UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-39311

CEREVEL THERAPEUTICS HOLDINGS, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**85-3911080**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
222 Jacobs Street, Suite 200 Cambridge, MA	**02141**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (844) 304-2048

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**CERE**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of shares of the Registrant's common stock on The Nasdaq Stock Market LLC on June 30, 2023, was $2.2 billion.

The number of shares of Registrant's common stock outstanding as of February 15, 2024 was 181,576,482.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 are incorporated by reference into Part I of this Annual Report on Form 10-K to the extent stated herein.

The Registrant intends to file either (i) a definitive proxy statement pursuant to Regulation 14A relating to the 2024 Annual Meeting of Stockholders, or (ii) an amendment to this Annual Report on Form 10-K/A, in either case within 120 days of the end of the Registrant's fiscal year ended December 31, 2023. Portions of such definitive proxy statement, if applicable, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

INTRODUCTORY NOTE

On December 6, 2023, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with AbbVie Inc., a Delaware corporation, or AbbVie, Symphony Harlan LLC, a Delaware limited liability company and a wholly owned subsidiary of AbbVie, or Intermediate Holdco, and Symphony Harlan Merger Sub Inc., a Delaware corporation and a direct wholly owned subsidiary of Intermediate Holdco, or Merger Sub, pursuant to which, and on the terms and subject to the conditions thereof, at the effective time of the Merger, or the Effective Time, Merger Sub will merge with and into Cerevel, with Cerevel surviving as a wholly owned subsidiary of AbbVie, which we refer to as the Merger.

Under the terms of the transaction, among other things, AbbVie will acquire all outstanding shares of Cerevel for $45.00 per share in cash. The transaction values Cerevel at a total equity value of approximately $8.8 billion. The boards of directors of both companies have approved the transaction. This transaction is expected to close in the middle of 2024, subject to Cerevel stockholder approval, regulatory approvals and other customary closing conditions.

The foregoing description of the Merger Agreement and the transactions contemplated thereunder is not complete and is qualified in its entirety by reference to the Merger Agreement, a copy of which is filed as an exhibit to the Current Report on Form 8-K, filed with the SEC on December 7, 2023, and incorporated herein by reference.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K, or this Annual Report, may constitute “forward-looking statements” for purposes of the federal securities laws, including the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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,” “can,” “target,” “future” or the negative of these terms or 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 Annual Report may include, for example, statements about:

- the structure, timing and ability to consummate the Merger;
- any anticipated effects of the Merger’s announcement, pendency or completion on the value of our common stock;
- our or AbbVie’s ability to obtain any required regulatory or stockholder approvals in connection with the Merger;
- any potential future costs or benefits of the Merger, including relating to expenses, restrictions on the conduct of our business, diversion of our management’s attention, ability to retain or hire employees, maintenance of relationships with collaborators, vendors and other business partners and payment of termination fees;
- the outcome of any legal proceedings that have been or may be instituted against us and others relating to the Merger;
- the format, objectives, likelihood of success, cost and timing of our clinical trials and other product development activities, including the design of clinical trials and preclinical studies, the timing of initiation and completion of clinical trials and related preparatory work, our ability to collect and interpret clinical trial data and the timing and outcome of regulatory interactions, including whether trials meet the criteria to serve as registrational;
- 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 on 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 available financial resources will enable us 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 our license agreement with Pfizer;
- 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 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 future financial performance;
- our ability to recognize the anticipated benefits of the tavapadon financing transaction (including our ability to receive future payments thereunder) and other financing and business development transactions;
- our ability to satisfy our payment obligations, remain in compliance with covenants under the 2027 Notes (as defined below), to service the interest on or to refinance the 2027 Notes or to make cash payments in connection with any conversion of the 2027 Notes, to the extent required;
- the effect of adverse market or macroeconomic conditions, including, among others, inflation, interest rates and economic uncertainty, market volatility resulting from global political or economic developments, war, international hostilities and terrorism, any future public health epidemics or outbreaks of infectious disease, the residual post-COVID environment and other factors on any of the foregoing or other aspects of our business operations, including but not limited to our clinical trials and other product development activities, healthcare systems and the global economy as a whole; and
- other risks and uncertainties, including those listed under the section titled "*Risk Factors*."

The forward-looking statements contained in this Annual Report 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 or important factors 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 sections titled "*Summary of Material Risks Associated with Our Business,*" "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations,*" set forth in this Annual Report. 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. 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 Annual Report 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 by these cautionary statements.

This Annual Report 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 as exhibits to this Annual Report. Unless the context otherwise requires, reference in this Annual Report to the terms "Cerevel," "the Company," "we," "us," "our," and similar designations refer to Cerevel Therapeutics Holdings, Inc., and where appropriate, our consolidated subsidiaries.

This Annual Report 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 Annual Report may appear without the ® or TM 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.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained the industry, market and competitive position data from our internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties that have not been independently verified which may, in the future, prove not to have been accurate.

SUMMARY OF MATERIAL 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*." These risks include, but are not limited to, the following:

- The conditions under the Merger Agreement to AbbVie's consummation of the Merger may not be satisfied at all or in the anticipated timeframe.
- The announcement of, or a failure to consummate, the Merger could negatively impact our business, financial condition, results of operations or our stock price.
- 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 U.S. Food and Drug Administration, or 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.
- 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.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- 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.
- BC Perception Holdings, LP, or Bain Investor, and Pfizer Inc., or Pfizer, have significant influence over us, and may have interests different from yours.
- 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 discussed in the section entitled "*Risk Factors*" and the other information set forth in this Annual Report, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. The risks summarized above or described in full elsewhere in this Annual Report 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.

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PART I

Item 1. 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, Alzheimer's disease psychosis, epilepsy, panic disorder and Parkinson's disease. We are advancing our extensive and diverse pipeline with numerous clinical trials underway or planned, including three ongoing Phase 3 trials and an open-label extension trial for tavapadon in Parkinson's, two ongoing Phase 2 trials and an open-label extension trial for emraclidine in schizophrenia, an ongoing Phase 2 proof-of-concept trial and an open-label extension trial for darigabat in focal epilepsy and an ongoing Phase 2 proof-of-concept trial for darigabat in panic disorder. See "*—Our Pipeline*" below. 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 approach to addressing neuroscience diseases, which incorporates three key pillars: (1) targeted neurocircuitry, where we seek to unlock new treatment opportunities by precisely identifying and targeting the neurocircuit that underlies a given neuroscience disease, (2) targeted receptor subtype selectivity, where we selectively target the receptor subtype(s) related to the disease physiology to minimize undesirable off-target effects while maximizing activity and (3) differentiated pharmacology, where we design full and partial agonists, antagonists and allosteric modulators to precisely fine-tune the receptor pharmacology and neurocircuit activity to avoid over-activation or over-suppression of the endogenous physiologic range. In addition, our portfolio is supported by robust data packages and rigorous clinical trial execution designed to elucidate the key points of differentiation for our compounds. We believe that this science-driven approach is critical to achieving optimal therapeutic activity while minimizing unintended side effects of currently available therapies.

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 pipeline has the potential to bring the next generation of transformative neuroscience therapies to patients.

Our Lead Programs

1. Emraclidine is a positive allosteric modulator, or PAM, that selectively targets the muscarinic acetylcholine 4 receptor subtype, or M4. In June 2021, we announced positive topline results for a Phase 1b trial of emraclidine in schizophrenia, consisting of Part A, a multiple ascending dose, or MAD, assessment and Part B, a pharmacodynamic, or PD, assessment. Emraclidine demonstrated a clinically meaningful and statistically significant improvement in the Positive and Negative Syndrome Scale, or PANSS, total score at six weeks and was generally well tolerated compared with placebo at the two dose levels evaluated in Part B. We initiated two Phase 2 clinical trials in schizophrenia, known as the EMPOWER trials, in June 2022 and a 52-week open-label extension trial to begin development of the required safety database in September 2022. In parallel, we are also prioritizing nonclinical and clinical safety pharmacology studies, including hepatic and renal insufficiency studies, along with other registration-enabling activities. In December 2022, we announced data from an eight-week ambulatory blood pressure monitoring trial providing clear evidence that emraclidine does not induce an increase in blood pressure with chronic dosing in people living with schizophrenia.

   In addition, we plan to evaluate the potential of this mechanism in other populations, including Alzheimer's disease psychosis. We initiated a Phase 1 trial evaluating the safety, tolerability and pharmacokinetics, or PK, in elderly healthy volunteers in December 2022 to support the future development of emraclidine in Alzheimer's disease psychosis. In the fourth quarter of 2022, the FDA granted Fast Track Designation for emraclidine for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis.

2. Darigabat 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, or focal epilepsy.

   In February 2022, we announced positive topline results for a Phase 1 trial of darigabat in a panic symptoms model in healthy volunteers. Both doses of darigabat demonstrated clinically meaningful and statistically significant anxiolytic activity compared with placebo in this proof-of-principle trial. Darigabat was generally well tolerated, with no serious adverse events and no discontinuations in the darigabat cohorts. We initiated a Phase 2 proof-of-concept trial of darigabat in panic disorder, known as ADAPT, in July 2023.

3. Tavapadon is a selective dopamine D1/D5 receptor partial agonist that we are developing for the treatment of Parkinson’s disease. We initiated a registration-directed Phase 3 program for tavapadon beginning in January 2020, which includes two trials as monotherapy in early-stage Parkinson’s, known as TEMPO-1 and TEMPO-2, one trial as adjunctive therapy in late-stage Parkinson’s, known as TEMPO-3, and an open-label extension trial, known as TEMPO-4.
4. CVL-871 is a selective dopamine D1/D5 receptor 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 the second quarter of 2021, the FDA granted Fast Track Designation for CVL-871 for the treatment of dementia-related apathy. We are conducting a Phase 2a exploratory trial in dementia-related apathy.

We believe that our lead programs 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.

