated and vest in connection with such sale event if (i) he is in continuous service through the date of such sale event or (ii) within the 12 month period following a sale event (A) his employment is terminated by us without cause (as defined in, and modified for severance purposes, in his employment agreement) or (B) he resigns for good reason (as defined in his employment agreement). Dr. Coles is also eligible to receive reimbursement of up to $18,000 per month in reasonable living and commuting expenses and applicable taxes, through November 28, 2020, subject to repayment of up to 50% of such amounts if Dr. Coles' employment is terminated by us for cause or he resigns without good reason within 24 months of the effective date of his employment agreement. Dr. Coles' agreement provided for the reimbursement by us of up to $75,000 of legal fees incurred in connection with the negotiation of his employment agreement and related agreements. Dr. Coles is eligible to participate in the employee benefit plans generally available to all our full-time employees, subject to the terms of those plans.

Dr. Coles' employment has no specified term but can be terminated at will by either party. If Dr. Coles' employment is terminated by us without cause or by him for good reason, Dr. Coles will be entitled to certain payments and benefits in addition to accrued obligations. These payments and benefits include (i) 24 months of salary continuation, (ii) a prorated amount of his target bonus, (iii) acceleration of an additional 12 months of vesting for his stock options and any other stock awards granted to him under our equity incentive plan and (iv) up to 24 months (dependent on COBRA eligibility for such period) of company-sponsored benefits continuation. In the event his employment is terminated within 12 months following a sale event (as defined in the agreement), in addition to the accelerated vesting of his stock option award and any other time-based equity awards described above, subject to certain limitations, he will be entitled to receive (i) 24 months of salary plus two times his target bonus payable in a lump sum, and (ii) up to 18 months (dependent on COBRA eligibility for such period) of company-sponsored benefits continuation.

John Renger, Ph.D. On March 16, 2019, we entered into an employment agreement with Dr. Renger for the position of Chief Scientific Officer effective as of April 8, 2019. Pursuant to his employment agreement, Dr. Renger is entitled to a base salary of $450,000 and an annual target bonus equal to 40% of his annual base salary. His salary is subject to increase from time to time by our board of directors in its discretion. Dr. Renger is eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. The employment agreement also provided for a $130,000 signing bonus, relocation expenses up to $150,000 (grossed up for any taxes imposed on the amounts reimbursed) and up to $3,000 monthly for living expenses for the first four months of his employment. Under his employment agreement, Dr. Renger was also promised an equity award of stock options subject to the terms of an award agreement and our equity incentive plan.

Dr. Renger's employment has no specified term but can be terminated at will by either party. If Dr. Renger's employment is terminated by us without cause, or if Dr. Renger terminates his employment for good reason (as such terms are defined in his employment agreement), Dr. Renger will be entitled to certain payments and benefits in addition to accrued obligations. These payments and benefits include (i) 12 months of salary continuation, (ii) a prorated amount of his target annual bonus for the year of such termination based on the number of days of Dr. Renger's service during the year his employment is terminated and (iii) up to 12 months (dependent on COBRA eligibility for such period) of company-sponsored benefits continuation.

Kathleen Tregoning, M.A. On July 7, 2020, we entered into an employment agreement with Ms. Tregoning for the position of Chief Corporate Affairs Officer effective as of July 13, 2020. Pursuant to her employment agreement, Ms. Tregoning is entitled to a base salary of $410,000 and an annual target bonus equal to 40% of

her annual base salary (for 2020 only, the annual bonus is subject to proration based on the number of days she was in active service during fiscal year 2020). Her salary is subject to increase from time to time by our board of directors in its discretion. Ms. Tregoning is eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. The employment agreement also provided for a $100,000 signing bonus, a promised equity award of stock options subject to the terms of an award agreement and our equity incentive plan and eligibility to participate in a co-invest program for other similarly situated executives.

Ms. Tregoning's employment has no specified term but can be terminated at will by either party. If Ms. Tregoning's employment is terminated by us without cause, or if Ms. Tregoning terminates her employment for good reason (as such terms are defined in her employment agreement), Ms. Tregoning will be entitled to certain payments and benefits in addition to accrued obligations. These payments and benefits include (i) 12 months of salary continuation, (ii) a prorated amount of her target annual bonus for the year of such termination based on the number of days of Ms. Tregoning's service during the year her employment is terminated and (iii) up to 12 months (dependent on COBRA eligibility for such period) of company-sponsored benefits continuation.

Bryan Phillips, J.D. On November 8, 2019, we entered into an employment agreement with Mr. Phillips for the position of Chief Legal Officer effective as of December 2, 2019. Pursuant to his employment agreement, Mr. Phillips was entitled to a base salary of $410,000 and an annual target bonus equal to 40% of his annual base salary. His salary was subject to increase from time to time by our board of directors in its discretion. Mr. Phillips was eligible to participate in our employee benefit plans generally available to our executive employees, subject to the terms of those plans. The employment agreement also provided for a $170,000 signing bonus and $200,000 in relocation and commuting expenses (grossed up for any taxes imposed on the amounts reimbursed). Under his employment agreement, Mr. Phillips was also promised an equity award of stock options subject to the terms of an award agreement and our equity incentive plan and eligibility to participate in a co-invest program for other similarly situated executives.

Mr. Phillips's employment had no specified term but could be terminated at will by either party. If Mr. Phillips's employment had been terminated by us without cause, or if Mr. Phillips had terminated his employment for good reason (as such terms are defined in his employment agreement), Mr. Phillips would have been entitled to certain payments and benefits in addition to accrued obligations. These payments and benefits included (i) 12 months of salary continuation, (ii) a prorated amount of his target annual bonus for the year of such termination based on the number of days of Mr. Phillip's service during the year his employment is terminated and (iii) up to 12 months (dependent on COBRA eligibility for such period) of company-sponsored benefits continuation.

As described above, Mr. Phillips resigned as Chief Legal Officer, effective on December 18, 2020, and provided transitional services through January 8, 2021. Mr. Phillips' resignation did not constitute a termination without cause or for good reason and he did not receive the severance payments and benefits described above.

Outstanding equity awards at 2020 fiscal year-end

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2020.

				Option awards(1)(2)	
Name	**Vesting start date**	**Number of securities underlying unexercised options exercisable (#)**	**Number of securities underlying unexercised options unexercisable (#)**	**option exercise price ($/share)**	**Option expiration date**
N. Anthony Coles, M.D.	11/27/2018	1,615,842	1,486,575	3.50	12/24/2028
	11/27/2018	538,613	495,525	10.28	12/24/2028
	10/28/2020(3)	—	196,335	9.88	10/28/2030
John Renger, Ph.D.	4/8/2019	200,364	280,511	3.50	4/02/2029
	4/8/2019	66,787	93,504	10.28	4/02/2029
	10/28/2020(3)	—	117,801	9.88	10/28/2030
Kathleen Tregoning, M.A.	7/29/2020	—	258,232	10.05	7/29/2030
	7/29/2020	—	86,077	14.44	7/29/2030
	12/4/2020(4)	—	78,229	15.45	12/4/2030
Bryan Phillips, J.D.	1/2/2020(5)	—	349,022	4.92	2/19/2030
	1/2/2020(5)	—	116,340	14.44	2/19/2030

(1) Unless otherwise noted, shares of stock subject to option awards will vest, if at all, as follows: 25% of the shares subject to the option will vest on the first anniversary of the vesting start date, with the remaining 75% of the shares subject to the option to vest ratably in 36 equal monthly installments thereafter (rounded down to the nearest whole number of shares on each such date) until the award fully vests upon the fourth anniversary of the vesting start date, subject to the named executive officer's continued service.

(2) With respect to awards granted prior to the consummation of the Business Combination, vesting of the option awards granted to each of the named executive officers accelerates upon the consummation of a sale event. In addition, Dr. Coles' awards provide that if he is terminated by us without cause or resigns for good reason, then the number of stock options that would have vested during the 12 month period following such termination of employment will become vested as of the date of such termination of employment.

(3) This award vests with respect to 50% of the option on the second anniversary of the vesting start date, with the remainder vesting in two equal installments thereafter.

(4) Represents an additional portion of Ms. Tregoning's new hire equity grant.

(5) Mr. Phillips resigned as Chief Legal Officer, effective on December 18, 2020, and provided transitional services through January 8, 2021. The portion of this option award that was unvested as of the conclusion of Mr. Phillips' transitional services was forfeited and became void.

Other compensation arrangements

Severance policy

We maintain a Severance Benefits Policy for Specified C-Suite Executives, or the Severance Policy, under which each senior executive officer that directly reports to our Chief Executive Officer other than on a temporary basis, or an Eligible Employee, is eligible to receive cash, equity acceleration and benefit continuation severance benefits.

Under the Severance Policy, if an Eligible Employee's employment is terminated by us for a reason other than cause, death or disability, or resigns for good reason within the period that begins three months prior to the

occurrence of the first event constituting a sale event and ends on the first anniversary of such event (as such terms are defined in the Severance Policy), then, subject to a release requirement, the Eligible Employee will be entitled to receive the following severance benefits:

- an amount equal to the sum of 12 months of such Eligible Employee's base salary and target bonus in the year the termination of employment occurs, payable in 12 equal monthly installments following such termination;
- acceleration of the vesting of such Eligible Employee's outstanding time-based vesting equity awards; and
- payment of continued health coverage required under applicable law for the Eligible Employee and any eligible dependents that were covered under our health care plans immediately prior to the termination date for up to 12 months.

Indemnification agreements

We have entered into indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides for indemnification and advancements by us of certain expenses and costs relating to claims, suits or proceedings arising from his or her service to us or, at our request, service to other entities, as officers or directors to the maximum extent permitted by applicable law.

401(k) plan

We maintain a tax-qualified retirement plan that provides eligible employees, including our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. Plan participants are able to defer eligible compensation subject to applicable annual limits established by the Code, and any regulations promulgated thereunder. Employees' pre-tax or Roth contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions. We match each participant's contribution up to a maximum of 6% of their eligible compensation. Our 401(k) plan is intended to be qualified under Section 401(a) of the Code with our 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code.

Health and welfare benefits

Our named executive officers are eligible to participate in our health and welfare plans that are generally available to all of our employees, including medical, dental and vision benefits, short-term and long-term disability insurance and life insurance.

Compensation risk assessment

We believe that although a portion of the compensation provided to our executive officers is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily because our compensation programs are designed to create a greater focus on long-term value creation while balancing the need to meet shorter-term goals. The framework and goals of our annual performance-based incentive plan are consistent for all employees with a maximum cap for all payouts. Furthermore, all compensation decisions for our executive officers are approved by the compensation committee of our board of directors, or our compensation committee.

In addition, our compensation committee is responsible for reviewing and approving the design, goals and payouts under our annual bonus plan and equity incentive program for our executive officers. Our

compensation committee directly engages an independent compensation consultant who advises on market competitive and best practices, as well as any potential risks related to our compensation programs. This includes pay mix, compensation vehicles, pay for performance alignment, performance measures and goals, payout maximums, vesting periods and compensation committee oversight and independence. Based on all the factors mentioned, we believe our compensation policies, programs and practices do not create risks that are reasonably likely to have a material adverse effect on the Company.

Director compensation

Retainers, meeting fees and expenses

Dr. Coles, our Chief Executive Officer, does not receive any compensation from us for his services on our board of directors as Chairperson. Dr. Coles' compensation during for his service as Executive Chairperson and then as Chief Executive Officer is set forth above in "*Executive and Director Compensation—2020 Summary Compensation Table.*" Each of our remaining non-employee directors is eligible to receive any of the following forms of compensation, as applicable, under our non-employee director compensation policy.

Non-employee director compensation policy

Pursuant to our non-employee director compensation policy, as amended, each non-employee director will receive an annual retainer of $50,000, an additional annual retainer of $25,000 for serving as the lead independent director and an additional $7,500 annual retainer for serving on the audit, compensation, nominating and corporate governance or science and technology committee (or a $15,000 annual retainer for serving as the chair of each such committee), to be paid quarterly in arrears and prorated based on the number of actual days served on the board of directors or applicable committee. In addition, each non-employee director will receive, on the date of our annual meeting of stockholders, an annual grant of a stock option with a grant date fair value, determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under ASC 718, equal to $428,000, that vests in full on the earlier of the one-year anniversary of the grant date or the next annual meeting of stockholders, and each new non-employee director will receive a stock option with a grant date fair value equal to $642,000, vesting in 36 monthly installments through the third anniversary of the grant date. The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director in a calendar year period shall not exceed $750,000 (or $1,000,000 for the calendar year in which the non-employee director is initially elected or appointed to the board of directors).

2020 non-employee director compensation table

The following table presents the total compensation for each person who served as a non-employee director of our board of directors during fiscal year 2020.

Name	Fees paid or earned in cash ($) (1)	Total ($)
Morris Birnbaum, M.D., Ph.D.	10,156	10,156
Marijn Dekkers, Ph.D.[2]	65,000	65,000
Doug Giordano, M.B.A.	11,481	11,481
Christopher Gordon, M.B.A.	11,481	11,481
Adam Koppel, M.D., Ph.D.	11,481	11,481
Norbert Riedel, Ph.D.[3]	76,916	76,916
Gabrielle Sulzberger, J.D., M.B.A.[4]	66,325	66,325
Ruth McKernan, Ph.D.[5]	4,375	4,375

(1) Amounts reflect cash retainers prorated for services following the Business Combination.

(2) As of December 31, 2020, Dr. Dekkers held 14,270 unvested restricted stock units.

(3) As of December 31, 2020, Dr. Riedel held 28,540 unvested restricted stock units.

(4) As of December 31, 2020, Ms. Sulzberger held 28,540 unvested restricted stock units.

(5) Dr. McKernan joined our board of directors on December 4, 2020, and her cash retainer and fees were prorated based on her service during 2020. In connection with her appointment, in accordance with the non-employee director compensation policy, Dr. McKernan was awarded an initial grant of 80,945 stock options. However, although this grant was deemed to be granted in respect of Dr. McKernan's commencement of service in 2020, this grant was not effective until January 4, 2021, the first trading day of the following month, and accordingly, will be reflected in the non-employee director compensation table for 2021. These options vest and become exercisable in 36 monthly installments over three years and are subject to full acceleration upon the occurrence of a change in control (as such term is defined in the 2020 Plan).

Description of capital stock

The following summary of certain provisions of our securities does not purport to be complete and is subject to our certificate of incorporation and bylaws and the provisions of applicable law. Copies of our certificate of incorporation and bylaws are filed as exhibits to the registration statement of which this prospectus is a part.

Authorized capitalization

General

The total amount of our authorized share capital consists of 500,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

As of March 31, 2021, 127,325,116 shares of our common stock were outstanding and held by 36 stockholders of record.

Common stock

Voting rights. Each holder of common stock is entitled to one vote for each share of common stock held of record by such holder on all matters voted upon by our stockholders, provided, however, that, except as otherwise required in our certificate of incorporation or by applicable law, the holders of common stock are not be entitled to vote on any amendment to our certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to our certificate of incorporation (including any certificate of designation relating to any series of preferred stock) or pursuant to the DGCL.

Dividend rights. Subject to any other provisions of our certificate of incorporation, as it may be amended from time to time, holders of shares of common stock are entitled to receive ratably, in proportion to the number of shares of common stock held by them, such dividends and other distributions in cash, stock or property when, as and if declared thereon by our board of directors from time to time out of our assets or funds legally available therefor.

Rights upon liquidation. Subject to the rights of holders of preferred stock, in the event of any liquidation, dissolution or winding up of our affairs, whether voluntary or involuntary, after payment or provision for payment of our debts and any other payments required by law and amounts payable upon shares of preferred stock ranking senior to the shares of common stock upon such dissolution, liquidation or winding up, if any, our remaining net assets will be distributed to the holders of shares of common stock and the holders of shares of any other class or series ranking equally with the shares of common stock upon such dissolution, liquidation or winding up, equally on a per share basis.

Other rights. No holder of shares of common stock is entitled to preemptive or subscription rights contained in our certificate of incorporation or bylaws. There are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of holders of the common stock will be subject to those of the holders of any shares of preferred stock with preferential rights that we may issue in the future.

Preferred stock

Our board of directors has the authority to issue shares of preferred stock from time to time on terms it may determine, to divide shares of preferred stock into one or more series and to fix the designations, preferences,

privileges, and restrictions of preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, sinking fund terms, and the number of shares constituting any series or the designation of any series to the fullest extent permitted by the DGCL. The issuance of preferred stock could have the effect of decreasing the trading price of common stock, restricting dividends on our capital stock, diluting the voting power of the common stock, impairing the liquidation rights of our capital stock or delaying or preventing a change in control of us.

Election of directors and vacancies

Subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances and the terms and conditions of the Registration and Shareholder Rights Agreement, the number of directors of our board of directors shall be fixed solely and exclusively by resolution duly adopted from time to time by our board of directors.

Under our bylaws, at all meetings of stockholders called for the election of directors, a plurality of the votes properly cast will be sufficient to elect such directors to our board of directors.

Except as the DGCL or the Registration and Shareholder Rights Agreement may otherwise require and subject to the rights, if any, of the holders of any series of preferred stock, in the interim between annual meetings of stockholders or special meetings of stockholders called for the election of directors and/or the removal of one or more directors and the filling of any vacancy in that connection, newly created directorships and any vacancies on our board of directors, including unfilled vacancies resulting from the removal of directors, may be filled only by the affirmative vote of a majority of the remaining directors then in office, although less than a quorum, or by the sole remaining director. All directors will hold office until the expiration of their respective terms of office and until their successors will have been elected and qualified. A director elected or appointed to fill a vacancy resulting from the death, resignation or removal of a director or a newly created directorship will serve for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until his or her successor will have been elected and qualified.

Subject to the rights, if any, of any series of our preferred stock, any director may be removed from office only with cause and then only by the affirmative vote of the holders of not less than two-thirds of the outstanding voting stock then entitled to vote at an election of directors. Any such director proposed to be removed from office is entitled to advance written notice as described in our certificate of incorporation. Subject to the terms and conditions of the Registration and Shareholder Rights Agreement, in case our board of directors or any one or more directors should be so removed, new directors may be elected at the same time for the unexpired portion of the full term of the director or directors so removed.

Notwithstanding the foregoing, any director elected pursuant to the right, if any, of the holders of preferred stock to elect additional directors under specified circumstances will serve for such term or terms and pursuant to such other provisions as specified in the relevant certificate of designations related to our preferred stock.

Quorum

The holders of a majority of the voting power of the capital stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, will constitute a quorum at all meetings of the stockholders for the transaction of business except as otherwise required by law or provided by our certificate of incorporation. If, however, such quorum will not be present or represented at any meeting of the stockholders, the holders of a majority of the voting power present in person or represented by proxy, will have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum will be present or represented. At such adjourned meeting at which a quorum will be present or represented, any business may be transacted which might have been transacted at the meeting as originally noticed. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting will be given to each stockholder entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

Anti-takeover effects of our certificate of incorporation and bylaws

Our certificate of incorporation and bylaws contain provisions that may delay, defer or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with the board of directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give the board of directors the power to discourage acquisitions that some stockholders may favor.

Authorized but unissued capital stock

Delaware law does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of Nasdaq, which would apply if and so long as our common stock remains listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. Additional shares that may be issued in the future may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

One of the effects of the existence of unissued and unreserved common stock may be to enable our board of directors to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise and thereby protect the continuity of management and possibly deprive stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Special meeting, action by written consent and advance notice requirements for stockholder proposals

Unless otherwise required by law, and subject to the rights, if any, of the holders of any series of preferred stock, special meetings of our stockholders, for any purpose or purposes, may be called only (i) by a majority of our board of directors or (ii) at any time when no annual meeting has been held for a period of 13 months after our last annual meeting, a special meeting in lieu thereof may be held, and such special meeting shall have, for the purposes of our bylaws or otherwise, all the force and effect of an annual meeting. Unless otherwise required by law, written notice of a special meeting of stockholders, stating the time, place and purpose or

purposes thereof, shall be given to each stockholder entitled to vote at such meeting, not less than 10 or more than 60 days before the date fixed for the meeting. Business transacted at any special meeting of stockholders will be limited to the purposes stated in the notice.

Our bylaws also provide that unless otherwise restricted by our certificate of incorporation or bylaws, any action required or permitted to be taken at any meeting of our board of directors or of any committee thereof may be taken without a meeting, if all members of our board of directors or of such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of our board of directors or committee.

In addition, our bylaws require advance notice procedures for stockholder proposals to be brought before an annual meeting of the stockholders, including the nomination of directors. Stockholders at an annual meeting may only consider the proposals specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors, or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered a timely written notice in proper form to our secretary, of the stockholder's intention to bring such business before the meeting.

These provisions could have the effect of delaying until the next stockholder meeting any stockholder actions, even if they are favored by the holders of a majority of our outstanding voting securities.

Amendment to certificate of incorporation and bylaws

The DGCL provides generally that the affirmative vote of a majority of the outstanding stock entitled to vote on amendments to a corporation's certificate of incorporation or bylaws is required to approve such amendment, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage.

Our certificate of incorporation provides that the following provisions therein may be amended, altered, repealed or rescinded only by the affirmative vote of the holders of at least $66^{2/3}$% in voting power of all the then outstanding shares of our stock entitled to vote thereon and the affirmative vote of at least $66^{2/3}$% of the outstanding shares of each class entitled to vote thereon as a class:

- the provisions regarding the size of our board of directors and the election of directors pursuant to the Registration and Shareholder Rights Agreement;
- the provisions prohibiting stockholder actions without a meeting;
- the provisions regarding calling special meetings of stockholders;
- the provisions regarding removal of directors;
- the provisions regarding the limited liability of our directors; or
- the provisions regarding the election not to be governed by Section 203 of the DGCL.

Our bylaws may be amended or repealed (i) by the affirmative vote of a majority of the entire board of directors then in office (subject to any bylaw requiring the affirmative vote of a larger percentage of the members of our board of directors) or (ii) without the approval of the board of directors, by the affirmative vote of the holders of $66^{2/3}$% of the outstanding voting stock entitled to vote on such amendment or repeal, voting as a single class, provided that if our board of directors recommends that stockholders approve such amendment or repeal at such meeting of stockholders, then such amendment or repeal shall only require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting as a single class.

Delaware anti-takeover statute

Section 203 of the DGCL provides that if a person acquires 15% or more of the voting stock of a Delaware corporation, such person becomes an “interested stockholder” and may not engage in certain “business combinations” with the corporation for a period of three years from the time such person acquired 15% or more of the corporation’s voting stock, unless:

(i) the board of directors approves the acquisition of stock or the merger transaction before the time that the person becomes an interested stockholder;

(ii) the interested stockholder owns at least 85% of the outstanding voting stock of the corporation at the time the merger transaction commences (excluding voting stock owned by directors who are also officers and certain employee stock plans); or

(iii) the merger transaction is approved by the board of directors and at a meeting of stockholders, not by written consent, by the affirmative vote of 2/3 of the outstanding voting stock which is not owned by the interested stockholder. A Delaware corporation may elect in its certificate of incorporation or bylaws not to be governed by this particular Delaware law.

Under our certificate of incorporation, we opted out of Section 203 of the DGCL and therefore are not subject to Section 203. However, our certificate of incorporation contains similar provisions providing that we may not engage in certain “business combinations” with any “interested stockholder” for a three-year period following the time that the stockholder became an interested stockholder, unless:

- prior to such time, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding certain shares; or
- at or subsequent to that time, the business combination is approved by our board of directors and by the affirmative vote of holders of at least $66^{2/3}$% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a “business combination” includes a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an “interested stockholder” is a person who, together with that person’s affiliates and associates, owns, or within the previous three years owned, 15% or more of our voting stock.

Under certain circumstances, this provision will make it more difficult for a person who would be an “interested stockholder” to effect various business combinations with a corporation for a three-year period. This provision may encourage companies interested in acquiring our company to negotiate in advance with our board of directors because the stockholder approval requirement would be avoided if our board of directors approves either the business combination or the transaction which results in the stockholder becoming an interested stockholder. These provisions also may have the effect of preventing changes in our board of directors and may make it more difficult to accomplish transactions which stockholders may otherwise deem to be in their best interests.

Our certificate of incorporation provides that (i) investment funds affiliated with Bain Capital Investors, LLC or Bain Capital Life Sciences Investors, LLC and their respective successors, transferees and affiliates, or (ii) any person whose ownership of shares in excess of the 15% limitation set forth therein is the result of any action taken solely by us (provided, that such person shall be an “interested stockholder” if such thereafter such

person acquires additional shares of voting stock of us, except as a result of further corporate actions not caused by such person) do not constitute “interested stockholders” for purposes of this provision.

Limitations on liability and indemnification of officers and directors

Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by the DGCL, and our bylaws provide that we will indemnify them to the fullest extent permitted by such law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. Under the terms of such indemnification agreements, we are required to indemnify each of our directors and officers, to the fullest extent permitted by the laws of the state of Delaware, if the basis of the indemnitee’s involvement was by reason of the fact that the indemnitee is or was a director or officer of us or any of its subsidiaries or was serving at our request in an official capacity for another entity. We must indemnify our officers and directors against all reasonable fees, expenses, charges and other costs of any type or nature whatsoever, including any and all expenses and obligations paid or incurred in connection with investigating, defending, being a witness in, participating in (including on appeal), or preparing to defend, be a witness or participate in any completed, actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative, or establishing or enforcing a right to indemnification under the indemnification agreement. The indemnification agreements also require us, if so requested, to advance within 10 days of such request all reasonable fees, expenses, charges and other costs that such director or officer incurred, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Exclusive jurisdiction of certain actions

Our bylaws require, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty, actions asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, actions to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws and actions asserting a claim against us governed by the internal affairs doctrine may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder’s counsel; provided, however, that the forgoing provisions will not apply to any claims arising under the Exchange Act or the Securities Act. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

In addition, our bylaws require that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Cambridge, Massachusetts.

Transfer agent

The transfer agent for our common stock is Continental Stock Transfer & Trust Company.

Stock exchange listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “CERE.”

Principal stockholders

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of March 31, 2021 by:

- each of our named executive officers;
- each of our directors;
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our common stock; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the person has the right to acquire, such as through the exercise of warrants or stock options or the vesting of restricted stock units, within 60 days of March 31, 2021. Common stock subject to warrants, options or other convertible securities that are currently exercisable or exercisable within 60 days of March 31, 2021 or subject to restricted stock units that vest within 60 days of March 31, 2021 are considered outstanding and beneficially owned by the person holding such warrants, options or restricted stock units for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, based on the information provided to us, we believe that the persons named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise noted, the business address of each of our directors and executive officers is 222 Jacobs Street, Suite 200, Cambridge, MA 02141. The percentage of beneficial ownership of our shares of common stock is calculated based on 127,325,116 shares of common stock outstanding as of March 31, 2021.

Name and address of beneficial owners	Number of shares	Percentage
Named Executive Officers and Directors:		
N. Anthony Coles, M.D.[1]	2,499,167	2.0%
Bryan Phillips, J.D.[1]	116,340	*
John Renger, Ph.D.[1]	333,939	*
Kathleen Tregoning, M.A.	—	—
Deborah Baron, M.B.A.	—	—
Morris Birnbaum, M.D., Ph.D.	—	—
Marijn Dekkers, Ph.D.[3]	661,890	*
Doug Giordano, M.B.A.	—	—
Christopher Gordon, M.B.A.[4]	—	—
Adam Koppel, M.D., Ph.D.[5]	—	—
Ruth McKernan, Ph.D., CBE, FMedSci[1]	8,993	*
Deval Patrick, J.D.[1]	7,532	*
Norbert Riedel, Ph.D.[2]	28,540	*
Gabrielle Sulzberger, J.D., M.B.A.[2]	14,270	*
All directors and executive officers as a group (19 persons)	4,521,618	3.6%
Five Percent Holders:		
BC Perception Holdings, LP[6]	60,632,356	47.6%
Pfizer Inc.[7]	27,349,211	21.5%

* Less than 1%

(1) Consists solely of options exercisable within 60 days of March 31, 2021.

(2) Consists solely of shares of common stock.

(3) Consists of 28,540 shares of common stock held directly by Dr. Dekkers and 633,350 shares of common stock held by Novalis LifeSciences Investments I, L.P., or Novalis LifeSciences. Dr. Dekkers, the Manager of the general partner of Novalis LifeSciences, has sole voting and dispositive power over the shares held by Novalis LifeSciences and, as a result, may be deemed to share beneficial ownership of the shares held by Novalis LifeSciences. The address of Novalis LifeSciences is 1 Liberty Lane E, Suite 100, Hampton, New Hampshire 03842.

(4) Does not include shares of common stock held by Bain Investor. Mr. Gordon, who is a member of our board of directors, is a managing director of Bain Capital Investors, LLC, or BCI, the ultimate general partner of Bain Investor, and as a result, and by virtue of the relationships described in footnote 7 below, may be deemed to share beneficial ownership of the shares held by Bain Investor. The address for Mr. Gordon is c/o Bain Capital Private Equity, LP, 200 Clarendon Street, Boston, MA 02116.

(5) Does not include shares of common stock held by Bain Investor. Dr. Koppel, who is a member of our board of directors, is a managing director of Bain Capital Life Sciences Investors, LLC, or BCLSI, which is the general partner of Bain Capital Life Sciences Fund, LP, or BCLSF, and, as a result, may be deemed to share beneficial ownership of the shares held by Bain Investor. The address for Dr. Koppel is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.

(6) Bain Capital Investors, LLC, or BCI, is the ultimate general partner of Bain Investor. As a result, BCI may be deemed to exercise voting and dispositive power with respect to the shares reported in the table above. Voting and investment decisions with respect to securities held by Bain Investor are made by the managing directors of BCI, of whom there are three or more and none of whom individually has the power to direct such decisions. The address of Bain Investor is c/o Bain Capital Private Equity, LP, 200 Clarendon Street, Boston, Massachusetts 02116.

(7) Ms. Baron and Dr. Birnbaum, each of whom is a member of our board of directors, are each employed by Pfizer. Neither Ms. Baron nor Dr. Birnbaum has voting or dispositive power over the shares held by Pfizer and each of them disclaims beneficial ownership of all such shares. The address of Pfizer is 235 East 42nd Street, New York, New York 10017.

Material United States federal income tax considerations

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common stock. This discussion applies only to shares of common stock that are held as capital assets for U.S. federal income tax purposes and is applicable only to holders who are receiving our shares of common stock in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences (such as the effects of Section 451 of the Code) that may apply if you are subject to special rules that apply to certain types of investors, including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the U.S.;
- persons that actually or constructively own five percent or more of our voting shares;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to the common stock;
- persons holding the common stock as part of a “straddle,” hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities; and
- tax-exempt entities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and will not seek, a ruling from the IRS as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our common stock through such entities. If a partnership (or other entity or arrangement classified as

a partnership or other pass-through entity for United States federal income tax purposes) is the beneficial owner of our common stock, the United States federal income tax treatment of a partner or member in the partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our common stock, we urge you to consult your own tax advisor.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK. EACH PROSPECTIVE INVESTOR IN OUR COMMON STOCK IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, INCLUDING THE APPLICABILITY AND EFFECT OF ANY UNITED STATES FEDERAL NON-INCOME, STATE, LOCAL, AND NON-U.S. TAX LAWS.

U.S. holders

This section applies to you if you are a “U.S. holder.” A U.S. holder is a beneficial owner of our shares of common stock who or that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) organized in or under the laws of the United States, any state thereof or the District of Columbia; or
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons (as defined in the Code) have authority to control all substantial decisions of the trust or (ii) it has a valid election in effect under Treasury Regulations to be treated as a U.S. person.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of our common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder’s adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under “*U.S. Holders—Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock*” below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute “qualified dividends” that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock. Upon a sale or other taxable disposition of our common stock, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the common stock so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of the shares would be subject to short-term capital gain treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its common stock so disposed of. A U.S. holder's adjusted tax basis in its common stock generally will equal the U.S. holder's acquisition cost for the common stock or less, in the case of a share of common stock, any prior distributions treated as a return of capital. In the case of any shares of common stock originally acquired as part of an investment unit, the acquisition cost for the share of common stock that were part of such unit would equal an allocable portion of the acquisition cost of the unit based on the relative fair market values of the components of the unit at the time of acquisition.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our shares of common stock, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Non-U.S. holders

This section applies to you if you are a "Non-U.S. holder." As used herein, the term "Non-U.S. holder" means a beneficial owner of our common stock who or that is for U.S. federal income tax purposes:

- a non-resident alien individual (other than certain former citizens and residents of the U.S. subject to U.S. tax as expatriates);
- a foreign corporation or
- an estate or trust that is not a U.S. holder;

but generally does not include an individual who is present in the U.S. for 183 days or more in the taxable year of disposition. If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership or sale or other disposition of our common stock.

Taxation of Distributions. In general, any distributions we make to a Non-U.S. holder of shares of our common stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax

treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder's adjusted tax basis in its shares of our common stock and, to the extent such distribution exceeds the Non-U.S. holder's adjusted tax basis, as gain realized from the sale or other disposition of the common stock, which will be treated as described under "*Non-U.S. Holders—Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock*" below.

The withholding tax does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A Non-U.S. corporation receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock. A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of our common stock, unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder); or
- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held our common stock, and, in the case where shares of our common stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of our common stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder's holding period for the shares of our common stock. There can be no assurance that our common stock will be treated as regularly traded on an established securities market for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower treaty rate).

If the second bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of shares of our common stock will be subject to tax at generally applicable U.S. federal income tax rates, and a buyer of such shares may be required to withhold U.S. federal income tax at a rate of 15% of the amount realized upon the disposition. We expect not to be classified as a "U.S. real property holding corporation" for U.S. federal income tax purposes. However, such determination is factual in nature and subject to change and no assurance can be provided as to whether we will be a "U.S. real property holding corporation" for U.S. federal income tax purposes in the future.

Information Reporting and Backup Withholding. Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of our shares of common stock. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will generally satisfy the certification requirements necessary to avoid the backup withholding as well. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes. Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred as the "Foreign Account Tax Compliance Act" or "FATCA") generally impose withholding at a rate of 30% in certain circumstances on dividends in respect of, and (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, securities (including shares of our common stock) which are held by or through certain foreign financial institutions (including investment funds), unless any such institution (i) enters into, and complies with, an agreement with the IRS to report, on an annual basis, information with respect to interests in, and accounts maintained by, the institution that are owned by certain U.S. persons and by certain non-U.S. entities that are wholly or partially owned by U.S. persons and to withhold on certain payments, or (ii) if required under an intergovernmental agreement between the United States and an applicable foreign country, reports such information to its local tax authority, which will exchange such information with the U.S. authorities. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Accordingly, the entity through which shares of our common stock are held will affect the determination of whether such withholding is required. Similarly, dividends in respect of, and (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock held by an investor that is a non-financial non-U.S. entity that does not qualify under certain exceptions will generally be subject to withholding at a rate of 30%, unless such entity either (i) certifies to the applicable withholding agent that such entity does not have any "substantial United States owners" or (ii) provides certain information regarding the entity's "substantial United States owners," which will in turn be provided to the U.S. Department of Treasury.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends in respect of our common stock. While withholding under FATCA generally would also apply to payments of gross proceeds from the sale or other disposition of securities (including shares of our common stock), proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. All holders should consult their tax advisors regarding the possible implications of FATCA on their investment in shares of our common stock.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, Jefferies LLC and Stifel, Nicolaus & Company, Incorporated are acting as book-running managers of this offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	4,480,000
Goldman Sachs & Co. LLC	4,200,000
Jefferies LLC	2,800,000
Stifel, Nicolaus & Company, Incorporated	2,240,000
Loop Capital Markets LLC	140,000
Siebert Williams Shank & Co., LLC	140,000
Total	14,000,000

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.90 per share. After the initial offering of the shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 2,100,000 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $1.50 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase 2,100,000 additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$ 1.50	$ 1.50
Total	21,000,000	24,150,000

We estimate that the total expenses of this offering, including registration, filing, accounting and legal fees and expenses, but excluding the underwriting discounts and commissions, will be approximately $725,000. We have also agreed to reimburse the underwriters for up to $40,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not, without the prior written consent of J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, Jefferies LLC and Stifel, Nicolaus & Company, Incorporated as representatives on behalf of the underwriters, and will not publicly disclose an intention to, during the period ending 90 days after the date of this prospectus, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise or (iii) file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance by us of shares of common stock to be sold in this offering, (ii) the issuance by us of shares of common stock upon the exercise of an option pursuant to stock plans or a warrant or the conversion of a security, in each case outstanding on the date of the underwriting agreement and described in this prospectus; (iii) the grant or issuance by us, or exercise or settlement (in cash, shares of common stock or otherwise) of options, restricted stock awards, restricted stock units or any other type of equity award to our employees, officers, directors, advisors, or consultants pursuant to the terms of an employee benefit plan in effect; (iv) our filing of a registration statement with the Securities and Exchange Commission on Form S-8 with respect to employee benefit plans issued under stock plans, or (v) the sale or issuance of or entry into an agreement to sell or issue shares of common stock or securities convertible into or exercisable for common stock by us in connection with any (a) merger, (b) acquisition of securities, businesses, property or other assets, (c) joint ventures, (d) strategic alliances, (e) equipment leasing arrangements or (f) debt financings, provided that the aggregate number of shares of common stock or securities convertible into or exercisable for common stock that we may issue pursuant to this clause (v) shall not exceed 5% of the outstanding shares of our common stock immediately following the closing of this offering, provided that such recipients enter into a lock-up agreement with the underwriters.