Our Other Programs

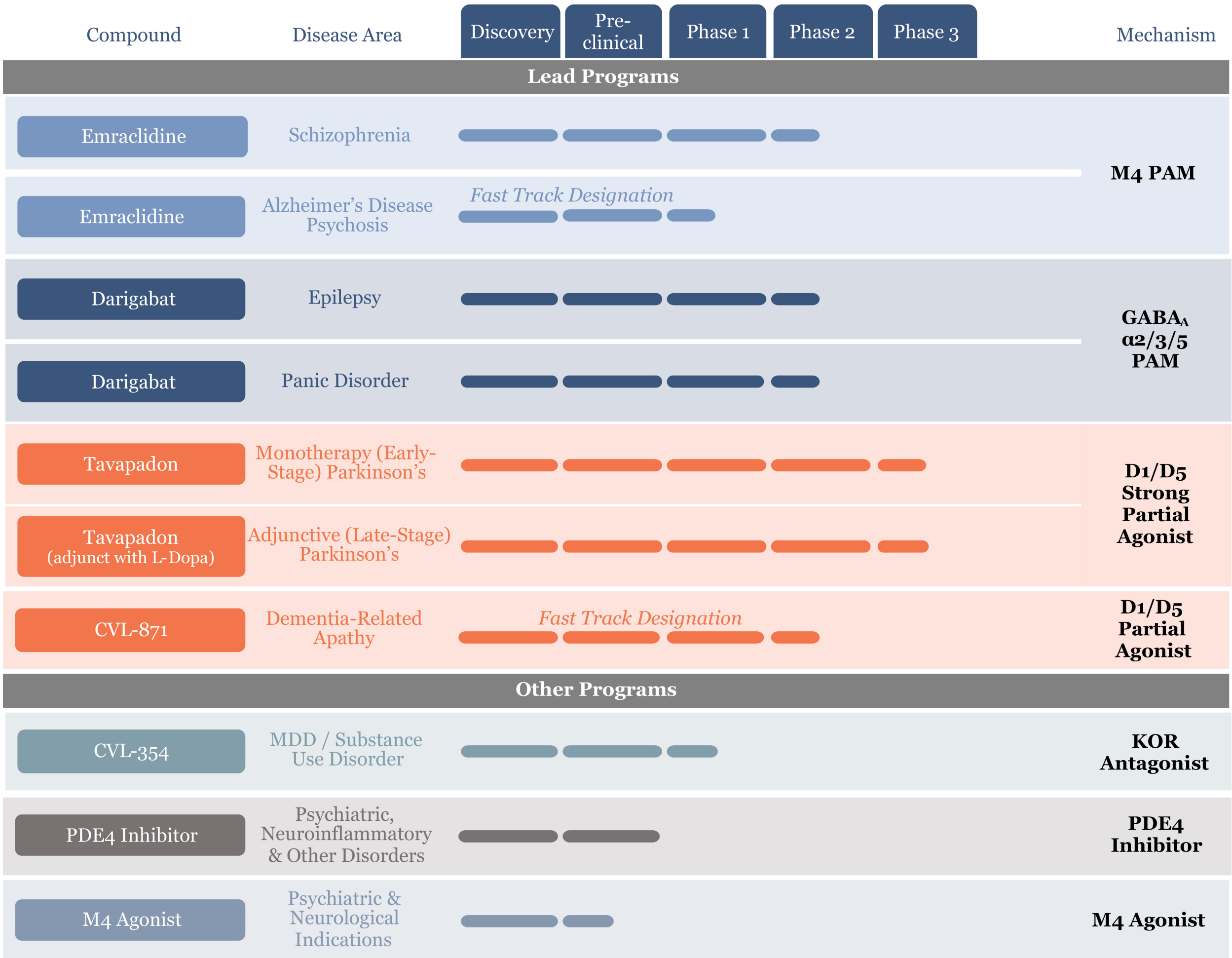
In addition to the lead programs described above, we plan to further characterize and appropriately advance our early clinical and preclinical pipeline across multiple potential neuroscience indications. Our other programs include:

- CVL-354, our selective kappa opioid receptor antagonist, or KORA, for the treatment of major depressive disorder, or MDD, and substance use disorder;
- our selective PDE4 inhibitor (PDE4D-sparing) program for the treatment of psychiatric, neuroinflammatory and other disorders; and
- our selective M4 agonist program for the treatment of psychiatric and neurological indications.

We are also pursuing other undisclosed targets, including those with disease-modifying potential for leading neuroscience diseases. These programs include 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 are designed to enable better understanding of therapeutic potential.

Our Pipeline

The following table summarizes our current portfolio of programs. This table does not include multiple additional preclinical programs that have not yet been disclosed.



Incorporation by Reference

For more information about our pipeline and programs, please see pages 4 to 45 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which are incorporated herein by reference.

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 are required to act in accordance with the FDA's good laboratory practices, or 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 a new drug application, or 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 emraclidine 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, marketed by Alkermes; Zyprexa, marketed by Eli Lilly; 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, Sumitomo Dainippon Pharma, 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 ASMs, including currently marketed therapies such as XCOPRI® (cenobamate), which was developed by SK Life Sciences and was approved by the FDA in November 2019. Additionally, there are next-generation therapies in development, such as XEN1101 being developed by Xenon Pharmaceuticals and NBI-921352 (formerly known as XEN901) being developed by Neurocrine Biosciences.

We may also face competition from other companies developing next-generation $GABA_A$ receptor modulators such as Engrail Therapeutics and Avenue Therapeutics. There are also several therapies that are either marketed or in development targeting rarer forms of epilepsy such as Lennox-Gastaut syndrome, CDKL5 deficiency disorder and Dravet syndrome that could have efficacy in broader epileptic populations, including fenfluramine from UCB (formerly Zogenix), ganaxalone from Marinus Pharmaceuticals and cannabinoid-based therapies from Jazz Pharmaceuticals (formerly 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 symptomatic and disease-modifying therapeutics being developed by other pharmaceutical and biotechnology companies, including Denali Therapeutics, Prothena, Roche, Voyager Therapeutics, Sage Therapeutics, Neurocrine Biosciences, Eli Lilly and AstraZeneca, 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.

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 certain significant transactions 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 our 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.

As partial consideration for the licensed assets, we issued to 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 $190.0 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*" achieve all of the commercial milestones, the total aggregate amount of such commercial milestones payable to Pfizer would total approximately $1.4 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 a valid claim included in the patents licensed to us under the Pfizer License Agreement 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 Rights

Shortly after our formation in July 2018, we entered into the Pfizer License Agreement, pursuant to which we acquired exclusive worldwide rights under certain Pfizer patents, patent applications and know-how to develop, manufacture and commercialize our current product candidates.

We have exclusive licenses under such Pfizer patents, patent applications and know-how pursuant to the terms of the Pfizer License Agreement, including certain patent rights in the United States and numerous foreign jurisdictions relating to our product candidates. As of December 31, 2023, 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 19 granted patents in the United States and 93 patents granted in foreign jurisdictions, including Canada, Japan, China or validated in various member states of the European Patent Office. Additionally, one patent application has been allowed in the United States. 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 43 patents granted in foreign jurisdictions, including Canada, China, Japan or validated in various member states of the European Patent Office. 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 three 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 three families, the portfolio includes two granted patents in the United States and 54 granted patents in foreign jurisdictions, including Israel, China, Japan, Mexico or validated in various member states of the European Patent Office. Additionally, four applications are pending in the United States and 12 applications are pending in foreign jurisdictions. A subset of the patents and patent applications in our M4 positive allosteric modulator portfolio relate to emraclidine. For emraclidine, the applicable patents and patent applications are directed to emraclidine, polymorphs thereof, compositions of matter and methods of treating schizophrenia, and, excluding any patent term adjustments or extensions, have statutory expiration dates in 2037 and 2044.
- 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 United States and 30 granted patents in foreign jurisdictions.

Additionally, four applications are allowed or pending in foreign jurisdictions. Excluding any patent term adjustments or extensions, the granted patent and any applications that may issue from this family have statutory expiration dates in 2037 and 2044.

- For our muscarinic M4 agonists, our portfolio includes three patent families 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 granted patent in the United States and 20 granted patents in foreign jurisdictions, including China and member states of the European Patent Office. Additionally, one application is pending in the United States and seven applications are pending in foreign jurisdictions. Excluding any patent term adjustments or extensions, any patents that may issue from these families will have statutory expiration dates in 2039, 2043 and 2044, depending on the family.
- For our PDE4B inhibitors, our portfolio includes six patent families directed to various PDE4B 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. The patent families include nine granted patents in the United States and 93 patents granted in foreign jurisdictions, including Canada, China, Japan or validated in various member states of the European Patent Office. Additionally, two patent applications are pending in the United States and eight patent applications are pending in foreign jurisdictions. Excluding any patent term adjustments or extensions, the granted patents and any applications that may issue from these families have statutory expiration dates in 2034, 2035, 2036, 2037 and 2043, depending on the family.

See the section entitled "—*Pfizer License Agreement*" for additional information on our rights under the Pfizer License Agreement.

Trade Secrets

In addition to patent rights, 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 December 31, 2023, our registered trademark portfolio contained 48 registered trademarks in foreign jurisdictions, including, but not limited to, Argentina, Brazil, China, Colombia, the European Union, Japan, Mexico, the Russian Federation, Switzerland, Turkey, the United Kingdom and Venezuela. In addition, we have two registered trademarks and five pending trademark applications in the United States. Further, there are three pending trademark applications in Canada, one pending trademark application in Mexico, and two pending trademark applications in South Korea.

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, or EU, 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.

U.S. drug development process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with GLPs and other applicable regulations;

- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations, or GCPs, to evaluate the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds may also be imposed by the FDA at any time before or during clinical trials due to safety concerns about the on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and approval process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for all claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission.

The FDA may refer an application for a novel drug to an advisory committee. 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.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs. After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives approval, the approval may be significantly limited to specific diseases and dosages, or the indications for use may be otherwise limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval, including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of approved products.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey an advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan Exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the "same drug," as defined by the FDA, or if a product candidate is determined to be contained within the competitor's product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

Expedited development and review programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug. For example, the Fast Track program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs are eligible for Fast Track Designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. With regard to a Fast Track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy Designation to expedite its development and review. A product candidate can receive Breakthrough Therapy Designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, 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 designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a Fast Track Designation or a Breakthrough Therapy Designation, may also be eligible for other types of FDA programs intended to expedite development and review such as priority review. An NDA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months of review for new molecular entity NDAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical studies, a product candidate may be eligible for accelerated approval. Drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting any accelerated approval. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track Designation, Breakthrough Therapy Designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion, of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may 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 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 requirements for post-market studies or clinical studies 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 the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Marketing Exclusivity

Marketing exclusivity under the FDCA can delay the submission or approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to an existing period of regulatory exclusivity or patent term protection if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Foreign Regulation

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. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulation.