Our directors and executive officers, and certain of our significant shareholders (such persons, the “lock-up parties”) have entered into lock-up agreements with the underwriters prior to the commencement of this

offering pursuant to which each lock-up party, with limited exceptions, for a period of 90 days after the date of this prospectus (such period, the “restricted period”), may not (and, if the lock-up party is not a natural person, may not cause or direct any of its affiliates to), without the prior written consent of J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, Jefferies LLC and Stifel, Nicolaus & Company, Incorporated as representatives of the underwriters, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant (collectively with the common stock, the “lock-up securities”)), (2) enter into any swap or other arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition or transfer to another, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, or (3) otherwise publicly announce any intention to engage in any of the foregoing. Such persons or entities have further acknowledged that they are not, and have not caused or directed any of their affiliates to be or become, currently a party to any agreement or arrangement that provides for, is designated to or which reasonably could be expected to lead to or result in a transfer as described in clause (1) or (2) above.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transactions relating to shares of common stock or other securities sold by us in this offering (other than any company-directed shares of our common stock purchased in this offering by our officers or directors) or in open market transactions after the completion of this offering, (b) transfers of lock-up securities: (i) as a bona fide gift or gifts in a transaction not involving a disposition for value, (ii) by will, other testamentary document or intestacy or (iii) by operation of law, provided that any lock-up securities received upon such transfer would be subject to restrictions similar to those in the immediately preceding paragraph, (c) if the lock-up party is an individual, for estate planning purposes, to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, provided that any lock-up securities received upon such transfer would be subject to restrictions similar to those in the immediately preceding paragraph, (d) if the lock-up party is a trust, distributions of common stock or any security directly or indirectly convertible into common stock to its beneficiaries in a transaction not involving a disposition for value, provided that any lock-up securities received upon such distribution would be subject to restrictions similar to those in the immediately preceding paragraph, (e) if the lock-up party is a corporation, limited liability company, partnership or other entity, transfers or distributions of shares of common stock or any security directly or indirectly convertible into common stock to members, stockholders, limited partners, general partners, subsidiaries or affiliates of the lock-up party or to any investment fund or other entity that manages or controls the lock-up party, provided that any lock-up securities received upon such distribution would be subject to restrictions similar to those in the immediately preceding paragraph, (f) transfers of common stock to us in connection with the exercise of options, warrants or other rights to acquire common stock or any security convertible into or exercisable for our common stock, including for the payment of exercise price and tax and remittance payments, provided that any such common stock would be subject to restrictions similar to those in the immediately preceding paragraph, (g) the conversion of any convertible preferred stock into, or the exercise of any option or warrant for, shares of common stock, provided that any such common stock would be subject to restrictions similar to those in the immediately preceding paragraph, (h) the establishment by

lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period, (i) transfers or dispositions to us of common stock or any security convertible into or exercisable or exchangeable for common stock pursuant to any contractual arrangement in effect on the date of the applicable lock-up agreement that provides for the repurchase of the lock-up party's common stock or other securities by us or in connection with the termination of the lock-up party's employment with or service to us and (j) transfers of shares of common stock to a bona fide third-party pursuant to a merger, consolidation, tender offer or other similar transaction approved by our board of directors and made to all shareholders involving a change of control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph.

J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

Record holders of our securities are typically the parties to the lock-up agreements with the underwriters referred to above, while holders of beneficial interests in our shares who are not also record holders in respect of such shares are not typically subject to any such agreements or other similar restrictions. Accordingly, we believe that certain holders of beneficial interests who are not record holders could enter into transactions with respect to those beneficial interests that negatively impact our stock price. In addition, a shareholder who is not subject to a lock-up agreement with the underwriters may be able to sell, short sell, transfer, hedge, pledge, lend or otherwise dispose of or attempt to sell short sell, transfer, hedge, pledge, lend or otherwise dispose of, their equity interests at any time after the closing of this offering.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CERE."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchases common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on the Nasdaq Capital Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on Nasdaq no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

European economic area

In relation to each member state of the European Economic Area, no shares of our common stock have been offered or will be offered pursuant to the offering to the public in that member state prior to the publication of a prospectus in relation to the shares of our common stock which has been approved by the competent authority in that member state or, where appropriate, approved in another member state and notified to the competent authority in that member state, all in accordance with the Prospectus Regulation, except that offers of shares of the common stock may be made to the public in that member state at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of common stock shall require us or any underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation, and each person who initially acquires any common stock or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares of common stock being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares of common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any common stock to the public other than their offer or resale in a member state to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of common stock in any member state means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of our common stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

No shares of our common stock have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the common stock which is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provisions in Article 74 (transitional provisions) of the Prospectus Amendment etc. (EU Exit) Regulations 2019/1234, except that the shares of common stock may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of underwriters for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA.

provided that no such offer of the shares of common stock shall require the Company or any of the underwriters to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the Shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018. In addition, in the United Kingdom, this prospectus is being distributed

only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares of our common stock in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Switzerland

Shares of our common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to shares of our common stock or this offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to this offering, us or shares of our common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of shares of our common stock will not be supervised by, the Swiss Financial Market Supervisory Authority, and the offer of shares of our common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Dubai international financial centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this prospectus. The shares of our common stock to which this prospectus relates may be illiquid, subject to restrictions on their resale or illiquid and subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares of our common stock. If you do not understand the contents of this prospectus, you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the shares of our common stock may not be offered or sold directly or indirectly to the public in the DIFC.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document (including as defined in the Corporations Act 2001 (Cth), or Corporations Act), has been or will be lodged with the Australian Securities and Investments Commission, or ASIC, or any other governmental agency, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document for the purposes of Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act. No action has been taken which would permit an offering of the shares of our common stock in circumstances that would require disclosure under Parts 6D.2 or 7.9 of the Corporations Act.

The shares of our common stock may not be offered for sale, nor may application for the sale or purchase or any shares of our common stock be invited in Australia (including an offer or invitation which is received by a person in Australia) and neither this prospectus nor any other offering material or advertisement relating to the shares of our common stock may be distributed or published in Australia unless, in each case:

(a) the aggregate consideration payable on acceptance of the offer or invitation by each offeree or invitee is at least A$500,000 (or its equivalent in another currency, in either case, disregarding moneys lent by the person offering the shares of our common stock or making the invitation or its associates) or the offer or invitation otherwise does not require disclosure to investors in accordance with Part 6D.2 or 7.9 of the Corporations Act;

(b) the offer, invitation or distribution complied with the conditions of the Australian financial services license of the person making the offer, invitation or distribution or an applicable exemption from the requirement to hold such license;

(c) the offer, invitation or distribution complies with all applicable Australian laws, regulations and directives (including, without limitation, the licensing requirements set out in Chapter 7 of the Corporations Act);

(d) the offer or invitation does not constitute an offer or invitation to a person in Australia who is a “retail client” as defined for the purposes of Section 761G of the Corporations Act; and

(e) such action does not require any document to be lodged with ASIC or the ASX.

Canada

Shares of our common stock may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to Section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

Shares of our common stock have not been offered or sold and will not be offered or sold in Hong Kong by means of any document other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to shares of our common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

Singapore

Each book-running manager has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each book-running manager has represented and agreed that it has not offered or sold any shares of our common stock or caused the shares of our common stock to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares of our common stock or cause the shares of our common stock to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of our common stock, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(a) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or

(b) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Japan

Shares of our common stock have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares of common stock nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Legal matters

The validity of the shares of our common stock offered by this prospectus will be passed upon by Goodwin Procter LLP, Boston, Massachusetts. Ropes & Gray LLP, Boston, Massachusetts, is acting as counsel for the underwriters in connection with this offering.

Experts

The consolidated financial statements of Cerevel Therapeutics Holdings, Inc. at December 31, 2020 and 2019, and for each of the two years in the period ended December 31, 2020, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

Changes in registrant's certifying accountant

Dismissal of Previous Independent Registered Public Accounting Firm.

On November 20, 2020, the audit committee of our board of directors, or our Audit Committee, approved the dismissal of WithumSmith+Brown, PC, or Withum, as our independent registered public accounting firm, effective immediately.

The reports of Withum on the financial statements of ARYA (our legal predecessor) as of June 9, 2020 and for the period from February 20, 2020 (inception) through June 9, 2020 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles. During the period from February 20, 2020 (inception) through June 9, 2020 and the subsequent interim period, there were no (i) disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K) with Withum on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Withum, would have caused Withum to make reference to the subject matter of the disagreements in its reports on our consolidated financial statements, or (ii) "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K).

We have provided Withum with a copy of these disclosures and requested that Withum furnish a letter addressed to the SEC stating whether it agrees with the statements above, and, if not, stating the respects in which it does not agree. A copy of Withum's letter dated November 20, 2020 is filed as Exhibit 16.1 hereto.

Engagement of New Independent Registered Public Accounting Firm.

On November 20, 2020, our Audit Committee approved the engagement of Ernst & Young LLP, or E&Y, as our independent registered public accounting firm for the fiscal year ending December 31, 2020. That engagement was effective immediately.

During the period from February 20, 2020 (inception) through November 20, 2020, neither we nor anyone on our behalf consulted with E&Y regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and a written report or oral advice was provided to us that E&Y concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K or any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

Where you can find more information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. We have also filed a registration statement on Form S-1, including exhibits, under the Securities Act, with respect to the common stock offered by this prospectus. This prospectus is part of the registration statement, but does not contain all of the information included in the registration statement or the exhibits. Our SEC filings are available to the public on the internet at a website maintained by the SEC located at http://www.sec.gov.

We also maintain a website at http://www.cerevel.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Cerevel Therapeutics Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cerevel Therapeutics Holdings, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Boston, Massachusetts
March 24, 2021

CEREVEL THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts and per share data)

	As of December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 383,623	$ 79,551
Prepaid expenses and other current assets	6,937	7,526
Total current assets	390,560	87,077
Property and equipment, net	24,165	1,476
Operating lease assets	24,459	26,015
Restricted cash	4,200	4,131
Other long-term assets	1,889	2,107
Total assets	$ 445,273	$ 120,806
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,993	$ 2,109
Accrued expenses and other current liabilities	22,519	10,175
Operating lease liabilities, current portion	2,036	2,592
Total current liabilities	29,548	14,876
Operating lease liabilities, net of current portion	30,969	25,819
Other long-term liabilities	236	2,288
Total liabilities	60,753	42,983
Commitments and contingencies (Notes 10, 15 and 16)		
Stockholders' equity:		
Preferred Stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common Stock, $0.0001 par value: 500,000,000 shares authorized; 127,123,954 and 60,930,932 shares issued and outstanding as of December 31, 2020 and 2019, respectively	13	6
Additional paid-in capital	775,417	322,115
Accumulated deficit	(390,910)	(244,298)
Total stockholders' equity	384,520	77,823
Total liabilities and stockholders' equity	$ 445,273	$ 120,806

The accompanying notes are an integral part of these consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share amounts and per share data)

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Operating expenses:		
Research and development	$ 103,303	$ 50,294
General and administrative	45,813	33,169
Total operating expenses	149,116	83,463
Loss from operations	(149,116)	(83,463)
Interest income, net	224	1,552
Other income (expense), net	(3,274)	(46,433)
Loss before income taxes	(152,166)	(128,344)
Income tax benefit (provision), net	24	(45)
Net loss and comprehensive loss	$ (152,142)	$ (128,389)
Reconciliation of net loss attributable to common stockholders:		
Net loss	$ (152,142)	$ (128,389)
Benefit related to the redemption of Series A-1 redeemable convertible preferred stock at less than the carrying value	3,871	—
Net loss attributable to common stockholders	$ (148,271)	$ (128,389)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.01)	$ (2.90)
Weighted-average shares used in calculating net loss per share, basic and diluted	73,643,315	44,209,264

The accompanying notes are an integral part of these consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series A Common Stock		Common stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
Balance at December 31, 2018 (as previously reported)	6,900,000	$ 78,937	3,833,333	$ 98,132	4,600,000	$ —	—	$ —	$ 38,533	$ (115,909)	$ (77,376)
Retroactive application of the recapitalization due to the Business Combination Transaction (refer to Note 3)	(6,900,000)	(78,937)	(3,833,333)	(98,132)	(4,600,000)	—	43,761,799	4	177,065	—	177,069
Balance at December 31, 2018, effect of Business Combination Transaction (refer to Note 3)	—	$ —	—	$ —	—	$ —	43,761,799	$ 4	$ 215,598	$ (115,909)	$ 99,693
Issuance of Series A-1 preferred stock and Series A common stock and common stock in exchange for cash	—	—	—	—	—	—	17,140,593	2	60,056	—	60,058
Issuance of common stock under equity incentive plans	—	—	—	—	—	—	28,540	—	—	—	—
Partial settlement of Equity Commitment liability upon issuance of Series A-1 preferred stock and Series A common stock	—	—	—	—	—	—	—	—	38,150	—	38,150
Equity-based compensation expense	—	—	—	—	—	—	—	—	8,311	—	8,311
Net loss	—	—	—	—	—	—	—	—	—	(128,389)	(128,389)
Balance at December 31, 2019, effect of Business Combination Transaction (refer to Note 3)	—	$ —	—	$ —	—	$ —	60,930,932	$ 6	$ 322,115	$ (244,298)	$ 77,823
Issuance of Series A-1 preferred stock and Series A common stock in exchange for cash (refer to Note 3)	—	—	—	—	—	—	2,500,000	—	25,000	—	25,000
Partial settlement of Equity Commitment liability upon issuance of Series A-1 preferred stock and Series A common stock (refer to Note 3)	—	—	—	—	—	—	—	—	5,530	—	5,530
Redemption of Series A-1 preferred stock with exchange (refer to Note 3)	—	—	—	—	—	—	—	—	(3,871)	3,871	—
Redemption of Series A common stock with exchange (refer to Note 3)	—	—	—	—	—	—	—	—	(1,659)	1,659	—
Issuance of additional common stock related to anti-dilution provisions of Series A-2 preferred stock (refer to Note 3)	—	—	—	—	—	—	15,208,762	2	(2)	—	—
Issuance of common stock, net of offering costs upon Business Combination Transaction (refer to Note 3)	—	—	—	—	—	—	48,441,450	5	417,783	—	417,788
Issuance of common stock under equity incentive plans	—	—	—	—	—	—	42,810	—	—	—	—
Equity-based compensation expense	—	—	—	—	—	—	—	—	10,521	—	10,521
Net loss	—	—	—	—	—	—	—	—	—	(152,142)	(152,142)
Balance at December 31, 2020	—	$ —	—	$ —	—	$ —	127,123,954	$ 13	$ 775,417	$ (390,910)	$ 384,520

The accompanying notes are an integral part of these consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Cash flows from operating activities:		
Net loss	$ (152,142)	$ (128,389)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	397	177
Non-cash rent expense under operating leases	(88)	2,396
Equity-based compensation	10,521	8,311
Change in fair value of Equity Commitment	3,530	51,562
Change in fair value of Share Purchase Option	(260)	(5,120)
Write-off of deferred offering costs	2,533	—
Changes in operating assets and liabilities, net:		
Prepaid expenses and other current assets	78	(6,810)
Operating lease asset	(342)	—
Other assets	(715)	(1,372)
Accounts payable	1,417	607
Accrued expenses and other liabilities	10,690	7,918
Operating lease liability	6,579	—
Net cash flows used in operating activities	(117,802)	(70,720)
Cash flows from investing activities:		
Purchases of property and equipment	(18,892)	(1,099)
Net cash flows used in investing activities	(18,892)	(1,099)
Cash flows from financing activities:		
Proceeds from issuance of common and preferred stock, net of offering costs	—	60,058
Proceeds from Business Combination Transaction, net of offering costs paid (see Note 3)	442,617	—
Deferred costs related to abandoned initial public offering and other financing activities	(1,782)	—
Net cash flows provided by financing activities	440,835	60,058
Net increase (decrease) in cash, cash equivalents, and restricted cash	304,141	(11,761)
Cash, cash equivalents and restricted cash, beginning of the period	83,682	95,443
Cash, cash equivalents and restricted cash, end of the period	$ 387,823	$ 83,682
Non-cash operating, investing, and financing activities		
Fixed asset additions included in accounts payable and other current liabilities	$ 4,488	$ 463
Unpaid offering costs included in accounts payable and other current liabilities	$ 140	$ —
Operating lease assets obtained in exchange for operating lease liabilities	$ 445	$ 27,303
Settlement of Equity Commitment liability upon issuance of Series A-1 Preferred Stock and Series A Common Stock	$ 5,530	$ 38,150

The accompanying notes are an integral part of these consolidated financial statements.

CEREVEL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations

Unless the context otherwise requires, references in these notes to “Cerevel,” “the company,” “we,” “us” and “our” and any related terms are intended to mean Cerevel Therapeutics Holdings, Inc. and its consolidated subsidiaries.

We are a clinical-stage biopharmaceutical company pursuing a targeted approach to neuroscience that combines a deep understanding of disease-related biology and neurocircuitry of the brain with advanced chemistry and central nervous system, or CNS, target receptor selective pharmacology to discover and design new therapies. We seek to transform the lives of patients through the development of new therapies for neuroscience diseases, including schizophrenia, epilepsy and Parkinson’s disease.

Business Combination Transaction

On October 27, 2020, ARYA Sciences Acquisition Corp II (ARYA) completed the acquisition of Cerevel Therapeutics, Inc., a private company, pursuant to the Business Combination Agreement dated July 29, 2020, as amended on October 2, 2020.

ARYA was incorporated as a Cayman Islands exempted company on February 20, 2020, and was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses.

Cerevel Therapeutics, Inc. was incorporated in Delaware on July 23, 2018, referred to as Inception, under the name Perception Holdco, Inc. which was subsequently changed to Cerevel Therapeutics, Inc. on October 23, 2018.

Our principal operations commenced on September 24, 2018 (Formation Transaction Date), when Cerevel Therapeutics, Inc. (Old Cerevel) acquired licensed technology to a portfolio of pre-commercial neuroscience assets from Pfizer in exchange for the issuance of Series A-2 Preferred Stock of Old Cerevel and obtained a $350.0 million equity commitment, or the Equity Commitment, from Bain Investor, an affiliate of Bain Capital, to develop the in-licensed assets in exchange for the issuance of Series A-1 Preferred Stock and Series A Common Stock of Old Cerevel, which we refer to collectively as the Formation Transaction. Bain Investor also received the option to purchase up to an additional 10.0 million shares of Old Cerevel at $10.00 per share, subject to Pfizer’s participation rights (Share Purchase Option). On the Formation Transaction Date, we received an initial investment of $115.0 million in equity funding from Bain Investor to begin operations. During 2019 we received an additional investment of $60.1 million in equity funding from Bain Investor. Bain Investor contributed an additional $25.0 million in equity funding in July 2020 (the Additional Financing Shares).

Upon the closing of the Business Combination Transaction, Old Cerevel became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc and the Stock Purchase Agreement, the Equity Commitment and the Share Purchase Option related to Old Cerevel were terminated. Upon completion of the Business Combination Transaction, and pursuant to the terms of the Business Combination Agreement, the existing shareholders of Old Cerevel exchanged their interests for shares of common stock of Cerevel Therapeutics Holdings, Inc. (New Cerevel). Net proceeds from this transaction totaled approximately $439.5 million.