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. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country.

Non-clinical studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labelling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements,

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain a MA, for a product in the EU, an applicant must submit a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

"Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicines produced by certain biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and (iv) 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 highly innovative or for which a centralized process is in the interest of patients in the EU, the centralized procedure may be optional.

"National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure, the CHMP 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 MA. 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 asked by 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 targets an unmet need and is of major interest from a public health perspective 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, excluding clock stops, 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 MA 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 MAA. Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Data and Market Exclusivity

In the EU, new products authorized for marketing (*i.e.* reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar (abbreviated) MA, for a period of eight years from the date on which the reference product was first authorized in the EU. During an additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall 10-year period can be extended to a maximum of 11 years if, during the first eight years of those 10 years, the MA 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. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product 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 MA based on a MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting a MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, prior to obtaining a MA, applicants have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for a six-month extension of the protection under a supplementary protection certificate, or SPC, provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, 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.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom, or the UK, ceased being an EU member state on January 31, 2020, and the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland).

Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in Great Britain currently aligns in many ways with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU.

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, has been the UK's standalone medicines and medical devices regulator. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in Great Britain (only), free of charge on January 1, 2021, unless the MA holder opted-out. In order to use the centralized procedure to obtain a MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore since Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a MA to commercialize products in the UK. The MHRA has been able to rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MA when determining an application for a Great Britain authorization (the so-called "EC Decision Reliance Procedure," or ECDRP); or use the MHRA's decentralized or mutual recognition procedures, or MRDCRP, which enabled MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in Great Britain. From January 1, 2024, the ECDRP has been replaced by the new International Recognition procedure, or IRP, which will allow the MHRA to conduct targeted assessments by recognizing approvals from trusted partner agencies such as the European Commission. The MRDCRP is incorporated under the umbrella of the IRP. Additionally, the "Unfettered Access Procedure" enables an MA holder in Northern Ireland to seek recognition in Great Britain.

There is no pre-MA orphan designation. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in Great Britain.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Healthcare Laws and Regulation

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain a MA. Such laws include, without limitation, state, federal and foreign anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. See "*Risk Factors — 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*" for additional information.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state and other healthcare programs and responsible individuals may be subject to imprisonment.

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. 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, or ASP, 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. 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 approved 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, the U.S. Centers for Medicare & Medicaid Services, or 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 U.S. 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. For example, the Inflation Reduction Act of 2022, or IRA, which was enacted in August 2022 (1) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

Further, on May 30, 2018, 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 EU, 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, certain EU member states have the option 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. EU 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 EU 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 EU 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 member states in the EU. 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 EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced EU 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.

Further to this, on December 13, 2021, Regulation No 2021/2282 on health technology assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. This Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provides the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Employees and Human Capital

As of December 31, 2023, we had 334 full-time employees, including approximately 99 employees with M.D. and/or Ph.D. degrees and approximately 239 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 with a common passion and mindset of striving to achieve our mission. 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 people living with neuroscience diseases. We believe that with a common goal and by embracing differences, we have a unique advantage in challenging the status quo to apply innovative thinking to long-existing medical challenges that better reflect the diversity of those who can potentially benefit from it. As of December 31, 2023, our workforce was self-reportedly approximately 58% women and approximately 40% Asian, Hispanic, Latino, Black or African American, and our senior leadership self-reportedly was approximately 44% women or minorities, reflecting the diversity, equity, and inclusion in workforce we strive to create throughout the company.

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 highest performing and most experienced 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 thoughtful benefits that are intended to meet the needs of 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 have implemented initiatives across our entire workforce through targeted hiring objectives, supplier and vendor diversity programs and inclusivity plans for clinical trials, the achievement of which were an element in our annual incentive plan goals for 2023. 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

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 Annual Report or in any other filings we make with the SEC. We have included our website address in this Annual Report 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 Securities Exchange Act of 1934, as amended, or 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 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.

Item 1A. 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 Annual Report, including our consolidated financial statements and the related notes included in this Annual Report 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 Annual Report 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 elsewhere in this Annual Report 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 Annual Report 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 the Merger

The conditions under the Merger Agreement to AbbVie's consummation of the Merger may not be satisfied at all or in the anticipated timeframe.

On December 6, 2023, we entered into the Merger Agreement with AbbVie, Intermediate Holdco and Merger Sub, pursuant to which Merger Sub will be merged with and into Cerevel, with Cerevel surviving the merger as a wholly owned subsidiary of AbbVie.

Consummation of the Merger is subject to approval by our stockholders; receipt of certain regulatory approvals; the expiration or termination of any applicable waiting period (and extensions thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976; obtaining all waivers and approvals under certain other specified antitrust laws, as applicable; the absence of any law or order by any governmental authority that would make illegal or otherwise prohibit, restrict or prevent the Merger; and other conditions specified in the Merger Agreement. As a result, there can be no assurance that the Merger will be consummated. These conditions are described in more detail in the Merger Agreement, which is filed as an exhibit to the Current Report on Form 8-K, filed with the SEC on December 7, 2023, and incorporated herein by reference.

The Company intends to pursue all required approvals in accordance with the Merger Agreement. However, no assurance can be given that the required approvals will be obtained and, even if all such approvals are obtained, no assurance can be given to the terms, conditions and timing of the approvals or that they will satisfy the terms of the Merger Agreement.

Furthermore, we and our board of directors have been named as defendants in lawsuits brought by purported holders of our common stock challenging our board of directors' actions in connection with the Merger and seeking, among other things, injunctive relief to enjoin the defendants from completing the Merger on the agreed-upon terms. See Note 17, *Legal Proceedings*, to our audited consolidated financial statements included elsewhere in this Annual Report for more information regarding such lawsuits. If a settlement or other resolution is not reached in the lawsuits and the plaintiffs secure injunctive relief prohibiting, delaying, or otherwise adversely affecting our ability to consummate the Merger, then such injunctive or other relief may prevent the Merger from becoming effective within the expected timeframe or at all.

The announcement of, or a failure to consummate, the Merger could negatively impact our business, financial condition, results of operations or our stock price.

Our announcement of having entered into the Merger Agreement could cause a material disruption to our business and there can be no assurance that the conditions to the consummation of the Merger will be satisfied. The Merger Agreement may also be terminated by us and/or AbbVie in certain specified circumstances, as described below. We are subject to several risks as a result of the announcement of the Merger Agreement, including, but not limited to, the following:

- if the Merger is not completed within the expected timeframe, or at all, the share price of our common stock will change to the extent that the current market price of our common stock reflects an assumption that the Merger will be consummated;
- certain costs related to the Merger, including the fees and/or expenses of our legal, accounting and financial advisors must be paid even if the Merger is not completed;
- pursuant to the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to the completion of the Merger, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities;
- the attention of our management may be directed towards the consummation of the Merger and related matters, and their focus may be diverted from the day-to-day business operations of our company, including from other opportunities that might otherwise be beneficial to us;
- our inability to retain existing key employees or hire new capable employees, given the uncertainty regarding our future, in order to execute on our continuing business operations;
- a failure to complete the Merger within the proposed timeframe, or at all, may result in negative publicity and/or a negative impression of us in the investment community or business community generally;
- difficulties maintaining relationships with collaborators, vendors, and other business partners;
- third parties may determine to terminate and/or attempt to renegotiate their relationship with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise;
- upon termination of the Merger Agreement by us or AbbVie under specified circumstances, we would be required to pay a termination fee of approximately $283.1 million; and
- we could be subject to litigation related to any failure to complete the Merger.

In addition, our executive officers and directors may have interests in the Merger that are different from, or are in addition to, those of our stockholders generally. These interests include without limitation the following:

- most members of the Board and each of our executive officers holds outstanding Cerevel equity awards;
- each of our executive officers is party to an employment agreement and/or is a participant in a severance program that provides for severance payments and benefits upon a qualifying termination in connection with a change in control (referred to as a “sales event” therein), which includes the Merger;
- each of our non-employee directors is subject to a compensation policy that provides upon the occurrence of a “sale event” (including the Merger), all equity retainer awards granted to non-employee directors will become fully vested and exercisable;
- each of our executive officers is eligible to receive a prorated target bonus with respect to fiscal year 2024 if the Effective Time of the Merger occurs in 2024; and
- certain of our executive officers’ compensatory payments were and/or will be subject to certain mitigation treatment in order to mitigate the potential impact of Sections 280G and 4999 of the United States Internal Revenue Code of 1986, as amended, or the Code, in connection with the Merger.

The Merger Agreement contains provisions that could make it difficult for a third party to acquire us prior to the completion of the Merger.

The Merger Agreement contains restrictions on our ability to obtain a third-party proposal for an acquisition of our company. These provisions include our agreement not to solicit or initiate any additional discussions with third parties regarding other proposals to acquire us, as well as restrictions on our ability to respond to such proposals, subject to fulfillment of certain fiduciary requirements of our board of directors. The Merger Agreement also contains certain termination rights, including, under certain circumstances, a requirement for us to pay to AbbVie a termination fee of approximately $283.1 million.

These provisions might discourage an otherwise-interested third-party from considering or proposing an acquisition of our company, even one that may be deemed of greater value to our stockholders than the Merger. Furthermore, even if a third-party elects to propose an acquisition, the concept of a termination fee may result in that third-party offering a lower value to our stockholders than such third-party might otherwise have offered.