For additional information on the Business Combination Transaction and the Additional Financing Shares, please read Note 3, *Business Combination*, to these consolidated financial statements. For additional information on our license arrangement with Pfizer, please read Note 6, *Pfizer License Agreement*, to these consolidated

financial statements. For additional information on the Equity Commitment and the Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to these consolidated financial statements. For additional information on our Stockholders' Equity, please read Note 11, *Stockholders' Equity*, to these consolidated financial statements.

2. Risks and Liquidity

We are subject to risks and uncertainties common to clinical-stage companies in the biopharmaceutical industry. These risks include, but are not limited to, the introduction of new products, therapies, standards of care or new technological innovations, our ability to obtain and maintain adequate protection for our licensed technology, data or other intellectual property and proprietary rights and compliance with extensive government regulation and oversight. In addition, we are dependent upon the services of our employees, including key personnel, consultants, third-party contract research organizations and other third-party organizations.

Our product candidates, currently under development or that we may develop, will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities. There can be no assurance that our research and development activities will be successfully completed, that adequate protection for our licensed or developed technology will be obtained and maintained, that products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable.

Our consolidated financial statements have been prepared on the basis of continuity of operations, the realization of assets and the satisfaction of liabilities in the ordinary course of business. Since Inception, we have incurred significant operating losses and, as of December 31, 2020, we had an accumulated deficit of $390.9 million and had not yet generated revenues. We anticipate that our expenses will increase significantly in connection with our ongoing activities to support our research, discovery and clinical development efforts and we expect to continue to incur significant expenses and operating losses for the foreseeable future.

Prior to the Business Combination, our operations were funded primarily with the proceeds received from the issuance of convertible preferred stock, convertible common stock and common stock, as described above in Note 1, *Nature of Operations*. We believe that our available cash resources as of December 31, 2020, of $383.6 million will enable us to fund our operating expense and capital expenditure requirements at least up to the next twelve months from the issuance date of these financial statements. For additional information on the Business Combination Transaction, please read Note 3, *Business Combination*, to these consolidated financial statements.

Impact of the COVID-19 Pandemic

In March 2020 the World Health Organization declared the COVID-19 outbreak a pandemic. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

We are closely monitoring the impact of the pandemic of COVID-19 on all aspects of our business, including how it will impact our operations and the operations of our suppliers, vendors and business partners. We have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address this pandemic; however, the spread of COVID-19 has caused us to modify our business practices, including implementing a temporary work-from-home policy for all employees who are able to perform their duties remotely and temporarily restricting all non-essential travel and discouraged employee attendance at industry events and in-person work-related meetings. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of COVID-19.

More specifically, the onset of the COVID-19 pandemic caused brief pauses in patient screening and enrollment in our Phase 3 trials of tavapadon for the treatment of Parkinson's (which we subsequently resumed in the second half of 2020), and we remain particularly vigilant about patient safety given the elderly nature of this population. While we have taken measures to revise clinical trial protocols, the ultimate extent to which COVID-19 impacts our business, results of operation and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others.

In addition, recurrences or additional waves of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience prolonged business shutdowns or other disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operation and financial condition. The estimates of the impact on our business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

We have not incurred any significant impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our consolidated financial statements.

3. Business Combination

On October 27, 2020, ARYA completed the acquisition of Old Cerevel pursuant to the Business Combination Agreement with Old Cerevel surviving the merger as a wholly owned subsidiary of ARYA. Net proceeds from this transaction totaled approximately $439.5 million. These proceeds were comprised of funds held in ARYA's trust account and funds received from the completion of a concurrent private investment in public equity financing (PIPE Financing), which included the $25.0 million received from Bain Investor in July 2020 (the Additional Financing Shares).

Pursuant to the terms of the Business Combination Agreement, the existing shareholders of Old Cerevel exchanged their interests for shares of common stock of New Cerevel. In addition, ARYA issued public warrants and private placement warrants (collectively, the warrants) in its IPO in June 2020, and upon the consummation of the Business Combination Transaction, each outstanding warrant of ARYA become one warrant to purchase one share of New Cerevel. None of the terms of the warrants were modified as a result of the Business Combination Transaction. Immediately after giving effect to the Business Combination Transaction, there were 127,123,954 shares of common stock issued and outstanding and 5,149,647 warrants outstanding to purchase shares of common stock of New Cerevel.

We accounted for the Business Combination Transaction as a reverse recapitalization, which is the equivalent of Old Cerevel issuing stock for the net assets of ARYA, accompanied by a recapitalization, with ARYA treated as the acquired company for accounting purposes. The determination of ARYA as the "acquired" company for accounting purposes was primarily based on the fact that subsequent to the business combination, Cerevel has a majority of the voting power of the combined company, Cerevel will comprise all of the ongoing operations of the combined entity, a majority of the governing body of the combined company and Cerevel's senior management will comprise all of the senior management of the combined company. The net assets of ARYA were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Cerevel. The shares and corresponding capital amounts and loss per share related to Old Cerevel's outstanding redeemable convertible preferred stock, redeemable convertible common stock and common stock prior to the Business Combination

Transaction have been retroactively restated to reflect the exchange ratio established in the Business Combination Agreement (1.00 Old Cerevel share for 2.854 shares of New Cerevel), or the Exchange Ratio.

In connection with the Business Combination Transaction, we incurred underwriting fees and other costs considered direct and incremental to the transaction totaling $24.6 million, consisting of legal, accounting, financial advisory and other professional fees. These amounts are reflected within additional paid-in capital in our consolidated balance sheet as of December 31, 2020. In addition, upon completion of our Business Combination Transaction, we also paid the remaining management fees payable under the agreement with Bain Investor to provide management services (Management Agreement), of approximately $3.0 million, which have been reflected in general and administrative expense in our consolidated statement of operations along with other incremental costs not considered directly attributable to the Business Combination Transaction for the year ended December 31, 2020.

PIPE Financing (Private Placement)

Concurrent with the execution of the Business Combination Agreement, we entered into subscription agreements (the Subscription Agreements) with certain investors, including, among others, Perceptive Life Sciences Master Fund Ltd, a fund managed by Perceptive Advisors, an affiliate of ARYA, as well as certain equity holders of Cerevel, including Pfizer and Bain Investor (collectively, the PIPE Investors). Pursuant to the Subscription Agreements, on October 27, 2020, each PIPE Investor subscribed for and purchased, and we issued and sold to such investors an aggregate of 32,000,000 shares of ARYA Common Stock for a purchase price of $10.00 per share, for aggregate gross proceeds of $320.0 million (the PIPE Financing).

Additional Financing Shares

Pursuant to the Subscription Agreement entered into with the Bain Investor (the Bain Subscription Agreement), Bain Investor, pre-funded a portion of its subscription amount by purchasing equity securities of Cerevel prior to Closing, the proceeds of which were used to fund Cerevel's ongoing operations prior to completion of the Business Combination. In July 2020, Bain Investor pre-funded $25.0 million of its $100.0 million subscription amount in exchange for 1,750,000 Series A-1 Preferred Stock and 750,000 Series A Common Stock. The Additional Financing Shares contained a redemption feature whereby these shares were required to be redeemed for a number of newly issued shares identical to the shares issued in a private placement, including a private investment in public equity in connection with a business combination between the company and a special purpose acquisition company or a Series B financing, in an aggregate amount equal to $25.0 million divided by the per share price paid by the other purchasers.

Upon the closing of the Business Combination Transaction, which satisfied the condition allowing for redemption as described above, the Additional Financing Shares were exchanged for 2,500,000 shares of New Cerevel common stock at the fair value of the New Cerevel common stock on the Closing Date. As a result of this exchange, we recognized a decrease to accumulated deficit related to the difference between the initial carrying value of the shares issued of Old Cerevel in July and the fair value of New Cerevel common stock of $3.9 million and $1.7 million for the Series A-1 Preferred Stock and Series A Common Stock, respectively.

Summary of Net Proceeds

The following table summarizes the elements of the net proceeds from the Business Combination Transaction as of December 31, 2020:

(In thousands)		Recapitalization
Cash - ARYA Trust and cash (net of redemptions)	$	147,122
Cash - PIPE Financing (including proceeds from Bain Investor July Additional Financing Shares)		320,000
Less: Underwriting fees and other offering costs paid prior to year end		(24,505)
Proceeds from Business Combination Transaction, net of offering costs paid per the Cash Flows from Financing Activities	$	442,617
Less: Other offering costs included in accounts payable and other current liabilities		(140)
Less: Acceleration of Cerevel management fees paid to Bain Investor included in G&A expense		(2,984)
Net proceeds from the Business Combination Transaction	$	439,493

In addition to the net proceeds disclosed above, we also assumed $0.3 million of prepaid assets of ARYA upon closing of the Business Combination Transaction.

Summary of Shares Issued

The following table summarizes the number of shares of common stock outstanding immediately following the consummation of the Business Combination Transaction:

	Number of Shares
ARYA shares outstanding prior to the Business Combination Transaction	19,186,500
Less: redemption of ARYA shares prior to the Business Combination Transaction	(245,050)
Common stock of ARYA	18,941,450
Shares issued pursuant to the PIPE Financing (including Bain Investor July 2020 Additional Financing Shares)	32,000,000
Business Combination and PIPE Financing shares	50,941,450
Conversion of Old Cerevel Series A-1 preferred shares for common stock	31,701,214
Conversion of Old Cerevel Series A common stock for common stock	18,260,729
Conversion of Old Cerevel Series A-2 preferred shares for common stock	10,940,449
Issuance of additional common stock related to anti-dilution protections of Old Cerevel Series A-2 preferred shares	15,208,762
Conversion of Old Cerevel common stock under the equity incentive plans for common stock	71,350
Total shares of New Cerevel common stock outstanding immediately following the Business Combination Transaction	127,123,954

4. Summary of Significant Accounting Policies

The following is a summary of significant accounting policies followed in the preparation of these financial statements.

Basis of Presentation

The accompanying consolidated financial statements include those of the company and its subsidiaries, Cerevel Therapeutics Inc., Cerevel Therapeutics LLC and Cerevel MA Securities Corporation, after elimination

of all intercompany accounts and transactions. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”).

As a result of the Business Combination Transaction, the shares and corresponding capital amounts and loss per share related to Old Cerevel’s outstanding redeemable convertible preferred stock, redeemable convertible common stock and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the Exchange Ratio establish in the Business Combination Agreement.

For additional information on the Business Combination Transaction and the Exchange Ratio, please read Note 3, *Business Combination*, to these consolidated financial statements.

Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. Our CODM is our Chairperson of the Board of Directors and Chief Executive Officer. We have determined that we operate as a single operating segment and have one reportable segment. All of our long-lived assets are held in the United States.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the fair value of preferred and common stock, the fair value of the Equity Commitment, the fair value of the Share Purchase Option, the fair value of stock options, the recoverability of the Company’s net deferred tax assets and the related valuation allowance and our accruals for research and development expense. We evaluate our estimates and assumptions on an ongoing basis using historical experience and other factors and adjust those estimates and assumptions when facts and circumstances change. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

We consider all short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash equivalents. As of December 31, 2020 and 2019, our cash equivalents consist primarily of amounts invested in money market accounts.

Restricted Cash

In connection with our entering into the lease agreement for our headquarters in Cambridge, MA, in July 2019 we were required to provide a security deposit in the form of a letter of credit. We have classified this amount as restricted cash within our consolidated balance sheet as of December 31, 2020 and 2019. Restricted cash was classified as a non-current asset as the associated lease term expires more than 12 months from December 31, 2020.

A reconciliation of the cash, cash equivalents and restricted cash reported within our consolidated balance sheets that sum to the total of the amounts shown in the consolidated statements of cash flows is as follows:

(In thousands)	As of December 31, 2020	As of December 31, 2019
Cash and cash equivalents	$ 383,623	$ 79,551
Restricted cash	4,200	4,131
Total cash, cash equivalents and restricted cash	$ 387,823	$ 83,682

Concentration of Credit Risk

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. All of our cash deposits are maintained at a large, creditworthy financial institution. Our deposits at times may significantly exceed federally insured limits. We do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. We do not have any significant off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Purchased assets that are not yet in service are recorded to construction-in-process and no depreciation expense is recorded. Once the assets are placed in service, they are reclassified to the appropriate asset class.

Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

Asset Category	Estimated Useful Life
Computer equipment and software	3 years
Furniture and fixtures	5 years
Laboratory equipment	5 years
Leasehold improvements	Shorter of useful life or remaining lease term

Costs of major additions and improvements are capitalized and amortized on a straight-line basis over the shorter of the lease term or the estimated useful life of the asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in the determination of net income or loss. The cost of normal, recurring, or periodic repairs and maintenance activities are expensed as incurred.

Impairment of Long-Lived Assets

Our long-lived assets consist primarily of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that we consider in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, we compare forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to

its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, we have not recorded any impairment losses on long-lived assets.

Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, issued to increase transparency and comparability among organizations related to their leasing activities. This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and lease liabilities on their balance sheet that arise from leases as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. We adopted this standard effective at Inception.

We determine if an arrangement is a lease at contract inception. Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. We use the implicit rate when readily determinable and use our incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date of the respective leases in determining the present value of the lease payments. Our incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

The lease payments used to determine our operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized in our operating lease assets in our consolidated balance sheets.

Our operating leases are reflected in operating lease assets and operating lease liabilities, current portion and operating lease liabilities, net of current portion in our consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term and included in operating expenses in our consolidated statements of operations and comprehensive loss.

For additional information on the adoption of the new leasing standards, please read Note 10, *Leases*, to these consolidated financial statements.

Fair Value Measurements

Certain of our assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

Level 1	Quoted prices in active markets for identical assets or liabilities.
Level 2	Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in our consolidated balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values, due to their short-term nature. We believe that the carrying value of the Equity Commitment and Share Purchase Option approximated their fair value based on Level 3 inputs throughout 2020 until these instruments were terminated upon closing of the Business Combination Transaction.

Fair Value of Equity Commitment and Share Purchase Option

The Equity Commitment and Share Purchase Option were free-standing financial instruments that may have required us to transfer equity upon settlement or exercise, respectively, and were recorded at fair value on the Formation Transaction Date. The fair value of each financial instrument on the Formation Transaction Date was allocated to the Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series A Common Stock.

We revalued these financial instruments each reporting period until the Equity Commitment and Share Purchase Option were terminated upon completion of the Business Combination Transaction. Changes in fair value of the Equity Commitment and Share Purchase Option were recognized as a component of other income (expense), net in our consolidated statements of operations and comprehensive loss through their termination upon closing of the Business Combination Transaction. We classified the fair value of the remaining Equity Commitment and the Share Purchase Option as an asset or a liability in our consolidated balance sheets.

Changes in the fair value of these instruments resulted from changes to one or multiple inputs, including adjustments to the discount rates, expected volatility and dividend yield as well as changes in the amount and timing of the anticipated future funding required in settlement of the Equity Commitment and upon exercise of the Share Purchase Option and the fair value of our preferred and common shares expected to be exchanged for that additional funding. Immediately prior to the closing of the Business Combination Transaction, these financial instruments were adjusted to their final fair value of zero and were terminated upon Closing.

For additional information on the Business Combination Transaction, please read Note 3, *Business Combination*, to these consolidated financial statements. For additional information on the valuation methodology for the Equity Commitment and Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to these consolidated financial statements.

Offering Costs

We capitalize certain underwriting, legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' (deficit) equity as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in our consolidated statements of operations and comprehensive loss.

Revenues

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable, and collectability is reasonably assured. We are a clinical stage company and have had no revenues to date.

Research and Development Expense

Research and development expenses include costs incurred in connection with the preclinical and clinical development of our product candidates including employee-related expenses, consisting of salaries, benefits and equity-based compensation for personnel engaged in our research and development activities, fees paid to other entities that conduct certain research and development activities on our behalf, as well as certain indirect costs incurred in support of overall research and development activities including facilities, depreciation and technology expenses.

Payments we make for research and development services prior to the services being rendered are recorded as prepaid assets in our consolidated balance sheets and are expensed as the services are provided. We estimate and accrue the value of goods and services received from CROs and other third parties each reporting period based on estimates of the level of services performed and progress in the period when we have not received an invoice from such organizations. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. We reassess and adjust our accruals as actual costs become known or as additional information becomes available. Our historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses in our accompanying statement of operations and comprehensive loss.

Equity-Based Compensation

We determine the fair value of each award issued under our equity-based compensation plan on the date of grant. We recognize compensation expense for service-based awards on a straight-line basis over the requisite service period which generally approximates the vesting term. For service-based awards with performance or market conditions, we recognize compensation expense on a straight-line basis over the requisite service period for each separate vesting portion of the award, with the amount of compensation expense recognized at any date at least equaling the portion of the grant-date fair value of the award that is vested at that date. Equity-based compensation expense for awards with performance conditions are recognized to the extent we determine that the condition is considered probable to be met. We reassess the probability of achieving these performance conditions each reporting period until the date such conditions are settled. Cumulative adjustments are recorded each period to reflect the estimated outcome of the performance condition.

We elected to account prospectively for forfeitures as they occur rather than apply an estimated forfeiture rate to equity-based compensation expense. We classify equity-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s salary and related costs are classified or in which the award recipient’s service payments are classified, as applicable.

Determination of the Fair Value – Preferred and Common Stock

Prior to the completion of the Business Combination Transaction, given the absence of an active market for our common stock, we were required to estimate the fair value of the company’s common stock at the time of each grant of an equity-based award. We utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants’ Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, to estimate the fair value of our common stock. Each valuation methodology includes estimates and assumptions that require judgment. These estimates and assumptions included a number of objective and subjective factors in determining the value of our common stock at each grant date, including the following factors:

- prices paid for our convertible preferred stock and common stock, and the rights, preferences, and privileges associated with our convertible preferred stock and common stock;

- the progress of our research and development efforts, including the status of preclinical studies and planned clinical trials for our investigational medicines;
- our stage of development and projected growth;
- the fact that the grants of equity-based awards involved illiquid securities in a private company;
- the likelihood of achieving a liquidity event for the common stock underlying the equity-based awards, such as an initial public offering (IPO), given prevailing market conditions;
- the analysis of IPOs and the market performance of similar companies in the biotechnology and pharmaceutical industries;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors; and
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry.

We used a hybrid methodology that combines both an income approach and a market approach to estimate the business enterprise value and our total equity value to calculate the fair value of our preferred stock and common stock during 2019 and throughout 2020, until completion of the Business Combination Transaction. A probability-weighted discounted cash flow analysis was first prepared reflecting multiple scenarios for future outcomes associated with the acquired product candidates in order to estimate the cash flows associated with estimated liquidity events (i.e., an IPO). We also used a PWERM to determine the fair value of pre-IPO funding scenarios. We then used a market approach to estimate the value as of each potential date of liquidity, resulting in an estimate of the total equity value, including the value of planned future funding. The value of the preferred stock and common stock was then estimated using an option pricing method, allocating total equity value based on an assumed future liquidity date, the liquidation preference of the preferred stock and the assumed funding in each scenario. Each of these scenarios was probability-weighted based on the expected outcomes to arrive at a final estimated fair value per share of the common stock.

Subsequent to the closing of the Business Combination Transaction, our board of directors determines the fair value of each share of common stock underlying stock-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant.

We believe our methodologies are reasonable based upon our internal peer company analyses and further supported by transactions involving our preferred stock. If different assumptions had been made, equity-based compensation expense, consolidated net loss and consolidated net loss per share could have been significantly different.

Determination of Fair Value – Stock Option Awards

Subsequent to the closing of the Business Combination Transaction, we estimate the fair value of our stock option awards using the Black Scholes method utilizing the “simplified method,” for determining the expected life of the award, which is based on the mid-point between the vesting date and the end of the contractual term as all options granted after becoming a public entity will be granted “at-the-money.” We determine the volatility for options granted based on an analysis of reported data for a peer group of companies. The expected volatility of granted options has been determined using a weighted-average of the historical volatility measures of this peer group of companies. We will continue to apply this method until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The risk-free interest rate utilized in our calculations is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on our common stock.

Prior to the closing of the Business Combination Transaction, we estimated the fair value of the stock option awards on the date of grant using the option pricing method, which is a variant of an income approach. The

option pricing method was used given that a portion of the option awards have an exercise price that is considered to be “deeply out of the money,” The option pricing method incorporated the probability of the performance and market conditions being met and adjustments to the estimated life and value of the options to reflect the necessary growth in the common share value for such shares to become exercisable. Given that the common stock represented a non-marketable equity interest in a private enterprise, an adjustment was made to account for the lack of liquidity that a stockholder would experience. This adjustment is commonly referred to as a discount for lack of marketability.

As there was no public market for our common stock prior to the closing of the Business Combination Transaction, we determined the volatility for options granted based on an analysis of reported data for a peer group of companies. The expected volatility of granted options were determined using a weighted-average of the historical volatility measures of this peer group of companies. The expected life of options for these awards were determined by probability-weighting the calculated expected life of the option at each month the option was eligible to be at- or in-the-money to estimate the overall adjusted expected life. We did not utilize the “simplified method” to determine expected life as this method is not valid for options that are “deeply out of the money.” The risk-free interest rate utilized in our calculations is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and does not have current plans to pay any dividends on our common stock.

In June 2018, the FASB issued an ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This standard expanded the scope of ASC Topic 718, *Compensation—Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. Prior to the adoption of this standard, the measurement date for non-employee awards was generally the date the services are completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. We adopted this standard effective January 1, 2019. Upon adoption, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award.

For additional information on the assumptions used in determining the grant date fair value of equity-based awards granted, as well as a summary of the equity-based award activity under our equity-based compensation plans for the years ended December 31, 2020 and 2019, please read Note 12, *Equity-Based Compensation* to these consolidated financial statements.

Common Stock Warrants and Derivative Financial Instruments

We review any common stock purchase warrants and other freestanding derivative financial instruments at each balance sheet date and account for them based on an assessment of the specific terms of the instrument and applicable authoritative guidance in accordance with ASC 480, *Distinguishing Liabilities from Equity (ASC 480)*.

The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company’s own common stock and whether the warrant holders could potentially require “net cash settlement” in a circumstance outside of the Company’s control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

We classify freestanding derivative financial instruments that are indexed in our own stock as:

a) Equity if they (i) require physical settlement or net-share settlement, or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement), or

b) Assets or liabilities if they (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company’s control), or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement)

We assess classification of our common stock warrants and other freestanding derivatives at each reporting date to determine whether a change in classification is required. Warrants to purchase an aggregate of 5,149,666 shares were issued by ARYA as part of the units sold in its IPO in June 2020. We determined that our 4,983,314 outstanding public common stock purchase warrants satisfied the criteria for classification as equity instruments at December 31, 2020. Our 166,333 private placement warrants were determined to be immaterial as of December 31, 2020. For additional information related to our warrants, please read Note 11, *Stockholders' Equity*, to these consolidated financial statements.

Income Taxes

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in our tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax basis of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

We assess the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax benefit (provision), net. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertain tax positions recognized in the consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Income tax benefit (provision), net includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss is comprised of two components: net loss and other comprehensive loss, which includes other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. There were no items qualifying as other comprehensive loss; accordingly, comprehensive loss equaled total net loss for the years ended December 31, 2020 and 2019.

Net Loss per Share

We calculate earnings per share in accordance with ASC 260, *Earnings per Share*. The two-class method of computing earnings per share is required for entities that have participating securities. Under the two-class method, net income is allocated between ordinary shares and participating securities based on dividends declared (or accumulated) and participating rights in undistributed earnings as if all the earnings for the reporting period had been distributed.

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents.

Diluted net loss per share is calculated by adjusting the net loss of the company for cumulative preferred stock dividends. Diluted net loss per share is calculated by adjusting the weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. For purposes of the dilutive net loss per share applicable to common stockholders calculation, warrants, stock options and unvested restricted stock

are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share applicable to common stockholders, as their effect would be anti-dilutive due to the fact that we were in a net loss position for the periods presented; therefore, basic and diluted net loss per share applicable to common stockholders were the same for the period presented.

Subsequent Event Considerations

We consider events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. For additional information on our evaluation of subsequent events, please read Note 19, *Subsequent Events*, to these consolidated financial statements.

Emerging Growth Company Status

We are an “emerging growth company” (EGC), as defined in the Jumpstart Our Business Startups Act (JOBS Act) and we may choose to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. We may take advantage of these exemptions until the company is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for complying with new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions until we no longer qualify as an EGC.

5. Recent Accounting Guidance

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Financial Instruments

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (ASU 2017-11)*. Part I of this standard addresses complexities associated with the accounting for financial instruments that contain down-round features. Part II addresses the difficulty of navigating Topic 480, *Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities. We adopted this standard as of December 31, 2020. The adoption of this standard did not have a material impact to our consolidated financial statements.

Fair Value Measurements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (ASU 2018-13)*, which modifies the disclosure requirements on fair value measurements with respect to Level 3 rollforwards, timing of liquidation of investments in certain entities that calculate net asset value, and measurement uncertainty. We adopted this standard effective January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements.

Collaborative Arrangements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This standard clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales.

The amendments to ASU No. 2018-18 became effective for us effective January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements as we have had no transactions applicable to this guidance; however, the standard may impact how we account for certain business transactions in the future.

Credit Losses

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements (ASU 2016-13).* The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. We adopted this standard on January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements.

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes*. The standard simplifies various aspects of the income tax accounting guidance in Topic 740, including the elimination of exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. We adopted this standard effective January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements.

6. Pfizer License Agreement

In August 2018 we entered into the Pfizer License Agreement pursuant to which we were granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how to develop, manufacture and commercialize certain compounds and products, which currently constitute the entirety of our asset portfolio, in the field of treatment, prevention, diagnosis, control and maintenance of all diseases and disorders in humans, subject to the terms and conditions of the Pfizer License Agreement. Additionally, Pfizer has an exclusive right of first negotiation in the event that we seek to enter into any significant transaction with a third party with respect to a product either globally or in certain designated countries. Significant transactions include exclusive licenses, assignments, sales, exclusive co-promotion arrangements, and other transfers of all commercial rights to a product globally or in certain designated countries, as well as exclusive distribution agreements globally or in certain designated countries.

Under the Pfizer License Agreement, we are solely responsible for the development, manufacture, regulatory approval and commercialization of compounds and products in the field. We are also required to use commercially reasonable efforts to develop and seek regulatory approval for a product that contains or incorporates one of certain scheduled compounds to exert a therapeutic effect on certain targets in each of the

following countries: United Kingdom, Germany, France, Italy, Spain, China, Japan and the United States, each a major market country. We are also required to use commercially reasonable efforts to commercialize each such product, if approved, in each major market country in which regulatory approval for such product has been obtained.

As partial consideration for the licensed assets, we issued Pfizer 3,833,333.33 shares of Old Cerevel Series A-2 Preferred Stock with an estimated fair value of $100.4 million, or $26.20 per share. We also reimbursed Pfizer for $11.0 million of direct transaction costs related to the Pfizer License Agreement, bringing the total consideration to $111.4 million, which was recorded as a charge to research and development expense as these assets had not yet reached technological feasibility and held no alternative future use at the time of the Transaction. The fair value of the Series A-2 Preferred Stock was established using an income approach for the valuation of the company's business enterprise value at the Formation Transaction Date, and the option pricing method for the fair value of all shares subject to the Formation Transaction. Upon the closing of the Business Combination Transaction, Pfizer's 3,833,333.33 shares of Series A-2 Preferred Stock were converted into 26,149,211 shares of common stock after giving effect to the anti-dilution protections and the Exchange Ratio established by the Business Combination.

We accounted for the acquisition of the Pfizer License Agreement as an asset acquisition. The Pfizer License Agreement is limited to the intellectual property and rights to develop certain non-commercially approved compounds with no existing revenues and we did not acquire an organized workforce of Pfizer employees nor any third-party arrangements that constitute a substantive process capable of developing the compounds. The assets acquired were measured based on the fair value of the Series A-2 Preferred Stock issued to Pfizer and direct transaction costs of $11.0 million, as the fair value of the equity given was more readily determinable than the fair value of the assets received.

Under the terms of the Pfizer License Agreement, we are also required to make regulatory approval milestone payments to Pfizer, ranging from $7.5 million to $40.0 million, on a compound-by-compound basis, upon the first regulatory approval in the United States for the first product containing or comprised of a given compound, with the amount of the payments determined by which designated group the compound falls into and with each such group generally characterized by the compounds' stage of development. Each such regulatory approval milestone is payable only once per compound. If all of our disclosed product candidates currently under development are approved in the United States, the total aggregate amount of such regulatory approval milestones payable to Pfizer would be approximately $220.0 million. No regulatory approval milestone payments were made or became due during the years ended December 31, 2020 and 2019.

In addition, we are required to pay Pfizer commercial milestone payments up to an aggregate of $170.0 million per product, when aggregate net sales of products under the Pfizer License Agreement in a calendar year first reach various thresholds ranging from $500.0 million to $2.0 billion. Each commercial milestone payment is payable only once upon first achievement of the applicable commercial milestone. If all of our disclosed product candidates currently under development achieve all of the commercial milestones, the total aggregate amount of such commercial milestones payable to Pfizer would total approximately $1.7 billion. No Pfizer commercial milestone payments were made or became due during the year ended December 31, 2020 and 2019.

We are also required to pay Pfizer tiered royalties on the aggregate net sales, during each calendar year, determined on a product-by-product basis, with respect to products under the Pfizer License Agreement, at percentages ranging from the low-single to mid-teens, with the royalty rate determined by which designated group the applicable compound for such product falls into and with each such group generally characterized by the compounds' stage of development, and subject to certain royalty deductions for the expiration of patent, regulatory and data exclusivity, generic competition and third-party royalty payments as set forth in the Pfizer License Agreement. The royalty term expires, on a product-by-product and country-by-country basis, on the later of (1) expiration of all regulatory or data exclusivity for such product in such country, (2) the date upon which

the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the Pfizer License Agreement, a valid claim of the licensed patents and (3) 12 years following the first commercial sale of such product in such country. No royalty payments were made or became due in the years ended December 31, 2020 and 2019.

Pfizer can terminate the Pfizer License Agreement in its entirety upon a material breach by the company, subject to specified notice and cure provisions. However, if such material breach is with respect to one or more, but not all, products, targets or countries, Pfizer's right to terminate is only with respect to such products, targets or countries. Either party may terminate the Pfizer License Agreement in its entirety upon event of a bankruptcy, insolvency or other similar proceeding of the other party or a force majeure event that prohibits the other party from performing for a period of time. Absent early termination, the term of the Pfizer License Agreement will continue on a country-by-country basis and product-by-product basis, until the expiration of the royalty term for the country and the product. Upon Pfizer's termination of the Pfizer License Agreement for our material breach or either party's termination for bankruptcy, insolvency or other similar proceeding or force majeure, we would grant Pfizer an exclusive, sublicensable, royalty-free, worldwide, perpetual license under certain intellectual property we develop during the term of the Pfizer License Agreement.

7. Equity Commitment and Share Purchase Option

Equity Commitment

In connection with the Formation Transaction, we entered into a Stock Purchase Agreement with Pfizer and Bain Investor pursuant to which Bain Investor contributed $115.0 million in exchange for 6,900,000 shares of Old Cerevel Series A-1 Preferred Stock and 4,600,000 shares of Old Cerevel Series A Common Stock. Additionally, Bain Investor had the ability, pursuant to conditions set forth in more detail below, to purchase a combination of additional shares of Series A-1 Preferred Stock and Series A Common Stock at a price of $10.00 per share. The Stock Purchase Agreement, among other things, provided that if we had not received $350.0 million in aggregate gross cash proceeds in exchange for equity interests, which such amount includes the proceeds received in the initial financing and subsequent financings and is referred to as the Financing Threshold, by September 24, 2022, Bain Investor would have been required to purchase that amount of shares of our common stock such that the Financing Threshold would have been met;

- if any time, prior to the Financing Threshold having been met, our cash balance was equal to or less than $10.0 million, Bain Investor would have been required to purchase an amount of additional shares of our Series A-1 Preferred Stock and Series A Common Stock that allowed us to maintain a reasonable level of cash to fund our operations in accordance with the previously agreed development plan for at least six months; and
- until the time the Financing Threshold was met, Bain Investor had the right to purchase up to that amount of shares of Series A-1 Preferred Stock and Series A Common Stock at a purchase price of $10.00 per share that results in the Financing Threshold having been met.

In June 2019, pursuant to the Stock Purchase Agreement, Bain Investor contributed an additional $0.1 million in exchange for additional shares of Series A-1 Preferred Stock and shares of Series A Common Stock. In December 2019, pursuant to the Stock Purchase Agreement, Bain Investor contributed an additional $60.0 million in exchange for additional shares of Series A-1 Preferred Stock and shares of Series A Common Stock. In July 2020, pursuant to the Stock Purchase Agreement, Bain Investor contributed an additional $25.0 million in exchange for additional shares of Series A-1 Preferred Stock and shares of Series A Common Stock. As a result of these transactions, the remaining Equity Commitment as of September 30, 2020 was $149.9 million.

Upon closing of the Business Combination Transaction, the remaining Equity Commitment of $149.9 million was considered satisfied and the Equity Commitment liability was remeasured to its final fair value of zero.

Share Purchase Option

Under the terms of the Stock Purchase Agreement entered into in connection with the Formation Transaction, Bain Investor retained an option to purchase a combination of shares of Series A-1 Preferred Stock and Common Stock at $10.00 per share up to an aggregate amount of $100.0 million, exercisable any time after the Equity Commitment is fulfilled and prior to the earlier of the company completing an IPO or the company receiving aggregate cash proceeds of $450.0 million from the issuance of equity securities inclusive of any proceeds received pursuant to the Share Purchase Option. Pfizer has rights to participate in the purchase of shares of Series A-1 Preferred Stock and Series A Common Stock upon exercise of the Share Purchase Option; however, any such participation would not increase the number of shares available under the Share Purchase Option.

Upon closing of the Business Combination Transaction, the remaining Share Purchase Option liability was remeasured to its final fair value of zero.

Fair Value of Equity Commitment and Share Purchase Option

During 2020 and 2019, a hybrid methodology that combines both an income approach and a market approach was used to estimate the fair value of these financial instruments and incorporated a probability weighted expected return (PWERM) related to pre-IPO funding. As of December 31, 2019, and throughout 2020, until the Equity Commitment and Share Purchase Option were terminated upon completion of the Business Combination Transaction, these financial instruments were valued based upon a probability weighted-average of two separate models prepared following an income approach and a market approach. The fair value of the funding obligation under each model was estimated as the net present value of the anticipated future funding, reduced by the value of the additional shares of preferred and common stock that would be exchanged for future funding.

Discount rates in our valuation models represented a measure of the credit risk associated with settling the financial instruments. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on our common stock. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period.

The following table represents the key inputs used in the fair value calculation for the financial instruments:

	As of December 31,	
	2020	2019
Risk free interest rate	—	1.57% - 1.59%
Expected term (in years)	—	0.36 - 1.42
Expected volatility	—	105.0% - 135.0%
Expected dividend yield	—	0.0%
Fair value of Series A-1 Preferred Stock per share	$ —	$ 16.35
Fair value of Series A Common Stock per share	$ —	$ 16.35

8. Fair Value Measurements

The following table presents information about our financial assets and liabilities measured at fair value on a recurring basis and indicates the level of fair value hierarchy utilized to determine such fair values:

As of December 31, 2020 *(In thousands)*	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents—money market funds	$ 383,623	$ —	$ —	$ 383,623
Restricted cash—money market funds	4,200	—	—	4,200
Total Assets	$ 387,823	$ —	$ —	$ 387,823
Liabilities:				
Equity Commitment	$ —	$ —	$ —	$ —
Share Purchase Option	—	—	—	—
Total Liabilities	$ —	$ —	$ —	$ —

As of December 31, 2019 *(In thousands)*	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents—money market funds	$ 79,551	$ —	$ —	$ 79,551
Restricted cash—money market funds	4,131	—	—	4,131
Total Assets	$ 83,682	$ —	$ —	$ 83,682
Liabilities:				
Equity Commitment	$ —	$ —	$ (2,000)	$ (2,000)
Share Purchase Option	—	—	(260)	(260)
Total Liabilities	$ —	$ —	$ (2,260)	$ (2,260)

As described in Note 7, *Equity Commitment and Share Purchase Option*, to these consolidated financial statements, the Equity Commitment and Share Purchase Option represent the only Level 3 assets and liabilities carried at fair market value as of December 31, 2019. The fair value measurements of the Equity Commitment and Share Purchase Option were sensitive to changes in the unobservable inputs used to value the financial instruments. Changes in the estimated future funding dates or fair value of the company's stock could result in changes to the fair value of each financial instrument. There were no transfers between Level 1, Level 2 and Level 3 during the year ended December 31, 2020 and 2019.