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, or similar foreign applications, preparation, discussions with the FDA or foreign regulatory authorities, an FDA or foreign regulatory authority 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 or jurisdiction 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 similar foreign requirements, 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 adverse events 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 pre-commercial activities. Substantially all of our product candidates were initially developed by Pfizer, which we in-licensed pursuant to 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. 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 $432.8 million, $351.5 million and $225.3 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we have 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 through clinical development, including as we advance these candidates into later-stage clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the clinical development of our product candidates;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities to establish sales, marketing and distribution capabilities;
- 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;
- 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; and
- make milestone, royalty, interest or other payments due under the Funding Agreements, our 2027 Notes and any future financing or other arrangements 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, one or more 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 incur 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. 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 the Funding Investors under the Funding Agreements;
- the settlement method used for the outstanding 2027 convertible senior notes, or the 2027 Notes;
- our headcount growth and associated costs as we expand our research and development and market development and pre-commercial planning activities;
- 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. For instance, the trading prices for our common stock and for other biopharmaceutical companies have been highly volatile. As a result, we may face difficulties raising capital through sales of our equity or debt securities or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, the post-COVID environment, future public health epidemics or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. 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, that could adversely impact our ability to conduct our business. The Merger Agreement generally restricts our ability to pay any dividends on our common stock during the interim period between the execution of the Merger Agreement and the Effective Time (or the date on which the Merger Agreement is earlier terminated). 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 other strategies, all of which could adversely affect the holdings or the rights of our stockholders.

We believe that our available financial resources will enable us to fund our operating expense and capital expenditure requirements through at least 12 months from the issuance date of our audited consolidated financial statements included elsewhere in this Annual Report. 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 most advanced product candidates and indications and ensuring the development of additional potential product candidates and indications.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications 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, therapeutic areas or indications may not lead to the development of 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, the ownership interest of our stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. 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, strategic alliances 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, research programs 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, 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 capital through arrangement with collaborators on terms unfavorable to us or pursue other strategies, all of which could adversely affect the holdings or the rights of our stockholders.

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 the development of any of our product candidates. Our future success and ability to generate revenue from our product candidates, which is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our product candidates 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 Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals or allowances 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 observed 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 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, policies 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 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 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. For instance, jurisdictions outside of the United States, such as the European Union, or EU, or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any 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 seek or 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 EU 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 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.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our developments plans.

It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials with specific aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The MHRA published its consultation outcome on March 21, 2023 in which it confirmed that it would update the existing legislation. The resulting legislative changes will ultimately determine the extent to which the UK regulations align with the CTR. Under the terms of the Protocol on Ireland/Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the UK not to closely align its regulations with the new approach has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be adversely impacted.

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

In order to obtain FDA approval of our product candidates, we must, among other things, demonstrate substantial evidence of the effectiveness of such product candidates. FDA has generally considered this demonstration to require data gathered from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population, or in some cases, one adequate and well-controlled trial plus other confirmatory evidence. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to granting any regulatory approval. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from the FDA or other 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. Even if our Phase 3 clinical trials as monotherapy 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 electrocardiogram, or ECG, multiple-dose ECG and a model-based analysis of Phase 1 data, we plan to collect time-matched pharmacokinetic and ECG measures in a subset of patients as a sub-study in our ongoing Phase 3 fixed-dose monotherapy 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 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 pandemic, the post-COVID environment and other 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. For instance, the COVID-19 pandemic and the post-COVID environment, including supply chain, labor market and other disruptions, as well as volatility in the global financial markets, in each case, driven by the pandemic, have impacted and may further impact our clinical trials or preclinical studies. For instance, certain of our clinical trials, including our Phase 3 trials of tavapadon for the treatment of Parkinson's, our Phase 2a trial of CVL-871 for the treatment of dementia-related apathy and our Phase 1 trial of emraclidine in elderly healthy volunteers to support development in Alzheimer's disease psychosis, predominantly enroll elderly subjects, and we remain particularly vigilant about patient safety given the elderly nature of these populations. 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 monotherapy 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 or unwilling 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 create data integrity challenges, require changes to the statistical analysis plan, require 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, Paxlovid, a treatment for COVID-19 approved in the U.S. and Europe, is contraindicated for concurrent use with some of our product candidates. As such, increased use of Paxlovid in the general population may cause delays in enrollment or increase the early termination rate in our clinical trials, which may impact our expected clinical trial timelines.

In addition, COVID-19, the post-COVID environment or future public health crises may impact our ability to retain principal investigators and site staff for our clinical trials. For instance, healthcare providers may have heightened exposure to COVID-19 or may be impacted due to prioritization of hospital resources toward the pandemic 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, as a result of supply chain, labor market and other disruptions driven by the pandemic and the post-COVID environment, COVID-19 has impacted and may further negatively affect our operations or the operations of our vendors, suppliers and business partners, including the third-party contract research organizations, or CROs, clinical sites and other vendors that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers and other suppliers, which could result in delays or disruptions in the supply of our product candidates. The negative impact COVID-19 or the post-COVID environment has on patient enrollment, site staffing or treatment or the timing and execution of our clinical trials has caused and could cause further 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 and the post-COVID environment have also caused volatility in the global financial markets, including inflationary headwinds, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 and the post-COVID environment impact our business, results of operations and financial condition will depend on future developments, including new variants or subvariants, which may impact rates of infection and the extent and effectiveness of actions to contain COVID-19 or treat its impact, including vaccination campaigns, COVID-19 treatments and lockdown measures, 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 substantially 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 adjunctive 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. Similarly, while darigabat demonstrated anxiolytic effects in a model of carbon dioxide inhalation that is associated with symptoms of anxiety/panic in healthy participants, we may not be able to replicate these results in patients with panic disorder. 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, in later-stage trials, emraclidine 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 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 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 such as ethics committees 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 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 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 efficacy and safety results adequate to obtain 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 the remaining payment 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 or publicly disclose interim, topline or preliminary data from our clinical trials. These publications or disclosures are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

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. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business.

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 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 adjunctive 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. Developing combination therapies using other compounds also exposes us to additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop.

If the FDA or similar foreign regulatory authorities revoke the approval of any proposed combination agents, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market such product candidates for combination therapy regimens. Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

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 the COVID-19 pandemic and the post-COVID environment on our ability to recruit and retain patients;
- the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the severity of the disease or condition under investigation;
- 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 drugs that may be approved for the indications that we are investigating;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- 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.

For instance, enrollment in our Phase 3 TEMPO program of tavapadon in Parkinson's has been impacted due to residual post-COVID landscape challenges and other factors. Furthermore, we are currently evaluating darigabat in a Phase 2 proof-of-concept trial in focal epilepsy, known as REALIZE. The recent approval and increased uptake of certain partial-onset seizure treatments, which are contraindicated in the REALIZE trial, as well as patients not meeting the necessary seizure frequency requirements and post-COVID landscape challenges at the clinical trial sites, have impacted our expected timeline for this trial. Slower-than-expected enrollment in the U.S. and delays in the startup of certain ex-U.S. clinical sites have impacted and may further impact the expected timeline for data for both Phase 2 EMPOWER trials of emraclidine in schizophrenia. 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. Finally, business disruptions, including those relating to natural disasters (including as a result of climate change), geopolitical incidents or macroeconomic conditions, may disrupt our clinical trials. For instance, certain of our ongoing clinical trials include select clinical sites located in Ukraine. The ongoing war in Ukraine has impacted and may further impact our ability to collect and interpret data from patients who were enrolled at those clinical sites, and further disruptions at those clinical sites may result in delays to our clinical trials. We will continue to closely monitor the rapidly evolving geopolitical situation in Ukraine and its impact on our clinical trial operations and timelines. We may from time to time implement mitigation measures to improve patient enrollment, but such mitigation measures may not sufficiently improve enrollment in a timely enough fashion (for instance, it could take longer than we expect to add new clinical sites, especially in new countries, and we may not be able to sufficiently increase enrollment at existing clinical sites), may have a negative impact on the quality of our data or may result in increased costs.

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 the vendors used to manufacture drug product or 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 or comparable foreign regulatory authorities notification or 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.

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 emraclidine, some moderate treatment-emergent increases in heart rate and blood pressure were observed following single doses of emraclidine (>10 mg), which may be due to emraclidine'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. In our Phase 1b trial of emraclidine, modest asymptomatic elevations in blood pressure and heart rate were observed with emraclidine compared to placebo, which decreased over time. Placebo-adjusted heart rate changes two hours post-dose at week six were 4.4 and 5.3 beats per minute for the emraclidine 30 mg once-daily and 20 mg twice-daily groups, respectively. The average blood pressure changes at week six for both emraclidine cohorts showed no clinically meaningful differences versus placebo.

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.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product. Other potentially significant negative consequences associated with adverse events include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or modify their approvals of a product;
- we may be required to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients;
- a product may become less competitive, and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

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 panic disorder, 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 receptor partial agonism has the potential to deliver promising therapeutic benefits above and beyond nonselective dopamine agonists. 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, such as dementia-related apathy. 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 Annual Report 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 are 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 our product candidates, 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 any 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 one or more of our 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 our 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;
- the 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. 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.

Cyberattacks 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, including confidential information such as proprietary business information and personal information of our employees and contractors, in connection with our business activities. As use of digital technologies has increased, our IT systems and those of our third-party service providers, strategic partners and other contractors or consultants are increasingly vulnerable to attack, damage and interruption from cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e.g., ransomware), viruses, malicious code, spamming, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors, natural disasters, terrorism, war, telecommunication and electrical failures or other threats. 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. We may not be successful in preventing or identifying cyberattacks and may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or successfully mitigate their effects due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. 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 cyberattacks. Similarly, our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants may not be successful in protecting our clinical and other data that is stored on their systems. Any cyberattack, 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 cyberattacks 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, 2023, we had U.S. federal net operating loss carryforwards totaling $533.2 million, all of which have an indefinite carryforward period. As of December 31, 2023, we had state net operating loss carryforwards totaling $549.0 million, with $542.2 million expiring at various dates between 2031 and 2043 and the remaining $6.8 million having an indefinite carryforward period. As of December 31, 2023, we also had U.S. federal and state research and development tax credit carryforwards of $33.3 million and $4.9 million, respectively, which begin to expire in 2039 for federal purposes and 2034 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 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 the future, 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 that may be subject to limitation by Sections 382 and 383 of the Code.

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 of 2022, as amended, or 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 consolidated 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.

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 SEC or other regulatory authorities.

Additionally, pursuant to Section 404 of the Sarbanes-Oxley Act, we are now required to furnish a report by our management on our internal control over financial reporting and an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Our compliance with such requirement necessitates that we incur substantial accounting expense and expend significant management efforts. We will continue to dedicate significant internal and external resources to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective, or such conclusion may not be reached within the prescribed timeframe. The price of our common stock could decline substantially due to a loss of confidence in the reliability of our financial statements.

Risks Related to Managing our Business and Operations

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 executive officers and other key employees within our organization. Our executive officers and other key employees may terminate their employment with us at any time. The loss of their services might impede the achievement of our operational and strategic 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 and the culture fit to be a leader in our organization. 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. Further, inflationary pressure may increase our costs, including employee compensation costs or result in employee attrition to the extent our compensation does not keep up with inflation, particularly if our competitors' compensation does. The Merger may make it more difficult to attract and retain qualified employees due to the uncertainty about whether or when the transaction will close and the impact of the Merger on our employees.

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 may not be able to hire and/or retain a sufficient number of employees or employees with the required expertise to develop our product candidates or operate our business successfully.

As of December 31, 2023, we had 334 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 qualified 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 that violates:

- study and trial protocols or the 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. Due to our limited financial resources, our limited operating history 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 any necessary relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or any necessary 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, and may have interests different from yours.

As of December 31, 2023, Bain Investor and Pfizer own, collectively, approximately 51.3% of the outstanding shares of our common stock. Furthermore, 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 entities 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 the Merger or any other merger or other significant corporate transaction, including a sale of substantially all of our assets. Some or all of these entities may have interests different than yours. For example, because these entities acquired their shares at prices substantially below the price at which other stockholders may have purchased shares or have held their shares for a longer period, they may be more interested in selling our 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 12 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, in the future, you may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq rules regarding corporate governance.

Our Amended and Restated 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 and as amended, by and between us and the other parties thereto, to the fullest extent permitted by law, the doctrine of corporate opportunity and any analogous doctrine does not apply to (1) Bain Investor, Pfizer, ARYA Sciences Holdings II and Perceptive Life Sciences Master Fund Ltd, (2) any member of our board of directors, non-voting observer or any officer who is not our or our subsidiaries' full-time employee or (3) any affiliate, partner, advisory board member, director, officer, manager, member or shareholder of Bain Investor, Pfizer, ARYA Sciences Holdings II or Perceptive Life Sciences Master Fund Ltd who is not our or our subsidiaries' full-time employee (any such person listed in (1), (2) or (3) being referred to herein as an External Party). Therefore, we have 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.

Our certificate of incorporation and amended and restated bylaws, and Delaware law, 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 amended and restated bylaws, or our 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:

- permitting 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;
- permitting our board of directors to amend our 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 our 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 preferred judicial forum for disputes with us or our directors, officers, stockholders, employees or agents. If, however, our forum provisions are found to be unenforceable, we and our stockholders may incur additional costs associated with resolving such matters.

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 (1) any derivative action or proceeding brought on our behalf, (2) 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, (3) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws or (5) any action asserting a claim against us governed by the internal affairs doctrine; provided, however, that the foregoing 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.

These 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 believes to be 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 or ethics committee 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 and certain foreign regulatory authorities require 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 and comparable foreign regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Similar requirements may exist in foreign jurisdictions.

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. Our failure or 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 or comparable foreign regulatory authorities 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 or comparable foreign regulatory authorities 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. For instance, we have terminated the participation of one investigator involved with our clinical trials due to issues observed during a site monitoring visit, and we notified the FDA accordingly. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post-COVID macroeconomic environment and the inexperience of new employees. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. Accordingly, enrollment in some of our clinical trials has been slower than expected as a result of these changes in the post-COVID clinical trial landscape. 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 $25.0 million in April 2024, such payment is subject to certain customary funding conditions, and, if those funding conditions are not satisfied or waived, we will not receive such payment. 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, active pharmaceutical ingredients, or 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 on acceptable terms. 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. We may not 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 product candidates. 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 various other 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 U.S. 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 or comparable foreign regulatory authorities in connection with any NDA or other application we may submit. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and similar foreign requirements. 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 and similar foreign 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 and similar foreign requirements.

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 or similar foreign 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, 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.

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 similar foreign requirements 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 and similar foreign regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and similar foreign requirements 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 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 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 or comparable foreign regulatory authorities 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.

Additionally, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

The FDA and certain foreign regulatory authorities strictly regulate 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 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. These programs are designed to encourage the research and development of product candidates that are intended to address serious conditions. These designations may confer benefits such as additional interaction with regulatory authorities and eligibility for expedited review procedures. However, there can be no assurance that we will successfully obtain such designations for 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 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 drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, 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 product candidates 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. Product candidates receiving Breakthrough Therapy Designation also receive the same benefits associated with Fast Track Designation, described below. 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.

Furthermore, the FDA has granted Fast Track Designation for emraclidine for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis and 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 drug or biologic 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 be eligible for Fast Track Designation. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

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 emraclidine for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis and 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 notices of award for cooperative grant funding from the National Institute on Drug Abuse, or NIDA, to support the development of CVL-354 in opioid use disorder. 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: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) 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.

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 that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. Federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for the purchase, lease, order, arrangement, 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 does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil fines and criminal 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 including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;
- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of 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 federal False Claims Act 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 federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, a person from 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, fictitious, or fraudulent statements or representations 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 does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments or other transfers of value made to physicians, certain non-physician practitioners including nurse practitioners, certified nurse anesthetists, anesthesiologist assistants, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals and to disclose ownership and investment interests held by physicians and their immediate family members;
- federal government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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 False Claims Act, and 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 and require the registration of pharmaceutical sales representatives.

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 have recently increased their scrutiny of interactions between healthcare companies and healthcare 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.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring 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, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

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. Private health insurers and other third-party payors in the U.S. often follow the coverage and reimbursement policies of government payors, including the Medicare or Medicaid programs. 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 have increasingly passed legislation and implemented 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.

For additional information related to marketing and reimbursement regulations in certain foreign countries, please read "*—EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU member states*."

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, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) 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. For instance, in August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, create an out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. In particular, the IRA allows CMS to begin negotiating prices for certain high-cost Medicare-covered small molecule drugs after they have spent seven years on the market. On August 29, 2023, CMS announced the list of the first ten drugs that will be subject to price negotiations. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. All of our disclosed product candidates are small molecule drugs and certain of them are being developed in indications that may rely heavily on Medicare reimbursement, such as Parkinson’s disease and Alzheimer’s disease psychosis. Accordingly, these new price-negotiation provisions may have a negative impact on our future revenue and profits. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA’s Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet fully known. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our 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. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. This Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal, and provides the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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 or comparable foreign regulatory authorities, we may only promote or market our product candidates in a manner consistent with their FDA-approved labeling (or the label approved by foreign regulatory authorities). 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 or comparable foreign regulatory authorities 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 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 and comparable foreign regulatory authorities 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 FDA and comparable foreign regulatory authorities, have fluctuated in recent years as a result. In addition, government funding of 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, other government agencies and comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies and comparable foreign regulatory authorities, 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, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, including as a result of reaching the debt ceiling, it could significantly impact the ability of the FDA and comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, 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.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. Even though the FDA has since resumed standard inspection operations, and any resurgence of the virus may lead to other inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU 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 typically governed by the national anti-bribery laws of EU member states and the Bribery Act 2010 in the United Kingdom. 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 United Kingdom despite its departure from the European Union.

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 some foreign countries, including some countries in the European Union, 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, some EU member states have the option 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 EU member states, can further reduce prices. An EU 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 regulations, which may require us 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.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (CCPA) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Other states have enacted similar consumer privacy laws that grant rights to data subjects and place privacy and security obligations on entities handling personal data of consumers or households. While we are not currently subject to laws such as the CCPA, such state privacy laws and similar legislation proposed at the state and federal level could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

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, we may seek to conduct clinical trials in the United Kingdom or the

European Economic Area, or the EEA, and may become subject to additional European data privacy laws, regulations and guidelines. We will be subject to the data protection laws of the European Union and United Kingdom in relation to personal data we collect from these territories. These laws impose additional obligations and risk upon our business, including substantial expenses and changes to business operations that are required to comply with these laws. For example, the European Union General Data Protection Regulation (EU GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA or in the context of our activities within the EEA. Companies that must comply with the EU GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the EU GDPR, and subject to additional compliance obligations and to local law derogations. Since the beginning of 2021, after the end of the transition period following the withdrawal of the United Kingdom from the European Union, or Brexit, we may also be subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the UK GDPR) which imposes separate but similar obligations to those under the EU GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. The subsequent separation of the data protection regimes of these territories mean we are required to comply with separate data protection laws in the European Union and United Kingdom, which may lead to additional compliance costs and could increase our overall risk.

The EU and UK GDPR (collectively, the GDPR), which deals with the processing of personal data and on the free movement of such data, imposes a broad range of strict requirements, including requirements relating to having lawful bases for processing personal data and transferring such information outside the EEA/UK, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, 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. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions).

The GDPR imposes strict rules on the transfer of personal data out of the EEA/UK to countries not regarded by European Commission and the United Kingdom government as providing adequate protection, or the third countries, including the United States and the efficacy and longevity of current transfer mechanisms between the European Economic Area, or the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework (DPF), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a EU GDPR transfer mechanism to U.S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. This may lead to additional compliance costs and could increase our overall risk.

We cannot assure you that 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 reputation and materially harm our business. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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. completed a business combination with 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 our licensed 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 substantially all of our current product candidates and the patents and patent applications related to them. 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*" in this Annual Report for additional information.

Additionally, Pfizer has an exclusive right of first negotiation in the event that we seek to enter into certain significant transactions 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 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 in-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 or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings 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 patents protecting any of our product candidates expire, 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 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 product candidates 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, manufacture or commercialize, 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.

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 our issued patents or any pending applications, or that we or, if applicable, a licensor were the first to invent the technology or file patent applications directed to it. 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. Furthermore, for U.S. 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. For U.S. applications in which all claims are entitled to a priority date after March 16, 2013, third parties can provoke derivations proceedings to determine if we or our licensor, as the case may be, derived the invention from them.

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.

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 not be held by a court to be invalid or unenforceable or that even if our patents are 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 independently develop products which have the same effect as our products and which do not infringe our patents or other intellectual property rights or will design around the claims of patents that cover our products.

The degree of future protection for our patent applications and patents 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 or to design around those claims;
- 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 or their exclusivity;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- it is possible that our 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 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, patent 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; or
- we may not develop additional proprietary technologies for which we can obtain patent protection.

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, the subject of our 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 than U.S. courts. 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.