An analysis of the changes in the Equity Commitment and Share Purchase Option are summarized as follows:

Equity Commitment (In thousands)	2020	2019
Beginning (liability) asset balance	$ (2,000)	$ 11,412
Change in fair value	(3,530)	(51,562)
Partial settlement of Equity Commitment liability upon issuance of Series A-1 Preferred Stock and Series A Common Stock	5,530	38,150
Ending asset (liability) balance	$ —	$ (2,000)

Share Purchase Option (In thousands)	2020	2019
Beginning liability balance	$ (260)	$ (5,380)
Change in fair value	260	5,120
Ending liability balance	$ —	$ (260)

9. Financial Statement Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
(In thousands)	2020	2019
Prepaid clinical trial services	$ 172	$ 4,421
Prepaid research and development expenses	1,650	1,876
Prepaid insurance	3,675	142
Other prepaid expenses	1,280	1,018
Other current assets	160	69
Prepaid expenses and other current assets	$ 6,937	$ 7,526

Property and Equipment, Net

Property and equipment, net consisted of the following:

	As of December 31,	
(In thousands)	2020	2019
Computer equipment	$ 96	$ 96
Furniture and fixtures	322	29
Laboratory equipment	101	—
Leasehold improvements	—	328
Construction-in-progress	23,728	1,205
Less: Accumulated depreciation	(82)	(182)
Property and equipment, net	$ 24,165	$ 1,476

Construction-in-progress primarily relates to the fit-out of our new headquarters in Cambridge, Massachusetts. Depreciation expense totaled $0.2 million for the years ended December 31, 2020 and 2019.

Other Long-Term Assets

Other long-term assets consisted of the following:

(In thousands)	As of December 31, 2020	As of December 31, 2019
Deferred expenses associated with financing activities	$ —	$ 1,485
Other prepaid expenses, net of current portion	1,389	—
Other	500	622
Other long-term assets	$ 1,889	$ 2,107

As of December 31, 2020, other prepaid expenses, net of current portion primarily consists of deposits paid under certain CRO agreements that will be held until the completion of the related clinical trials which are anticipated to end more than twelve months from the balance sheet date.

As of December 31, 2019, other long-term assets include approximately $1.5 million of deferred expenses for professional fees incurred directly associated with our previously anticipated IPO. In June 2020, upon signing of the term sheet for our Business Combination Transaction, we abandoned our previously anticipated IPO and other financing activities and wrote-off approximately $2.5 million deferred financing costs directly associated with those efforts.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	As of December 31, 2020	As of December 31, 2019
External research and development services	$ 8,893	$ 3,257
Accrued compensation and personnel costs	9,489	3,111
Accrued construction-in-progress	2,618	433
Accrued deferred expenses associated with financing activities	96	515
Professional fees and consulting services	1,150	2,785
Other	273	74
Accrued expenses and other current liabilities	$ 22,519	$ 10,175

Other Long-Term Liabilities

Other long-term liabilities consisted of the following:

(In thousands)	As of December 31, 2020	As of December 31, 2019
Equity Commitment liability	$ —	$ 2,000
Share Purchase Option liability	—	260
Other	236	28
Other long-term liabilities	$ 236	$ 2,288

Other Income (Expense), net

Other income (expense), net consisted of the following:

(In thousands)	As of December 31, 2020	As of December 31, 2019
Loss on fair value remeasurement of Equity Commitment	$ (3,530)	$ (51,562)
Gain on fair value remeasurement of Share Purchase Option	260	5,120
Other, net	(4)	9
Other income (expense), net	$ (3,274)	$ (46,433)

10. Leases

We lease certain office space and equipment. At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present. Leases with a term greater than one year are recognized on the balance sheet as operating lease assets, operating lease liabilities, current portion and operating lease liabilities, net of current portion. We have elected not to recognize leases with terms of one year or less on our balance sheets. We have also elected to account for the lease and non-lease components as a combined lease component for real estate leases. For non-real estate leases, the lease component and non-lease component will be accounted for as separate components, with the contract consideration being allocated based on the fair values of the components. Operating lease liabilities and their corresponding operating lease assets are recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In January 2019 we entered into an operating lease for office space at 131 Dartmouth Street, Boston, Massachusetts. The lease commenced in April 2019 and terminated on November 30, 2020.

In July 2019 we entered into an operating lease with a ten-year term located at 222 Jacobs Street, Cambridge Massachusetts. This space serves as our corporate headquarters and is comprised of office and laboratory space. Under the terms of the lease, we have the option to extend for two five-year terms and we have assessed whether to include the renewal periods as part of the lease term based on a variety of factors, such as the fair market value rental rate, the economic life of leasehold improvements, as well as the current and anticipated stages of the company at the inception and conclusion of the original lease term. The renewal options have been excluded from the lease term and will be reassessed, as necessary.

In September 2020 we amended the lease to add approximately 1,000 square feet to bring the total space to approximately 61,000 square feet. Operating leases are amortized over the lease term and included in costs and expenses in the consolidated statements of operations and comprehensive loss. Variable lease costs are recognized in costs and expenses in the consolidated statements of operations and comprehensive loss as incurred.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to our operating leases for the years ended December 31, 2020 and 2019:

(In thousands)	For the year ended December 31, 2020	For the year ended December 31, 2019
Lease cost(1)		
Operating lease cost	$ 6,132	$ 3,467
Total lease cost	$ 6,132	$ 3,467
Other information		
Operating cash flows used for operating leases	$ 6,044	$ 1,070
Weighted-average remaining lease term (in years)	9.17	9.76
Weighted-average discount rate	9.90%	9.85%

(1) Short-term lease costs and variable lease costs incurred for the years ended December 31, 2020 and 2019, were $1.5 million and $0.0 million, respectively.

As of December 31, 2020, future minimum commitments under our operating leases were as follows:

(In thousands)	As of December 31, 2020
Maturity of lease liabilities	
Fiscal year ended December 31, 2021	$ 5,737
Fiscal year ended December 31, 2022	5,918
Fiscal year ended December 31, 2023	6,096
Fiscal year ended December 31, 2024	6,289
Fiscal year ended December 31, 2025	6,457
Thereafter	29,084
Total future lease payments	$ 59,581
Less: Tenant improvement allowance receivable	(5,595)
Less: Effect of discounting	(20,981)
Present value of lease liabilities	$ 33,005

The following table summarizes the presentation of our operating leases in our consolidated balance sheets as of December 31, 2020 and 2019:

(In thousands)	As of December 31, 2020	As of December 31, 2019
Assets		
Operating lease assets	$ 24,459	$ 26,015
Total lease assets	$ 24,459	$ 26,015
Liabilities		
Current lease liabilities	$ 2,036	$ 2,592
Noncurrent lease liabilities	30,969	25,819
Total lease liabilities	$ 33,005	$ 28,411

11. Stockholders' Equity

The consolidated statement of stockholders' equity has been retroactively adjusted for all periods presented to reflect the Business Combination and reverse recapitalization as defined in Note 3, *Business Combination*.

Preferred Stock

Upon closing of the Business Combination Transaction, pursuant to the terms of the Amended and Restated Certificate of Incorporation, the Company authorized 10,000,000 shares of preferred stock with a par value $0.0001 per share. Our board of directors has the authority, without further action by the stockholders to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, voting, and other rights, preferences and privileges of the shares. There were no issued and outstanding shares of preferred stock as of December 31, 2020.

In connection with the closing of the Business Combination Transaction, all previously issued and outstanding Series A-1 Convertible Preferred Stock and Series A-2 Convertible Preferred Stock were exchanged for common stock in Cerevel pursuant to the Exchange Ratio established in the Business Combination Agreement, subject to certain anti-dilution protections related to the Series A-2 Convertible Preferred Stock and the redemption feature that was redeemed related to the July Additional Financing Shares issued to Bain Investor. All fractional shares were rounded down.

Common Stock

Pursuant to the terms of the Amended and Restated Certificate of Incorporation, we authorized 500,000,000 shares of common stock with a par value $0.0001. Immediately following closing of the Business Combination Transaction and as of December 31, 2020, there were 127,123,954 shares of common stock issued and outstanding.

As discussed in Note 3, *Business Combination*, we have retroactively adjusted the shares issued and outstanding prior to October 27, 2020 to give effect to the Exchange Ratio established in the Business Combination Agreement to determine the number of shares of common stock into which they were converted.

Voting

The holders of our common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there is no cumulative voting.

Dividends

Common stockholders are entitled to receive dividends whenever funds are legally available and when declared by the board of directors. No dividends have been declared to date.

Warrants

ARYA issued public warrants and private placement warrants (collectively, the warrants) in its Initial Public Offering in June 2020. Upon the consummation of the Business Combination Transaction each outstanding warrant of ARYA become one warrant to purchase one share of Cerevel Therapeutics Holdings, Inc. Pursuant to the agreement, no fractional warrants were issued upon separation of the units and only whole warrants will trade. If a holder would be entitled to receive a fractional warrant, we rounded down to the nearest whole number of warrants to be issued to the warrant holder. None of the terms of the warrants were modified as a result of the Business Combination Transaction. Immediately following the Business Combination and as of December 31, 2020, there were 4,983,314 public warrants and 166,333 private placement warrants outstanding.

These warrants will become exercisable beginning on June 9, 2021. Each whole warrant entitles the holder to purchase one share of common stock at an exercise price of $11.50 per share. The warrants will expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

12. Equity-Based Compensation

Equity-based Compensation Expense

The following table summarizes equity-based compensation expense included in our consolidated statements of operations and comprehensive loss:

(In thousands)	For the periods ended December 31, 2020	2019
Research and development	$ 3,239	$ 2,602
General and administrative	7,282	5,709
Total equity-based compensation expense included in total operating expense	$ 10,521	$ 8,311

Equity Incentive Plans

2018 Old Cerevel Equity Incentive Plan

Our 2018 Old Cerevel Equity Incentive Plan, as amended, (the 2018 Plan) provided for us to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, officers, directors, consultants and advisors. Under the 2018 Plan incentive stock options could only be granted to employees. The 2018 Plan was administered by the plan administrator, provided therein, which had discretionary authority, subject only to the express provisions of the 2018 Plan, to interpret the 2018 Plan; determine eligibility for and grant awards; determine form of settlement of awards (whether in cash, shares of stock, other property or a combination of the foregoing), determine, modify, or waive the terms and conditions of any award; prescribe forms, rules and procedures; and otherwise do all things necessary to carry out the purposes of the 2018 Plan. The exercise price of each award requiring exercise was 100% of the fair market value of stock subject to the award, determined as of the date of the grant, or such higher amount as the Administrator determined in connection with the grant, and the term of stock option was not greater than ten years. The vesting and other restrictions were determined at the discretion of the plan administrator. We generally grant equity-based awards with service, market and performance conditions. Upon completion of the Business Combination Transaction we ceased granting awards under the 2018 Plan and, as described below, all awards under the 2018 Plan were converted into awards under the 2020 New Cerevel Plan with the same terms and conditions.

Prior to the closing of the Business Combination Transaction, the number of stock options granted under our 2018 Plan represented the maximum Available Vesting Amount (defined below) number of shares eligible to vest. The Available Vesting Amount was equal to the number of shares subject to the stock option multiplied by an equity ratio of total capital received from investors (up to a maximum of $350.0 million) divided by $350.0 million. The total amount of shares for each award is capped at a specified maximum percentage of our fully diluted shares for each award, which for all awards, in total, represents 10% of our fully diluted shares at the point in time first $350 million of funding is achieved. Based on the terms of the awards, we concluded that such awards include both market and performance conditions. As a result of our Business Combination Transaction, the final Available Vesting Amount under our 2018 Plan was achieved due to the remaining Equity Commitment being satisfied by the funding obtained during the Business Combination and concurrent PIPE Financing, including investors other than the Bain Investor. The number of shares available to vest was reduced to be less than the maximum number of shares eligible if Bain Investor had funded the entire Equity Commitment. As such, we recorded the fair value of the stock options to account for the change in probability of

the performance condition in which Bain Investor satisfied part of the Equity Commitment and the Business Combination and PIPE Financing were considered to satisfy the remaining Equity Commitment by recording a cumulative catch-up adjustment as if the performance condition achieved had been applied since the grant date. Upon satisfaction of the performance condition 3,554,598 Old Cerevel options remained outstanding under the 2018 Plan.

2020 Old Cerevel Equity Incentive Plan

On July 27, 2020, our Board of Directors approved the 2020 Old Cerevel Equity Incentive Plan (the Old 2020 Plan), pursuant to which 355,888 shares of common stock were reserved for issuance. The vesting eligibility and administration of our Old 2020 Plan is substantially identical to our 2018 Plan. Upon completion of the Business Combination Transaction we ceased granting awards under the Old 2020 Plan and, as described below, all awards under the Old 2020 Plan were converted into awards under the New Cerevel 2020 Plan with the same terms and conditions. As of October 27, 2020, prior to the Business Combination Transaction, 337,792 Old Cerevel options remained outstanding under the Old 2020 Plan.

Conversion of Awards

Each Old Cerevel option from our 2018 Plan and Old 2020 Plan that was outstanding immediately prior to the Business Combination Transaction, whether vested or unvested, was converted into an option to purchase a number of shares of common stock (each such option, an “Exchanged Option”) equal to the product (rounded down to the nearest whole number) of (i) the number of shares of Old Cerevel common stock subject to such Old Cerevel option immediately prior to the Business Combination and (ii) the Exchange Ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (A) the exercise price per share of such Old Cerevel option immediately prior to the consummation of the Business Combination, divided by (B) the Exchange Ratio. Except as specifically provided in the Business Combination Agreement, following the Business Combination, each Exchanged Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Old Cerevel option immediately prior to the consummation of the Business Combination. All stock option activity was retroactively restated to reflect the Exchanged Options.

As of the Closing Date, the 3,554,598 options and 25,000 restricted stock units (“RSUs”) outstanding under the 2018 Plan were converted into 10,144,864 options and 71,350 RSUs upon completion of the Business Combination after effect of the Exchange Ratio. As of the Closing Date, the 337,792 stock options awards outstanding under the 2020 Plan were converted into 964,051 stock options upon completion of the Business Combination after effect of the Exchange Ratio. This effect of the Exchange Ratio has been retroactively adjusted throughout our consolidated financial statements.

New Cerevel 2020 Plan and ESPP

On October 27, 2020, our Board of Directors approved the 2020 New Cerevel Equity Incentive Plan (2020 Plan), pursuant to which 24,050,679 shares of common stock were reserved for issuance. As of December 31, 2020, 11,514,661 shares remain available for future issuance under the 2020 Plan. The 2020 Plan provides for New Cerevel to grant incentive stock options or nonqualified stock options for the purchase of common stock, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock Awards, cash-based awards, and dividend equivalent rights, to employees, officers, directors and consultants of New Cerevel. Incentive stock options may only be granted to employees. The 2020 Plan is administered by the plan administrator, provided therein, which has discretionary authority, subject only to the express provisions of the 2020 Plan, to interpret the 2020 Plan; determine eligibility for and grant awards; determine form of settlement of awards (whether in cash, shares of stock, other property or a combination of the foregoing), determine, modify, or waive the terms and conditions of any award; prescribe forms, rules and procedures; and otherwise do all things necessary to carry out the purposes of the 2020 Plan.

At a special meeting of stockholders held on October 26, 2020, stockholders considered and approved the Cerevel Therapeutics Holdings, Inc. Employee Stock Purchase Plan (the ESPP). The ESPP provides employees with an opportunity to acquire shares of common stock at a discounted price. An aggregate of 1,655,924 shares were initially reserved and available for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2021, by 1.0% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser amount as determined by our board of directors; provided that the total number of shares of common stock that become available for issuance under the ESPP will never exceed 16,559,240. If our capital structure changes because of a stock dividend, stock split or similar event, the number of shares that can be issued under the ESPP will be appropriately adjusted. No awards were granted under the ESPP as of December 31, 2020.

Stock Options

Stock options granted to employees under our plans generally vest, if at all, as follows: 25% will vest on the first anniversary of the vesting start date, with the remaining 75% to vest ratably in 36 equal monthly installments thereafter until the award fully vests upon the fourth anniversary of the vesting start date. The vesting of these awards is generally contingent upon the respective grantee's continued employment.

Stock options granted to our non-employee directors vest, if at all, in 36 monthly installments through the third anniversary of the grant date.

The assumptions that we used to determine the fair value of stock options granted to employees and directors were as follows, presented on a weighted average basis:

	For the periods ended December 31,	
	2020	2019
Risk free interest rate	0.76%	2.10%
Expected term (in years)	6.13	6.23
Expected volatility	99.1%	81.1%
Expected dividend yield	0.0%	0.0%

The following table summarizes our stock option activity as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life *(in years)*	Aggregate Intrinsic Value *(in thousands)*
Outstanding at December 31, 2019	14,261,340	$ 5.20	9.49	$ 23,768
Granted	3,370,353	9.92		
Exercised	—	—		
Forfeited	(236,057)	6.80		
Canceled due to achievement of performance condition	(4,930,968)	5.40		
Outstanding at December 31, 2020	12,464,668	$ 6.37	8.57	$ 127,301
Options exercisable as of December 31, 2020	4,250,006	$ 5.20	8.18	$ 48,377

The aggregate intrinsic value represents the difference between the closing stock price of our common stock and the exercise price of in-the-money options. Our closing stock price as reported on NASDAQ as of December 31, 2020 was $16.58.

Stock options granted in 2020 and 2019, on an as-converted basis based upon the Exchange Ratio, had weighted average grant-date fair values of $6.12 and $4.91, respectively. No stock options were exercised during the years ended December 31, 2020 and 2019.

As of December 31, 2020 and 2019, total unrecognized equity-based compensation expense relating to stock options was $22.7 million and $16.6 million, respectively. This amount is expected to be recognized over a weighted average period of 3.0 years and 1.6 years, respectively.

Restricted Stock Units

Restricted stock unit awards granted under the Plan generally vest in three equal annual installments beginning on the first anniversary of the vesting start date.

The following table summarizes our restricted stock activity as follows:

	Restricted Stock Units	
	Number of Units	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2019	114,160	$ 2.00
Granted	—	—
Vested	(42,810)	1.97
Forfeited	—	—
Non-vested at December 31, 2020	71,350	$ 2.02

The total fair value of restricted stock units that vested was $0.1 million for the years ended December 31, 2020 and 2019.

As of December 31, 2020 and 2019, total unrecognized equity-based compensation expense relating to restricted stock unit awards was $0.1 million and $0.2 million, respectively. This amount is expected to be recognized over a weighted average period of 1.2 years and 2.2 years, respectively.

13. Net Loss Per Share

As a result of the Business Combination Transaction, the Company has retroactively restated the weighted average shares outstanding prior to October 27, 2020 to give effect to the Exchange Ratio.

The following table sets forth the computation of the basic and diluted net loss per share:

(In thousands, except share amounts and per share data)	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Numerator:		
Net loss	$ (152,142)	$ (128,389)
Benefit related to the redemption of Series A-1 redeemable convertible preferred stock at less than the carrying value	3,871	—
Net loss attributable to common stockholders	$ (148,271)	$ (128,389)
Denominator:		
Weighted-average shares used in calculating net loss per share, basic and diluted	73,643,315	44,209,264
Net loss per share attributable to common stockholders, basic and diluted	$ (2.01)	$ (2.90)

Our net loss in our loss per share calculation in the table above was adjusted to derive net loss attributable to common stockholders reflecting the benefit related to the redemption of the outstanding Series A-1 redeemable convertible preferred stock at less than carrying value which was treated as a return from the preferred stockholder. A redemption of Series A redeemable common stock for an amount less than the carrying value also took place in 2020; however, we did not recognize the benefit for contributions from redeemable common stock at less than carrying value as income was not allocated to such common stock under two-class method. As such, the redemption of the Series A redeemable common stock at less than carrying value did not impact our numerator in our net loss per share calculation.