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 products or their methods of use or manufacture. 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 or jury 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.

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 technical and management personnel’s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court or jury 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.

In any third-party litigation, there could also 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.

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, for example, as part of employment or consulting agreements, 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, including in derivation proceedings in the USPTO. 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 may be necessary or important to our business operations. We may also 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. In many cases, these institutions also have obligations to the U.S. government or other funding sources. These obligations may restrict the scope of any license that we may be able to negotiate. 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 have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities, 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. 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.

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.

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 in various jurisdictions, 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 third-party defendant could counterclaim that the patent 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, or not appreciative of its potential relevance, 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 or being unable to be the basis of future litigation. Defense of these claims of invalidity, regardless of their merit, as well as assertion of our infringement claims, 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 also 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-examination, 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.

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.

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 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 effect of these changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, now and in the future, all of which could have a material adverse effect on our business and financial condition.

On June 1, 2023, the European Unitary Patent system and the European Unified Patent Court, or UPC, were successfully launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system started and granted thereafter, are subject to the jurisdiction of the UPC, unless affirmatively opted out. This was a significant change in European patent practice, and deciding whether to opt-in or opt-out of the Unitary Patent practice entails strategic and cost considerations. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court’s existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

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 owned or licensed patents or marketing of competing products by third parties in violation of our proprietary rights generally. The initiation of proceedings for infringement against 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 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 Convertible Senior Notes

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;
- 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, including the impact of inflation and rising interest rates, and domestic or international political instability; 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.

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

The stock market in general, and Nasdaq and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Historically, securities class action litigation has often been brought against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

Conversion of the 2027 Notes will dilute the ownership interest of our existing stockholders or may otherwise depress the price of our common stock.

The conversion of some or all of the 2027 Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the 2027 Notes may encourage sales of our common stock by investors who view the 2027 Notes as a more attractive means of equity participation in us and/or short selling of our common stock pursuant to hedging or arbitrage activity that we expect many investors in the 2027 Notes to employ. In addition, anticipated conversion of the 2027 Notes into shares of our common stock could depress the 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 and directors 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 never declared or paid any cash dividends on our capital stock and have no current plans to pay cash dividends on our common stock in the foreseeable future. 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. The Merger Agreement generally restricts our ability to pay any dividends on our common stock during the interim period between the execution of the Merger Agreement and the Effective Time (or the date on which the Merger Agreement is earlier terminated). As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the 2027 Notes.

As of December 31, 2023, we had $569.6 million of liabilities, including $112.2 million of secured financing liabilities pursuant to the Funding Agreements and $337.4 million aggregate carrying value of indebtedness pursuant to the 2027 Notes. We may also incur additional indebtedness (including financial liabilities) to meet future financing needs. We are not restricted under the terms of the Indenture from incurring additional debt, securing then-existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the Indenture that could have the effect of diminishing our ability to make payments on our indebtedness, including the 2027 Notes, when due.

Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing on acceptable terms or at all;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2027 Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the 2027 Notes, and our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under any then-existing indebtedness. If we fail to comply with these covenants or to make payments under any then-existing indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and any then-existing other indebtedness becoming immediately payable in full.

We may be unable to raise the funds necessary to repurchase the 2027 Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and any other then-existing indebtedness may limit our ability to repurchase the 2027 Notes or pay cash upon their conversion.

Noteholders may, subject to a limited exception, require us to repurchase their 2027 Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the 2027 Notes to be repurchased, plus accrued and unpaid interest, if any to, but excluding, the fundamental change repurchase date. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2027 Notes or pay any cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing any other indebtedness may restrict our ability to repurchase the 2027 Notes or pay any cash amounts due upon conversion. Our failure to repurchase the 2027 Notes or pay any cash amounts due upon conversion when required will constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing any other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under any other indebtedness and the 2027 Notes. For additional information on the 2027 Notes, please read Note 9, *2027 Convertible Senior Notes*, to our audited consolidated financial statements included elsewhere in this Annual Report.

Provisions in the Indenture could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the 2027 Notes and the Indenture could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the 2027 Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

The accounting method for convertible debt securities that may be settled in cash, such as the 2027 Notes, could have a material effect on our reported financial results.

The accounting method for reflecting the 2027 Notes on our consolidated balance sheets, accruing interest expense for the 2027 Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition.

In August 2020, the Financial Accounting Standards Board published an Accounting Standards Update, which we refer to as ASU 2020-06, which simplified certain of the accounting standards that apply to convertible notes. ASU 2020-06 eliminated the cash conversion and beneficial conversion feature models that require separate accounting for embedded conversion features as a component of equity. Instead, the entity would account for the convertible debt or convertible preferred stock securities as a single unit of account, unless the conversion features require bifurcation and recognition as derivatives. Additionally, the guidance requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and to include the effect of potential share settlement for instruments that may be settled in cash or shares. ASU 2020-06 became effective for us beginning on January 1, 2022.

In accordance with ASU 2020-06, the 2027 Notes are reflected as a liability on our consolidated balance sheets, with the initial carrying amount equal to the principal amount of the 2027 Notes, net of issuance costs. The issuance costs are treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the 2027 Notes. As a result of this amortization, the interest expense that we expect to recognize for the 2027 Notes for accounting purposes will be greater than the cash interest payments we will pay on the 2027 Notes, which will result in lower reported net income or higher reported net loss, as the case may be.

In addition, the shares of common stock underlying the 2027 Notes are reflected in our diluted earnings per share using the “if converted” method, in accordance with ASU 2020-06. Under that method, diluted earnings per share would generally be calculated assuming that all the 2027 Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share to the extent we are profitable in the future, and accounting standards may change in the future in a manner that may adversely affect our diluted earnings per share.

Furthermore, in certain circumstances, including if any of the conditions to the convertibility of the 2027 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the 2027 Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their 2027 Notes and could materially reduce our reported working capital.

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

Adverse market or macroeconomic conditions or market volatility resulting from global economic developments, including those affecting the financial services industry, could adversely affect our business operations and our financial condition and results of operations.

Adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, the post-COVID environment or other factors, could materially and adversely affect our business operations. For instance, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank Corp. and Silvergate Capital Corp. were each swept into receivership, and uncertainty remains over liquidity concerns in the broader financial services industry. We may maintain cash balances at third-party financial institutions in excess of the FDIC standard insurance limit. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board announced a program to provide up to $25.0 billion of loans to financial institutions secured by certain of such government securities held by financial institutions, widespread demands for customer withdrawals or other liquidity needs of financial institutions may exceed the capacity of such program, and there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of such banks or financial institutions, or that they would do so in a timely fashion. These events could result in a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations, including, but not limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- potential or actual breach of statutory, regulatory or contractual obligations, including obligations that require us to maintain letters of credit or other credit support arrangements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our partners, vendors or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a partner may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a vendor or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any partner, vendor or supplier, or the failure of any partner to make payments when due, or any breach or default by a partner, vendor or supplier, or the loss of any significant supplier relationships, could cause us to suffer material losses and may have a material adverse impact on our business.

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 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.

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. Our share price 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, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

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 securities;
- reduced liquidity for our securities;

- 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 securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The price of our common stock may be volatile.

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

- our failure to complete, delays in completing, or other developments related to the pending Merger;
- 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 and post-COVID environment 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, rising interest rates, inflation, fuel prices, foreign currency fluctuations, international tariffs, boycotts, curtailment of trade and other business restrictions, social, political and economic risks, natural disasters and acts of war or terrorism, such as the conflicts involving Ukraine and Russia, or Israel and its surrounding regions.

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to materially protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes policies and processes for assessing, identifying, and managing risk from cybersecurity threats as well as a cybersecurity incident response plan.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other strategic, operational, legal, compliance and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify cybersecurity risks to our critical systems, information and our broader enterprise IT environment;
- an information security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors.

We have not identified any known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations or financial condition.

For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "*Risk Factors*," in this Annual Report.

Governance

Our Board considers cybersecurity risk as part of its overall risk oversight function and has delegated to the Audit Committee oversight over our information security and technology risks, including our information security, cybersecurity and related risk management programs.

The Audit Committee receives periodic reports from our Chief Digital Officer on our cybersecurity risks and risk management program as well as presentations on cybersecurity topics as part of the Audit Committee's continuing education on topics that impact public companies. In addition, management updates the Audit Committee, as necessary, regarding any potentially material cybersecurity incidents.

The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program through our overall enterprise risk management program, which includes processes designed to identify, assess, categorize, and monitor key current and evolving risks that may affect us, including cybersecurity risks.

Our management team, including our Chief Digital Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The Chief Digital Officer oversees a team of information security professionals who are responsible for assessing and managing cybersecurity threats on a day-to-day basis. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our Chief Digital Officer has served in the role since 2019 and has experience in application security, intrusion detection, penetration testing, complex threat modeling and unconventional cyber-attack vectors.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal information security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties.

Our principal executive offices are located in Cambridge, Massachusetts and consist of approximately 61,000 square feet of leased office 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.

Item 3. Legal Proceedings.

Information pertaining to legal proceedings is provided in Note 17, *Legal Proceedings*, to our audited consolidated financial statements included elsewhere in this Annual Report and is incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed on The Nasdaq Stock Market LLC under the symbol "CERE".

Holders of Our Common Stock

As of February 15, 2024, we had approximately three holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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. Additionally, the Merger Agreement generally restricts our ability to pay any dividends on our common stock during the interim period between the execution of the Merger Agreement and the Effective Time (or the date on which the Merger Agreement is earlier terminated).

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.

Recent Sales of Unregistered Securities

None.