Since we were in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share as the inclusion of all potential dilutive securities would have been anti-dilutive. The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock or two class methods, due to their anti-dilutive effect:

	As of December 31, 2020	As of December 31, 2019
Stock options outstanding	12,464,668	14,261,340
Restricted stock units outstanding	71,350	114,160
Warrants	5,149,647	—
Shares to be issued upon settlement of remaining Equity Commitment	—	49,929,121
Shares to be issued upon exercise of Share Purchase Option	—	28,540,304
Total	17,685,665	92,844,925

14. Income Taxes

A reconciliation of our provision for income tax expenses computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Statutory tax rate	21.0%	21.0%
State tax expense, net of federal benefit	5.7%	4.0%
Executive compensation	(1.1)%	—
Non-deductible fair value adjustment	(0.5)%	(7.5)%
Other non-deductible expenses	—	(0.1)%
Tax credits	2.6%	1.3%
Other	0.2%	—
Valuation allowance	(27.9)%	(18.7)%
Effective tax rate	0.0%	0.0%

Current and Deferred Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of our deferred tax assets and liabilities are summarized as follows:

(In thousands)	As of December 31, 2020	As of December 31, 2019
Deferred tax assets		
Net operating loss carryforwards	$ 57,949	$ 22,086
Operating lease liabilities	8,895	7,697
Tax credits	6,217	1,819
Equity-based compensation	2,983	2,236
Accruals and reserves	2,361	720
Amortization	736	862
Other deferred tax assets	—	33
Total gross deferred tax assets	79,141	35,453
Valuation allowance	(68,970)	(26,447)
Total deferred tax assets	10,171	9,006
Deferred tax liabilities		
Depreciation	(1,772)	—
Operating lease assets	(6,592)	(7,014)
Prepaid expenses	(1,809)	(2,020)
Total deferred tax liabilities	(10,173)	(9,034)
Net deferred income tax assets (liabilities)	$ (2)	$ (28)

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2020 and 2019, because we believe that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately $42.5 million and $24.0 million during the years ended December 31, 2020 and 2019, respectively. The increases were primarily as a result of the increase in our unbenefited net operating loss and tax credits for both periods.

Significant components of deferred income tax assets and liabilities include temporary differences related to net operating loss carryforwards, lease liabilities, stock compensation, and tax credits. Deferred income tax assets in the table above include approximately $213.9 million of federal net operating loss carryforwards, all of which have an indefinite carryforward period. The deferred tax assets also include approximately $206.2 million of state net operating loss carryforwards which begin to expire in 2038 through 2040. The Company also had federal and state research and development tax credits of $5.7 million and $0.7 million, respectively, which expire at various dates through 2040 for federal purposes and 2035 for state purposes. Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

For financial reporting purposes, loss before income taxes includes $152.2 million and $128.3 million for the years ended December 31, 2020 and 2019, respectively. We have no foreign operations and as such, the pretax loss is generated entirely in the United States.

The income tax (benefit) provision consists of the following:

(In thousands)	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Current tax expense		
Federal	$ —	$ —
State	2	17
Foreign	—	—
Deferred tax expenses		
Federal	(26)	28
State	—	—
Foreign	—	—
Income tax (benefit) provision, net	$ (24)	$ 45

As of December 31, 2020 and 2019, we had no unrecognized tax benefits. As of December 31, 2020 and 2019, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our consolidated statements of operations.

We will recognize interest and penalties related to uncertain tax positions in income tax expense. For the years ended December 31, 2020 and 2019, we generated research credits but have not conducted a study to document the qualified activities. This study may result in an adjustment to our research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against our research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

We file income tax returns in the U.S. federal tax jurisdiction and state jurisdictions. Our initial tax return period for U.S. federal income taxes was the 2018 period and we currently remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for all periods since Inception.

15. Legal Proceedings

We, from time to time, may be party to litigation arising in the ordinary course of business. We were not subject to any material legal proceedings during the years ended December 31, 2020, or 2019, and, to the best of our knowledge, no material legal proceedings are currently pending or threatened.

16. Commitments and Contingencies

As of December 31, 2020, we have several ongoing clinical studies in various clinical trial stages. Our most significant contracts relate to agreements with CROs for clinical trials and preclinical studies and clinical manufacturing organizations (CMOs), which we enter into in the normal course of business. The contracts with CROs and CMOs are generally cancellable, with notice, at our option.

Guarantees and Indemnification Obligations

We enter into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, we indemnify and agree to reimburse the indemnified party for losses and costs incurred by the

indemnified party in connection with any patent, copyright, trade secret or other intellectual property or personal right infringement claim by any third party with respect to our technology. The term of these indemnification agreements is generally perpetual after execution of the agreement. In addition, we have entered into indemnification agreements with members of our board of directors that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of its status or service as directors or officers. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited. To date, we have not incurred any losses or any material costs related to this indemnification obligation and no claims with respect thereto were outstanding. We do not believe that the outcome of any claims under indemnification arrangements will have a material effect on our financial position, results of operations and cash flows, and we have not accrued any liabilities related to such obligations in our consolidated financial statements as of December 31, 2020 or 2019.

17. Employee Benefit Plans

401(k) Savings Plan

In April 2019 we implemented a 401(k) Savings Plan, which is available to substantially all regular employees in the U.S. over the age of 21. Participants may make voluntary contributions. We make matching contributions according to the 401(k) Savings Plan's matching formula. All matching contributions and participant contributions vest immediately. The expense related to our 401(k) Savings Plan primarily consists of our matching contributions.

Expense related to our 401(k) Savings Plan for the years ended December 31, 2020 and 2019, was $1.4 million and $0.4 million, respectively.

18. Related Party Transactions

As of December 31, 2020, Pfizer held 27,349,211 shares of common stock and had appointed two members to our board of directors. As of December 31, 2019, after the retroactive impact of the Business Combination Transaction, Pfizer held 10,940,449 shares of common stock and had appointed two members to our board of directors. For additional information on our license agreement with Pfizer, please read Note 6, *Pfizer License Agreement*, to these consolidated financial statements.

As of December 31, 2020, Bain Investor held 60,632,356 shares of common stock and had appointed four members to our Board of Directors. As of December 31, 2019, after the retroactive impact of the Business Combination Transaction, Bain Investor held 49,961,943 shares of common stock and had appointed three members to our board of directors.

Management Agreement

In connection with the initial financing, on the Formation Transaction Date, we entered into an agreement with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP, which are entities related to Bain Investor, whereby such entities will provide certain management services to us for a fee of $1.0 million per year, paid in quarterly, non-refundable installments (Management Agreement).

This agreement obligated to pay such entities, in the aggregate, a $5.0 million fee upon the completion of a qualified public offering or change of control transaction, less any quarterly fees previously paid to such entities. Upon completion of our Business Combination Transaction, described in Note 3, *Business Combination*, of our audited consolidated financial statements, we paid the remaining approximately $3.0 million of management fees payable under the Management Agreement and no additional fees remain payable pursuant to this agreement. Inclusive of this final payment made under the Management Agreement, we incurred management fees to Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP totaling $3.8 million and $1.0 million during the years ended December 31, 2020 and 2019, respectively.

Following the closing of the Business Combination, we entered into a new management agreement with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP providing for the expense reimbursement and indemnification of such entities.

19. Subsequent Events

We have completed an evaluation of all subsequent events after the audited balance sheet date of December 31, 2020 through March 24, 2021, the issuance date of these financial statements, to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements as of December 31, 2020, and events which occurred subsequently but were not recognized in the consolidated financial statements. We have concluded that no subsequent events have occurred that require disclosure, except as already disclosed within these consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts and per share data)
(Unaudited)

	As of	
	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 343,287	$ 383,623
Prepaid expenses and other current assets	6,524	6,937
Total current assets	349,811	390,560
Property and equipment, net	27,597	24,165
Operating lease assets	24,187	24,459
Restricted cash	4,200	4,200
Other long-term assets	2,309	1,889
Total assets	$ 408,104	$ 445,273
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,755	$ 4,993
Accrued expenses and other current liabilities	24,257	22,519
Operating lease liabilities, current portion	2,139	2,036
Total current liabilities	34,151	29,548
Operating lease liabilities, net of current portion	32,952	30,969
Other long-term liabilities	965	236
Total liabilities	68,068	60,753
Commitments and contingencies (Notes 11 and 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value: 500,000,000 shares authorized; 127,325,116 and 127,123,954 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	781,914	775,417
Accumulated deficit	(441,891)	(390,910)
Total stockholders' equity	340,036	384,520
Total liabilities and stockholders' equity	$ 408,104	$ 445,273

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share amounts and per share data)
(Unaudited)

	For the Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 36,561	$ 26,959
General and administrative	14,010	10,743
Total operating expenses	50,571	37,702
Loss from operations	(50,571)	(37,702)
Interest income, net	15	204
Other income (expense), net	(425)	(15,710)
Loss before income taxes	(50,981)	(53,208)
Income tax benefit (provision), net	—	—
Net loss and comprehensive loss	$ (50,981)	$ (53,208)
Net loss per share, basic and diluted	$ (0.40)	$ (0.87)
Weighted-average shares used in calculating net loss per share, basic and diluted	127,225,535	60,944,732

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY(1)
(In thousands, except share amounts)
(Unaudited)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2020	127,123,954	$ 13	$ 775,417	$ (390,910)	$ 384,520
Issuance of common stock under equity incentive plans related to vesting of RSUs	14,270	—	—	—	—
Issuance of common stock under equity incentive plans related to exercise of options	186,892		742		742
Reclassification of private placement warrants from equity to other long-term liabilities	—	—	(305)	—	(305)
Equity-based compensation expense	—	—	6,060	—	6,060
Net loss	—	—	—	(50,981)	(50,981)
Balance at March 31, 2021	127,325,116	$ 13	$ 781,914	$ (441,891)	$ 340,036

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2019	60,930,932	$ 6	$ 322,115	$ (244,298)	$ 77,823
Issuance of common stock under equity incentive plans related to vesting of RSUs	14,270	—	—	—	—
Equity-based compensation expense	—	—	2,970	—	2,970
Net loss	—	—	—	(53,208)	(53,208)
Balance at March 31, 2020	60,945,202	$ 6	$ 325,085	$ (297,506)	$ 27,585

(1) Historical share and capital amounts were retroactively restated for reverse recapitalization as described in Note 1, *Nature of Operations*.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	For the Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (50,981)	$ (53,208)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	63	95
Non-cash rent expense under operating leases	(184)	508
Equity-based compensation	6,137	2,970
Change in fair value of Equity Commitment and Share Purchase Option	—	15,710
Change in fair value of private placement warrants	424	—
Changes in operating assets and liabilities, net:		
Prepaid expenses and other current assets	426	940
Operating lease asset	(14)	(459)
Other assets	3	(1,167)
Accounts payable	3,176	4,806
Accrued expenses and other liabilities	1,975	351
Operating lease liability	2,557	—
Net cash flows used in operating activities	(36,418)	(29,454)
Cash flows from investing activities:		
Purchases of property and equipment	(4,660)	(2,556)
Net cash flows used in investing activities	(4,660)	(2,556)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	742	—
Net cash flows provided by financing activities	742	—
Net decrease in cash, cash equivalents and restricted cash	(40,336)	(32,010)
Cash, cash equivalents and restricted cash, beginning of the period	387,823	83,682
Cash, cash equivalents and restricted cash, end of the period	$ 347,487	$ 51,672
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 343,287	$ 47,541
Restricted cash	4,200	4,131
Total cash, cash equivalents and restricted cash	$ 347,487	$ 51,672
Supplemental cash flow disclosures from non-cash operating, investing, and financing activities:		
Fixed asset additions included in accounts payable and other current liabilities	$ 3,252	$ 3,357
Deferred unpaid transaction costs related to financing activities	$ 461	$ 1,047

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of Operations

Unless the context otherwise requires, references in these notes to “Cerevel,” “the company,” “we,” “us” and “our” and any related terms are intended to mean Cerevel Therapeutics Holdings, Inc. and its consolidated subsidiaries.

We are a clinical-stage biopharmaceutical company pursuing a targeted approach to neuroscience that combines a deep understanding of disease-related biology and neurocircuitry of the brain with advanced chemistry and central nervous system, or CNS, target receptor selective pharmacology to discover and design new therapies. We seek to transform the lives of patients through the development of new therapies for neuroscience diseases, including schizophrenia, epilepsy and Parkinson’s disease.

On October 27, 2020, ARYA Sciences Acquisition Corp II (ARYA) completed the acquisition of Cerevel Therapeutics, Inc. (Old Cerevel), a private company and our predecessor, pursuant to the Business Combination Agreement dated July 29, 2020, as amended on October 2, 2020 (Business Combination Agreement). ARYA was incorporated as a Cayman Islands exempted company on February 20, 2020, and was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. Cerevel Therapeutics, Inc. was incorporated in Delaware on July 23, 2018, under the name Perception Holdco, Inc., which was subsequently changed to Cerevel Therapeutics, Inc. on October 23, 2018.

Our principal operations commenced on September 24, 2018 (Formation Transaction Date), when Old Cerevel licensed technology to a portfolio of pre-commercial neuroscience assets from Pfizer Inc. (Pfizer) in exchange for the issuance of Series A-2 Preferred Stock of Old Cerevel and obtained a $350.0 million equity commitment (the Equity Commitment), from BC Perception Holdings, LP (Bain Investor), an affiliate of Bain Capital, to develop the in-licensed assets in exchange for the issuance of Series A-1 Preferred Stock and Series A Common Stock of Old Cerevel. Bain Investor also received the option to purchase up to an additional 10.0 million shares of Old Cerevel at $10.00 per share, subject to Pfizer’s participation rights (the Share Purchase Option). On the Formation Transaction Date, we received an initial investment of $115.0 million in equity funding from Bain Investor to begin operations. During 2019 we received an additional investment of $60.1 million in equity funding from Bain Investor. Bain Investor contributed an additional $25.0 million in equity funding in July 2020 (the Additional Financing Shares).

Upon the closing of the transactions contemplated by the Business Combination Agreement (the Business Combination or the Business Combination Transaction), Old Cerevel became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc. and the Equity Commitment and the Share Purchase Option related to Old Cerevel were terminated. Upon completion of the Business Combination Transaction, and pursuant to the terms of the Business Combination Agreement, the existing shareholders of Old Cerevel exchanged their interests for shares of common stock of Cerevel Therapeutics Holdings, Inc. (New Cerevel). Net proceeds from this transaction totaled approximately $439.5 million.

We accounted for the Business Combination Transaction as a reverse recapitalization which is the equivalent of Old Cerevel issuing stock for the net assets of ARYA, with ARYA treated as the acquired company for accounting purposes. The net assets of ARYA were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Cerevel. The shares and corresponding capital amounts and loss per share related to Old Cerevel’s outstanding redeemable convertible preferred stock, redeemable convertible common stock, and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the exchange ratio (the Exchange Ratio) established in the Business Combination Agreement (1.00 share of Old Cerevel for 2.854 shares of New Cerevel).

For additional information on the Business Combination Transaction and the Additional Financing Shares, please read Note 3, *Business Combination*, to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 (our Annual Report). For additional information on our license arrangement with Pfizer, please read Note 6, *Pfizer License Agreement*, to our audited consolidated financial statements included in our Annual Report. For additional information on the Equity Commitment and the Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included in our Annual Report.

2. Risks and Liquidity

We are subject to risks and uncertainties common to clinical-stage companies in the biopharmaceutical industry. These risks include, but are not limited to, the introduction of new products, therapies, standards of care or new technological innovations, our ability to obtain and maintain adequate protection for our licensed technology, data or other intellectual property and proprietary rights and compliance with extensive government regulation and oversight. In addition, we are dependent upon the services of our employees, including key personnel, consultants, third-party contract research organizations and other third-party organizations.

Our product candidates, currently under development or that we may develop, will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities. There can be no assurance that our research and development activities will be successfully completed, that adequate protection for our licensed or developed technology will be obtained and maintained, that products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable.

Our consolidated financial statements have been prepared on the basis of continuity of operations, the realization of assets and the satisfaction of liabilities in the ordinary course of business. Since our inception, we have incurred significant operating losses and, as of March 31, 2021, had an accumulated deficit of $441.9 million and had not yet generated revenues. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities to support our research, discovery and clinical development efforts and we expect to continue to incur significant expenses and operating losses for the foreseeable future.

Prior to the Business Combination Transaction, our operations were funded primarily from the issuance of convertible preferred stock, convertible common stock and common stock. Upon the closing of the Business Combination Transaction in October 2020, we received net proceeds totaling approximately $439.5 million, as described above in Note 1, *Nature of Operations*. We believe that our available cash resources as of March 31, 2021, of $343.3 million will enable us to fund our operating expense and capital expenditure requirements through at least twelve months from the issuance date of these financial statements.

Impact of the COVID-19 Pandemic

We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business, including how it will impact our operations and the operations of our customers, suppliers, vendors and business partners. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy and we cannot presently predict the scope and severity of any potential business shutdowns or disruptions. We have not incurred any significant impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that could have a material adverse impact on our business, results of operations and financial condition. The extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence. The estimates of the impact on our business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include those of the company and its subsidiaries, Cerevel Therapeutics Inc., Cerevel Therapeutics LLC and Cerevel MA Securities Corporation, after elimination of all intercompany accounts and transactions. The accompanying unaudited condensed consolidated financial statements and notes hereto have been prepared in conformity with the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting and, therefore, omit or condense certain footnotes and other information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) as set forth in the Financial Accounting Standards Board's (FASB) accounting standards codification. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the FASB.

In the opinion of management, all adjustments necessary for a fair statement of the financial information, which are of a normal and recurring nature, have been made for the interim periods reported. Results of operations for the three months ended March 31, 2021 and 2020, are not necessarily indicative of the results for the entire fiscal year or any other period. The condensed consolidated financial statements for the three months ended March 31, 2021 and 2020, have been prepared on the same basis as and should be read in conjunction with the audited consolidated financial statements and notes included in our Annual Report.

As a result of the Business Combination Transaction, the shares and corresponding capital amounts and loss per share related to Old Cerevel's outstanding redeemable convertible preferred stock, redeemable convertible common stock and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the Exchange Ratio established in the Business Combination Agreement. For additional information on the Business Combination Transaction and the Exchange Ratio, please read Note 3, *Business Combination*, to our audited consolidated financial statements included in our Annual Report.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to, the fair value of the Equity Commitment and Share Purchase Option, the fair value of stock options, the recoverability of our net deferred tax assets and the related valuation allowance and the accrual for research and development expense. The impact on accounting estimates and judgments on our financial condition and results of operations due to COVID-19 has introduced additional uncertainties. We evaluate our estimates and assumptions on an ongoing basis using historical experience and other factors and adjust those estimates and assumptions when facts and circumstances change. Actual results could differ materially from those estimates.