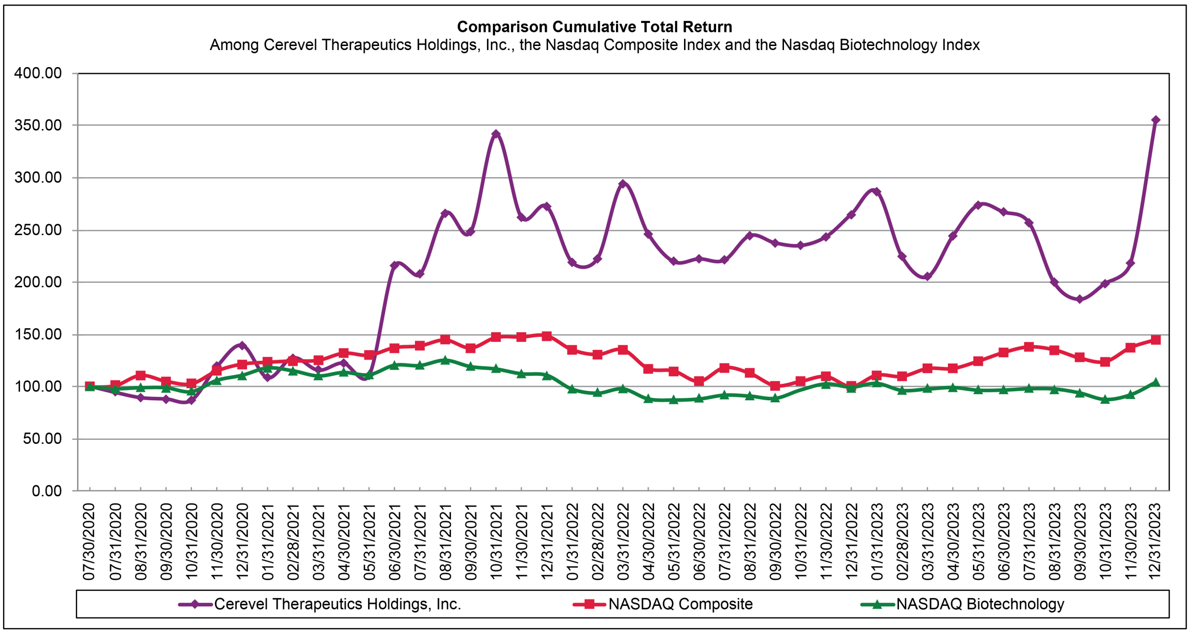
Issuer Purchases of Equity Securities

None.

Performance Graph

The graph below compares the cumulative total stockholder return on our common stock with the cumulative total return on the Nasdaq Composite Index and the Nasdaq Biotechnology Index over the same period. The graph assumes an initial investment of $100.00 in our common stock at the market close on July 30, 2020, which was approximately the date on which the Class A common shares and redeemable warrants comprising the units sold in the initial public offering of ARYA, our predecessor, began separate trading. Data for the Nasdaq Composite Index and the Nasdaq Biotechnology Index assume reinvestment of dividends. Total return equals stock price appreciation plus reinvestment of dividends.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



The information included under the heading Performance Graph is "furnished" and not "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be "soliciting material" subject to Regulation 14A or incorporated by reference in any filing under the Securities Act or the Exchange Act.

Item 6. Reserved.

Item 7. 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 audited consolidated financial statements and notes thereto included elsewhere in this Annual Report. Certain of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, 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 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, Alzheimer's disease psychosis, epilepsy, panic disorder and Parkinson's disease. We are advancing our extensive and diverse pipeline with numerous clinical trials underway or planned, including three ongoing Phase 3 trials and an open-label extension trial for tavapadon in Parkinson's, two ongoing Phase 2 trials and an open-label extension trial for emraclidine in schizophrenia, an ongoing Phase 2 proof-of-concept trial and an open-label extension trial for darigabat in focal epilepsy and an ongoing Phase 2 proof-of-concept trial for darigabat in panic disorder. 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 approach to addressing neuroscience diseases, which incorporates three key pillars: (1) targeted neurocircuitry, where we seek to unlock new treatment opportunities by precisely identifying and targeting the neurocircuit that underlies a given neuroscience disease, (2) targeted receptor subtype selectivity, where we selectively target the receptor subtype(s) related to the disease physiology to minimize undesirable off-target effects while maximizing activity and (3) differentiated pharmacology, where we design full and partial agonists, antagonists and allosteric modulators to precisely fine-tune the receptor pharmacology and neurocircuit activity to avoid over-activation or over-suppression of the endogenous physiologic range. In addition, our portfolio is supported by robust data packages and rigorous clinical trial execution designed to elucidate the key points of differentiation for our compounds. We believe that this science-driven approach is critical to achieving optimal therapeutic activity while minimizing unintended side effects of currently available therapies.

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 pipeline has the potential to bring the next generation of transformative neuroscience therapies to patients.

The Merger

On December 6, 2023, we entered into the Merger Agreement with AbbVie, Intermediate Holdco and Merger Sub, pursuant to which, and on the terms and subject to the conditions thereof, at the Effective Time, Merger Sub will merge with and into Cerevel, with Cerevel surviving as a wholly owned subsidiary of AbbVie.

Under the terms of the transaction, among other things, AbbVie will acquire all outstanding shares of Cerevel for $45.00 per share in cash. The transaction values Cerevel at a total equity value of approximately $8.8 billion. The boards of directors of both companies have approved the transaction. This transaction is expected to close in the middle of 2024, subject to Cerevel stockholder approval, regulatory approvals and other customary closing conditions.

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 uncertainty surrounding introduction of new products, therapies, standards of care or technological innovations, our ability to obtain and maintain adequate protection for our in-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 President and 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.

Our financial condition and results of operations may also be impacted by other factors we may not be able to control, such as global supply chain disruptions, global trade disputes and/or political instability, including due to war, international hostilities or terrorism. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. Additionally, rising inflation rates may affect us by increasing operating expenses, such as employee-related costs and clinical trial expenses, and as a result negatively impacting our results of operations.

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, 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 contract research organizations, or CROs, third-party contract manufacturing organizations, or 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 or successful.

We believe that our available financial resources will enable us to fund our operating expense and capital expenditure requirements through at least 12 months from the issuance date of our audited consolidated financial statements included elsewhere in this Annual Report. 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.

In the future, we will require additional capital to meet operational needs and capital requirements. We are eligible to receive up to $125.0 million pursuant to the Funding Agreements (as defined herein), of which approximately $100.0 million has been received to date and $25.0 million is expected to be received in April 2024, subject to certain customary funding conditions. Except for this source of funding, we do not have any committed external source of liquidity. 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. We have historically raised funding through the sale of equity or debt securities and intend to consider future opportunities to raise additional funding when market conditions are favorable for us to do so. 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. However, the trading prices for our common stock and for other biopharmaceutical companies have been highly volatile. As a result, we may face difficulties raising capital through sales of our equity or debt securities or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, including due to war, international hostilities or terrorism, high inflation, the post-COVID environment, future public health epidemics or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. 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, that could adversely impact our ability to conduct our business. 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 other 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, as of December 31, 2023, we have not yet generated revenues. We have funded our operations primarily with the net proceeds received from the issuance of preferred stock, common stock and convertible senior notes, net proceeds from the consummation of our Business Combination (as defined herein) and our Funding Agreements.

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

- advance our clinical-stage product candidates through clinical development, including as we advance these candidates into later-stage clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the clinical development of our product candidates;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities to establish sales, marketing and distribution capabilities;
- 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;
- 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; and
- make milestone, royalty, interest or other payments due under the Funding Agreements, our 2027 convertible senior notes, or the 2027 Notes, and any future financing or other arrangements with third parties.

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 CROs and investigative clinical trial sites;
- expenses incurred with consultants and other third parties who supplement our internal capabilities and conduct research and development activities on our behalf;
- costs associated with research materials and supplies and services associated with our laboratory;
- materials and supply costs associated with the manufacture of drug substance and drug product for preclinical testing and clinical trials; 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 annual research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities as we continue to invest in activities to develop our product candidates and preclinical programs. 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 without limitation:

- 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;
- the efficacy and safety profile of our product candidates; and
- the impact of adverse macroeconomic, labor and other market conditions on our supply chain and clinical trial operations and timelines.

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 and equity-based compensation for personnel in executive, finance, human resources, market research and development, legal and other corporate functions. General and administrative expenses also include legal fees incurred relating to corporate and patent matters, professional fees incurred for auditing, consulting services, market development and pre-commercial planning activities, and insurance costs, facilities-related costs 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 annual general and administrative expenses will increase as we continue to build general corporate infrastructure to support the growth of our organization as we expand our research and development organization and market development and pre-commercial planning activities.

Interest Income, Net

Interest income consists of interest earned on our cash, cash equivalents, marketable securities and restricted cash.

Interest Expense

Interest expense consists of interest charged on the outstanding principal balance of the 2027 Notes and amortization of debt issuance costs utilizing the effective interest method over the expected term of the 2027 Notes.

Other Income (Expense), Net

Other income (expense), net primarily consists of gains (losses) on the fair value remeasurement of our financing liabilities. Other income (expense), net also reflects amounts for other miscellaneous income and expense unrelated to our core operations as well as gains (losses) on the fair value remeasurement of the private placement warrants through their cashless exercise and settlement in September 2021.

As permitted under ASC 825, *Financial Instruments*, we elected the fair value option for our financing liabilities, wherein the financial instruments were initially measured at their issue-date estimated fair value and are subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Changes in the fair value of our financing liabilities, excluding the impact of the change in fair value attributable to instrument-specific credit risk, are separately presented as a component of other income (expense), net in our consolidated statements of operations and comprehensive loss. The portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized and separately presented as a component of other comprehensive income (loss). Changes in the fair value of our financing liabilities can result from changes to one or multiple inputs, including changes to discount rates, changes in the expected achievement or timing of any sales-based, development or regulatory milestones, changes in the amount or timing of expected net cash flows, changes in the probability or timing of certain clinical events, or changes in the assumed probability or timing associated with regulatory approval.

The private placement warrants were determined to be free-standing financial instruments that were reclassified from equity to other long-term liabilities on March 31, 2021. We revalued the private placement warrants on a recurring basis each reporting period through their cashless exercise and settlement in September 2021, 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 the private placement warrants resulted 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.

Significant judgment is employed in determining the appropriateness of the assumptions underlying the initial fair value determination for each of these instruments and for each subsequent period through their settlement or termination.