Restricted Cash

In connection with our entering into the lease agreement for our headquarters in Cambridge, MA, in July 2019 we were required to provide a security deposit in the form of a letter of credit. We have classified this amount as restricted cash within our consolidated balance sheet as of March 31, 2021 and December 31, 2020.

Common Stock Warrants and Derivative Financial Instruments

We review any common stock purchase warrants and other freestanding derivative financial instruments at each balance sheet date and account for them based on an assessment of the specific terms of the instrument and applicable authoritative guidance in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480).

Our assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

We classify freestanding derivative financial instruments that are indexed in our own stock as:

a) Equity if they (i) require physical settlement or net-share settlement, or (ii) give the company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement), or

b) Assets or liabilities if they (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the company's control), or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement)

We assess classification of our common stock warrants and other freestanding derivatives at each reporting date to determine whether a change in classification is required. Warrants to purchase an aggregate of 5,149,666 shares were issued by ARYA as part of the units sold in its IPO in June 2020. We determined that our 4,983,314 outstanding public warrants satisfied the criteria for classification as equity instruments as of March 31, 2021, and December 31, 2020, respectively.

We determined our 166,333 private placement warrants were immaterial as of December 31, 2020. In certain circumstances, the identity of the holder may result in different settlement amounts, and therefore our private placement warrants are not considered indexed in our own stock in the manner contemplated by ASC Section 815-40-15. Accordingly, we reclassified our private placement warrants as long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021.

Emerging Growth Company Status

We are an "emerging growth company" (EGC), as defined in the Jumpstart Our Business Startups Act (JOBS Act) and we may choose to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. We may take advantage of these exemptions until the company is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for complying with new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions until we no longer qualify as an EGC.

For additional information related to our other significant accounting policies, please read Note 4, *Summary of Significant Accounting Policies*, to our audited consolidated financial statements included in our Annual Report.

Recent Accounting Guidance

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the company as of the specified effective date. Unless otherwise discussed, the company believes that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Collaborative Arrangements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This standard clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. We adopted this standard on January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements as we have had no transactions applicable to this guidance; however, the standard may impact how we account for certain business transactions in the future.

Credit Losses

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements (ASU 2016-13).* The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. We adopted this standard on January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements.

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes*. The standard simplifies various aspects of the income tax accounting guidance in Topic 740, including the elimination of exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. We adopted this standard effective January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements.

4. Pfizer License Agreement

In August 2018, we entered into a license agreement with Pfizer (the Pfizer License Agreement) pursuant to which we were granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how to develop, manufacture and commercialize certain compounds and products, which currently constitute the entirety of our asset portfolio, subject to the terms and conditions of the Pfizer License Agreement.

Under the Pfizer License Agreement, we are solely responsible for the development, manufacture, regulatory approval and commercialization of compounds and products in the field and we will pay Pfizer tiered royalties on the aggregate net sales during each calendar year, determined on a product-by-product basis, with respect to products under the Pfizer License Agreement, and we may pay potential milestone payments to Pfizer, based on the successful achievement of certain regulatory and commercial milestones. To date, no regulatory or commercial approval milestone payments or royalty payments were made or became due under this agreement.

For additional information on our Pfizer License Agreement, please read Note 6, *Pfizer License Agreement*, to our audited consolidated financial statements included in our Annual Report.

5. Fair Value Measurements

The following table presents information about our financial assets and liabilities measured at fair value on a recurring basis and indicates the level of fair value hierarchy utilized to determine such fair values:

As of March 31, 2021 *(In thousands)*	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents—money market funds	$ 343,287	$ —	$ —	$ 343,287
Restricted cash—money market funds	4,200	—	—	4,200
Total Assets	$ 347,487	$ —	$ —	$ 347,487
Liabilities:				
Private placement warrants	$ —	$ —	$ 729	$ 729
Total Liabilities	$ —	$ —	$ 729	$ 729

As of December 31, 2020 *(In thousands)*	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents—money market funds	$ 383,623	$ —	$ —	$ 383,623
Restricted cash—money market funds	4,200	—	—	4,200
Total Assets	$ 387,823	$ —	$ —	$ 387,823
Liabilities:				
Private placement warrants	$ —	$ —	$ —	$ —
Total Liabilities	$ —	$ —	$ —	$ —

There have been no impairments of our assets measured and carried at fair value during the three months ended March 31, 2021. In addition, there were no changes in valuation techniques, inputs utilized or transfers between fair measurement levels in the periods presented.

The carrying amounts reflected in our condensed consolidated balance sheets for our cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair value due to the short-term nature of these assets and liabilities.

The private placement warrants represent the only Level 3 assets and liabilities carried at fair market value as of March 31, 2021. The fair value measurement of the private placement warrants is sensitive to changes in the unobservable inputs used to value the financial instrument. Changes in the inputs could result in changes to the fair value of each financial instrument.

The following table provides a roll forward of the liability associated with our private placement warrants:

(In thousands)	Amount
Liability, December 31, 2020	$ —
Reclassification from equity	(305)
Change in fair value	(424)
Liability, March 31, 2021	$ (729)

We reclassified our private placement warrants from equity to other long-term liabilities as of March 31, 2021. Our estimate of the fair value of our private placement warrant liability was determined through a binomial lattice model utilizing a discount rate of 0.80%, an expected volatility implied by the market price of the public warrants of 37.7%, an expected dividend yield of 0% and the fair values of our common stock and public warrants as of March 31, 2021.

6. Financial Statement Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Prepaid clinical trial services	$ 807	$ 172
Prepaid research and development expenses	1,433	1,650
Prepaid insurance	2,678	3,675
Other prepaid expenses	1,444	1,280
Other current assets	162	160
Prepaid expenses and other current assets	$ 6,524	$ 6,937

Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Computer equipment	$ 881	$ 96
Furniture and fixtures	322	322
Laboratory equipment	545	101
Construction in progress	25,941	23,728
Less: Accumulated depreciation	(92)	(82)
Property and equipment, net	$ 27,597	$ 24,165

Construction-in-progress primarily relates to the build-out of our headquarters in Cambridge, Massachusetts.

Other Long-Term Assets

Other long-term assets consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Deferred expenses associated with financing activities	$ 461	$ —
Other prepaid expenses, net of current portion	1,363	1,389
Other	485	500
Other long-term assets	$ 2,309	$ 1,889

As of March 31, 2021 and December 31, 2020, other prepaid expenses, net of current portion, primarily consists of deposits paid under certain clinical research organization (CRO) agreements that will be held until the completion of the related clinical trials which are anticipated to end more than twelve months from the balance sheet date.

Deferred expenses associated with financing activities as of March 31, 2021, are comprised of costs incurred with third parties directly related to the Funding Agreements described in Note 14, *Subsequent Events*.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	As of	
(In thousands)	March 31, 2021	December 31, 2020
External research and development services	$ 16,002	$ 8,893
Accrued compensation and personnel costs	4,483	9,489
Accrued construction-in-progress	1,930	2,618
Accrued deferred expenses associated with financing activities	424	96
Professional fees and consulting services	1,263	1,150
Other	155	273
Accrued expenses and other current liabilities	$ 24,257	$ 22,519

Other Long-Term Liabilities

Other long-term liabilities consisted of the following:

	As of	
(In thousands)	March 31, 2021	December 31, 2020
Private placement warrants	$ 729	$ —
Other	236	236
Other long-term liabilities	$ 965	$ 236

Other Income (Expense), net

Other income (expense), net consisted of the following:

	For the Three Months Ended March 31,	
(In thousands)	2021	2020
Loss on fair value remeasurement of Equity Commitment	$ —	$ (15,760)
Gain on fair value remeasurement of Share Purchase Option	—	50
Loss on fair value remeasurement of private placement warrants	(424)	—
Other, net	(1)	—
Other income (expense), net	$ (425)	$ (15,710)

The Equity Commitment and Share Purchase Option were free-standing financial instruments that were recorded at fair value on the Formation Transaction Date. We revalued these financial instruments each reporting period and classified the fair value of the remaining Equity Commitment and the Share Purchase Option as an asset or a liability in our condensed consolidated balance sheets through their termination. We recognized the changes in fair value of the Equity Commitment and Share Purchase Option as a component of other income (expense), net in our condensed consolidated statements of operations and comprehensive loss.

For additional information on the Equity Commitment and Share Purchase Option and their related valuation, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included in our Annual Report.

7. Stockholders' Equity

The condensed consolidated statement of stockholders' equity has been retroactively adjusted for all periods presented to reflect the Business Combination and reverse recapitalization as discussed in Note 3, *Summary of Significant Accounting Policies.*

Preferred Stock

Upon closing of the Business Combination Transaction, pursuant to the terms of our Certificate of Incorporation, we authorized 10,000,000 shares of preferred stock with a par value of $0.0001 per share. Our board of directors has the authority, without further action by our stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, voting, and other rights, preferences and privileges of the shares. There were no issued and outstanding shares of preferred stock as of March 31, 2021 and December 31, 2020.

Common Stock

Pursuant to the terms of our Certificate of Incorporation, we authorized 500,000,000 shares of common stock with a par value of $0.0001 per share. There were 127,325,116 and 127,123,954 shares of common stock issued and outstanding as of March 31, 2021 and December 31, 2020, respectively.

Voting

The holders of our common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there is no cumulative voting.

Dividends

Common stockholders are entitled to receive dividends whenever funds are legally available and when declared by the board of directors. No dividends have been declared to date.

Warrants

ARYA issued public warrants and private placement warrants (collectively, the warrants) in its Initial Public Offering in June 2020. Upon the consummation of the Business Combination Transaction each outstanding warrant of ARYA become one warrant to purchase one share of Cerevel Therapeutics Holdings, Inc. Pursuant to the agreement, no fractional warrants were issued upon separation of the units and only whole warrants will trade. If a holder would be entitled to receive a fractional warrant, we rounded down to the nearest whole number of warrants to be issued to the warrant holder. None of the terms of the warrants were modified as a result of the Business Combination Transaction.

As of March 31, 2021 and December 31, 2020, we determined that our 4,983,314 public warrants outstanding satisfied the criteria for classification as equity instruments in our condensed consolidated balance sheet.

As of March 31, 2021 and December 31, 2020, there were 166,333 private placement warrants outstanding. The fair value of our private placement warrants as of March 31, 2021, totaled approximately $0.7 million. We reclassified our private placement warrants from equity to other long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021. Upon establishment of this liability, we reclassified approximately $0.3 million from additional paid-in capital and recognized a charge of approximately $0.4 million to other income (expense), net, resulting from the change in fair value of these warrants. We did not recognize a liability in relation to our private placement warrants prior to March 31, 2021, as we previously determined that the fair value of these warrants was immaterial.

The warrants will become exercisable beginning on June 9, 2021. Each whole warrant entitles the holder to purchase one share of common stock at an exercise price of $11.50 per share. The warrants will expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

8. Equity-Based Compensation

Equity-based Compensation Expense

The following table summarizes equity-based compensation expense included in our condensed consolidated statements of operations and comprehensive loss:

In thousands	For the Three Months Ended March 31, 2021	For the Three Months Ended March 31, 2020
Research and development	$ 1,797	$ 910
General and administrative	4,340	2,060
Total equity-based compensation expense included in total operating expense	$ 6,137	$ 2,970

The following table summarizes equity-based compensation expense by award type included in our condensed consolidated statements of operations and comprehensive loss:

In thousands	For the Three Months Ended March 31, 2021	For the Three Months Ended March 31, 2020
Stock options	$ 6,038	$ 2,948
Restricted stock units	22	22
Employee stock purchase plan	77	—
Total equity-based compensation expense included in total operating expense	$ 6,137	$ 2,970

Stock Options

The following table summarizes our stock option activity for the three months ended March 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life *(in years)*	Aggregate Intrinsic Value *(in thousands)*
Outstanding at December 31, 2020	12,464,668	$ 6.37	8.57	$ 127,301
Granted	4,423,523	$ 12.87		
Exercised	(186,892)	$ 3.97		
Forfeited	(617,107)	$ 7.02		
Outstanding at March 31, 2021	16,084,192	$ 8.14	8.48	$ 90,771
Options exercisable as of March 31, 2021	4,805,971	$ 5.36	7.59	$ 40,249

The aggregate intrinsic value represents the difference between the closing stock price of our common stock and the exercise price of in-the-money options. Our closing stock price as reported on Nasdaq as of March 31, 2021, was $13.73.

As of March 31, 2021, total unrecognized equity-based compensation expense relating to stock options was $60.0 million. This amount is expected to be recognized over a weighted average period of 3.5 years.

Stock options granted during the three months ended March 31, 2021, include awards granted in conjunction with our annual awards made in February 2021.

The weighted-average assumptions that we used to determine the fair value of stock options granted to employees and directors are summarized as follows:

	For the Three Months Ended March 31,	
	2021	2020
Risk free interest rate	0.65%	1.56%
Expected term (in years)	6.07	6.01
Expected volatility	95.0%	105.0%
Expected dividend yield	0.0%	0.0%
Weighted-average grant date fair value	$ 9.81	$ 2.54

9. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share:

(In thousands, except share amounts and per share data)	For the Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss	$ (50,981)	$ (53,208)
Denominator:		
Weighted-average shares used in calculating net loss per share, basic and diluted	127,225,535	60,944,732
Net loss per share, basic and diluted	$ (0.40)	$ (0.87)

Since we were in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share as the inclusion of all potential dilutive securities would have been anti-dilutive. The shares in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	As of	
	March 31, 2021	March 31, 2020
Stock options outstanding	16,084,192	14,922,159
Restricted stock units outstanding	57,080	99,890
Warrants outstanding	5,149,647	—
ESPP shares issuable	17,921	—
Shares to be issued upon settlement of remaining Equity Commitment	—	49,929,121
Shares to be issued upon exercise of Share Purchase Option	—	28,540,304
Total	21,308,840	93,491,474

10. Income Taxes

For the three months ended March 31, 2021 and 2020, we did not record income tax benefits for net operating losses incurred or for the research and development tax credits generated in each period due to the uncertainty of realizing a benefit from those items.

We have evaluated the positive and negative evidence bearing upon our ability to realize our deferred tax assets, which primarily consist of net operating loss carryforwards and research and development tax credits. We have considered our history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and have concluded that it is more likely than not that we will not realize the benefits of our deferred tax assets. As a result, as of March 31, 2021 and December 31, 2020, we have recorded a full valuation allowance against our net deferred tax assets.

11. Legal Proceedings

We, from time to time, may be party to litigation arising in the ordinary course of business. We were not subject to any material legal proceedings as of March 31, 2021, or December 31, 2020, and, to the best of our knowledge, no material legal proceedings are currently pending or threatened.

12. Commitments and Contingencies

As of March 31, 2021, we have several ongoing clinical studies in various clinical trial stages. Our most significant contracts relate to agreements with CROs for clinical trials and preclinical studies and contract manufacturing organizations (CMOs) for the manufacturing of drug substance, which we enter into in the normal course of business. The contracts with CROs and CMOs are generally cancellable, with notice, at our option.

Guarantees and Indemnification Obligations

We enter into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, we indemnify and agree to reimburse the indemnified party for losses and costs incurred by the indemnified party in connection with any patent, copyright, trade secret or other intellectual property or personal right infringement claim by any third party with respect to our technology. The term of these indemnification agreements is generally perpetual after execution of the agreement. In addition, we have entered into indemnification agreements with members of our board of directors and our executive officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments we could be

required to make under these indemnification agreements is unlimited. To date, we have not incurred any losses or any material costs related to these indemnification obligations and no claims with respect thereto were outstanding. We do not believe that the outcome of any claims under indemnification arrangements will have a material effect on our financial position, results of operations and cash flows, and we have not accrued any liabilities related to such obligations in our condensed consolidated financial statements as of March 31, 2021 and December 31, 2020.

13. Related Parties

As of March 31, 2021, and December 31, 2020, Pfizer held 27,349,211 shares of common stock and had nominated two members to our board of directors. For additional information on our license agreement with Pfizer, please read Note 4, *Pfizer License Agreement*, to these condensed consolidated financial statements.

As of March 31, 2021, and December 31, 2020, Bain Investor held 60,632,356 shares of common stock and had nominated four members to our board of directors.

Management Agreement

Following the closing of the Business Combination, we entered into a new management agreement with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP providing for the expense reimbursement and indemnification of such entities.

14. Subsequent Events

We have completed an evaluation of all subsequent events after the unaudited balance sheet date of March 31, 2021, through May 17, 2021, the issuance date of these financial statements, to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the condensed consolidated financial statements as of March 31, 2021, and events which occurred subsequently but were not recognized in the condensed consolidated financial statements. We have concluded that no subsequent events other than the following have occurred that require disclosure:

Funding Agreements

On April 12, 2021 (the Effective Date), we entered into a funding agreement with NovaQuest Co-Investment Fund XVI, L.P. (NovaQuest and the NovaQuest Funding Agreement) and a funding agreement with BC Pinnacle Holdings, LP (Bain, the Bain Funding Agreement and, together with the NovaQuest Funding Agreement, the Funding Agreements), pursuant to which NovaQuest and Bain will provide funding to support our development of tavapadon for the treatment of Parkinson’s disease.

Pursuant to the Funding Agreements, we will receive up to $62.5 million in funding from each of NovaQuest and Bain, for a combined total of up to $125 million in funding (the Total Funding Commitment), of which approximately $31.3 million (25% of the Total Funding Commitment) was received within 10 business days of the Effective Date, and $37.5 million (30% of the Total Funding Commitment), approximately $31.3 million (25% of the Total Funding Commitment) and $25.0 million (20% of the Total Funding Commitment) will be received on the first, second and third anniversaries of the Effective Date, respectively, subject to certain customary funding conditions.

In return, we agreed to pay to NovaQuest and Bain (1) upon approval of tavapadon by the FDA, a combined $187.5 million (1.5x of the Total Funding Commitment) (the Approval Milestone Payment), with 50% of the Approval Milestone Payment due within 30 days of FDA approval and 12.5% of the Approval Milestone Payment due on each of the first four anniversaries of FDA approval, (2) upon first reaching certain cumulative U.S. net sales thresholds, certain sales milestone payments and (3) combined tiered, mid-single digit to low-double digit royalties on annual net sales of tavapadon in the U.S.

At the time that NovaQuest and Bain collectively receive an aggregate of approximately $531.3 million (4.25x of the Total Funding Commitment), our payment obligations under the Funding Agreements will be fully satisfied. We have the option to satisfy our payment obligations to NovaQuest and Bain upon the earlier of FDA approval or May 1, 2025 by paying an amount equal to the Total Funding Commitment multiplied by a certain factor (which will initially be 3.00x and will increase over time to a maximum of 4.25x), less amounts previously paid to NovaQuest and Bain.

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14,000,000 shares

Common stock

PROSPECTUS

J.P. Morgan **Goldman Sachs & Co. LLC** **Jefferies** **Stifel**

Co-Managers

Loop Capital Markets **Siebert Williams Shank**

July 1, 2021