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 our consolidated financial statements or our tax returns. Deferred tax assets and liabilities are determined based on the 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 December 31, 2023 and 2022, we continue to maintain a full valuation allowance against all of our net 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 audits 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 2022, 2021 and 2020 tax years. To the extent we have loss and credit carryforwards, the tax years in which the carryforward was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. 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

The following table summarizes our results of operations for the years ended December 31, 2023, 2022 and 2021:

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	2022 vs. 2021
Operating expenses:					
Research and development	$ 334,641	$ 280,259	$ 161,855	19 %	73 %
General and administrative	112,624	87,589	58,243	29 %	50 %
Total operating expenses	447,265	367,848	220,098	22 %	67 %
Loss from operations	(447,265)	(367,848)	(220,098)	22 %	67 %
Interest income, net	43,865	13,537	157	224 %	8522 %
Interest expense	(10,567)	(3,918)	—	170 %	**
Other income (expense), net	(18,372)	6,878	(5,393)	(367)%	(228)%
Loss before income taxes	(432,339)	(351,351)	(225,334)	23 %	56 %
Income tax benefit (provision), net	(503)	(160)	—	214 %	**
Net loss	$ (432,842)	$ (351,511)	$ (225,334)	23 %	56 %

** – Not meaningful

Research and Development

The following table summarizes the components of research and development expense for the years ended December 31, 2023, 2022 and 2021:

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	2022 vs. 2021
Tavapadon	$ 60,395	$ 57,953	$ 48,858	4 %	19 %
Emraclidine	97,709	74,331	15,472	31 %	380 %
Darigabat	23,915	22,388	19,461	7 %	15 %
CVL-871	3,489	3,904	4,773	(11)%	(18)%
Other research and development programs	18,119	21,999	15,973	(18)%	38 %
Unallocated	26,159	20,302	13,773	29 %	47 %
Personnel costs	76,960	61,176	34,325	26 %	78 %
Equity-based compensation	27,895	18,206	9,220	53 %	97 %
Total research and development	$ 334,641	$ 280,259	$ 161,855	19 %	73 %

For 2023 compared to 2022, the increase in research and development expense reflects the continued advancement of our tavapadon, emraclidine and darigabat programs. Increases in personnel costs, equity-based compensation and unallocated costs, including technology and facilities, reflect our continued expansion of capabilities to advance our pipeline. The increases in expenses associated with our emraclidine program for the comparative period primarily reflects an increase in expense incurred in the current year for the advancement of our two ongoing Phase 2 trials, our open-label extension trial and registration-enabling activities in schizophrenia and our ongoing Phase 1 trial to support future development in Alzheimer's disease psychosis, partially offset by a decrease in expense incurred in relation to our ambulatory blood pressure monitoring trial that was completed in December 2022. The increases in expenses associated with our tavapadon program for the comparative period primarily reflects increases associated with registration-enabling activities and our ongoing Phase 3 trials. The decreases in other research and development programs for the comparative period primarily reflects the timing of early-stage research and development activities.

For 2022 compared to 2021, the increase in research and development expense primarily reflects the continued advancement of our tavapadon, emraclidine and darigabat programs as well as increased investment in our preclinical and discovery research efforts. The increase in unallocated costs primarily reflects an increase in certain facilities-related costs following our laboratory becoming operational in the second quarter of 2021. The increase in personnel costs and equity-based compensation reflects the continued growth of our workforce as we expanded our capabilities to advance our pipeline.

For 2023 and 2022 expense associated with other research and development programs was reduced by $3.5 million and $4.4 million, respectively, related to the reimbursement of certain research and development costs as a result of cooperative grant funding from government agencies and/or other third-party institutions. For 2021, expense associated with other research and development programs was reduced by $0.9 million related to the reimbursement of certain research and development costs as a result of cooperative grant funding from government agencies.

General and Administrative

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	2022 vs. 2021
General and administrative	$ 112,624	$ 87,589	$ 58,243	29 %	50 %

For 2023 compared to 2022, the increase in general and administrative expense was primarily due to higher personnel costs, including equity-based compensation, and direct expenses associated with the potential Merger, partially offset by a reduction in spend associated with professional fees and services.

For 2022 compared to 2021, the increase in general and administrative expense was primarily due to higher personnel costs, including equity-based compensation, and other costs to support organizational growth and the advancement of our programs, including market research and development activities.

Interest Income, Net

The following table summarizes the components of interest income, net for the years ended December 31, 2023, 2022 and 2021:

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	2022 vs. 2021
Interest income, net	$ 43,865	$ 13,537	$ 157	224 %	8522 %

For 2023 compared to 2022, the increase in interest income, net, reflects increased interest income earned on higher average comparable cash, cash equivalent and marketable security balances and higher returns earned on our marketable securities.

For 2022 compared to 2021, the increase in interest income, net, reflects increased interest income earned on higher average comparable cash, cash equivalent and marketable security balances and higher returns earned on our marketable securities.

Interest Expense

The following table summarizes the components of interest expense for the years ended December 31, 2023, 2022 and 2021:

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	2022 vs. 2021
Interest expense	$ (10,567)	$ (3,918)	$ —	170 %	**

Interest expense consists of interest accrued on the principal balance of the 2027 Notes issued in August 2022 and the amortization of debt issuance costs. For additional information related to the 2027 Notes, please read *Note 9, 2027 Convertible Senior Notes*, to our audited consolidated financial statements included elsewhere in this Annual Report.

Other Income (Expense), Net

The following table summarizes the components of other income (expense), net for the years ended December 31, 2023, 2022 and 2021:

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	2022 vs. 2021
Gain (loss) on fair value remeasurement of financing liability, related party	$ (9,173)	$ 3,438	$ (751)	(367)%	(558)%
Gain (loss) on fair value remeasurement of financing liability	(9,173)	3,438	(751)	(367)%	(558)%
Loss on fair value remeasurement of private placement warrants	—	—	(3,881)	**	(100)%
Other, net	(26)	2	(10)	(1400)%	(120)%
Other income (expense), net	$ (18,372)	$ 6,878	$ (5,393)	(367)%	(228)%

For 2023, other income (expense), net primarily reflects net losses recognized on the fair value remeasurement of our financing liabilities associated with the Funding Agreements that were entered into in April 2021. The net loss on the fair value remeasurement of our financing liabilities was primarily due to the passage of time and the impact of changes in market inputs, including volatility and discount rates.

For 2022, other income (expense), net primarily reflects net gains recognized on the fair value remeasurement of our financing liabilities associated with the Funding Agreements. The changes in the fair value remeasurement of our financing liabilities were primarily due to the impact of changes in the estimated timing of certain clinical events and changes in market inputs, primarily risk-free rates, partially offset by the passage of time.

For 2021, other income (expense), net primarily reflects net losses recognized on the fair value remeasurement of our financing liabilities and private placement warrants. Changes in fair value remeasurement of our financing liabilities were primarily due to changes in discount rates, changes in the amount or timing of expected net cash flows and the passage of time. Changes in fair value remeasurement of our private placement warrants were primarily due to changes in the fair values of our common stock and public warrants, as well as changes in the volatility implied by the market price of our public warrants through their cashless exercise and settlement in September 2021.

For additional information related to the fair value of our financing liabilities associated with the Funding Agreements, please read Note 8, *Financing Liabilities*, and Note 10, *Fair Value Measurements*, to our audited consolidated financial statements included elsewhere in this Annual Report. For additional information on our private placement warrants, please read *Note 13, Stockholders' Equity*, to our audited consolidated financial statements included elsewhere in this Annual Report.

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 $432.8 million, $351.5 million and $225.3 million for the years ended December 31, 2023, 2022 and 2021, respectively, and as of December 31, 2023, we have not yet generated revenues.

Our cash, cash equivalents and marketable securities totaled $1,176.2 million as of December 31, 2023. Until required for use in our business, we typically invest our cash in money market funds and investment grade short to intermediate-term fixed income securities. We attempt to minimize credit risk related to our cash, cash equivalents and marketable securities by maintaining balances primarily in custodial accounts only with accredited financial institutions and maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity and investment type.

In October 2020, ARYA Sciences Acquisition Corp II, or 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. We refer to this transaction as the Business Combination. Net proceeds from the Business Combination totaled approximately $439.5 million. Upon closing of the Business Combination, Cerevel Therapeutics, Inc. became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc., and the then existing stockholders of Cerevel Therapeutics, Inc. exchanged their equity interests of Cerevel Therapeutics, Inc. for shares of common stock of Cerevel Therapeutics Holdings, Inc. Prior to the Business Combination, our operations were funded primarily from the issuance of convertible preferred stock, convertible common stock and common stock.

Upon the consummation of the Business Combination, there were 4,983,314 public warrants and 166,333 private placement warrants, or collectively, the warrants, outstanding. Each outstanding warrant of ARYA became one warrant to purchase one share of our common stock. Each whole warrant entitled the holder to purchase one share of our common stock at an exercise price of $11.50 per share. The warrants became exercisable beginning on June 9, 2021. In July 2021, we announced the redemption of all of the outstanding public warrants with a redemption date of August 30, 2021, or the Redemption Date. An aggregate of 4,822,947 public warrants were exercised prior to the Redemption Date for an equal number of shares of our common stock resulting in gross proceeds of approximately $55.5 million. The 160,367 public warrants that remained unexercised following the Redemption Date were redeemed for the redemption price of $0.01 per public warrant. In September 2021, the 166,333 private placement warrants were cashless exercised and settled in exchange for the issuance of 111,426 shares of our common stock.

In April 2021, we 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 up to $125.0 million in funding, or the Total Funding Commitment, to support our development of tavapadon for the treatment of Parkinson's disease over four years, of which approximately $31.1 million (25% of the Total Funding Commitment, net of $0.2 million of fees incurred by Bain and NovaQuest) was received in April 2021, $37.5 million (30% of the Total Funding Commitment) was received in April 2022, $31.3 million (25% of the Total Funding Commitment) was received in April 2023 and $25.0 million (20% of the Total Funding Commitment) is expected to be received in April 2024, subject to certain customary funding conditions. We refer to the NovaQuest Funding Agreement and the Bain Funding Agreement, collectively, as the Funding Agreements and NovaQuest and Bain, collectively, as the Funding Investors.

In July 2021, we completed a follow-on public offering of our common stock pursuant to which we issued and sold 14,000,000 shares of our common stock at a price to the public of $25.00 per share. The aggregate net proceeds from this offering totaled approximately $328.3 million, after deducting underwriting discounts and commissions of $21.0 million and offering expenses of approximately $0.7 million.

In November 2021, we entered into an open market sales agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale of up to $250.0 million of our common stock from time-to-time in "at-the-market" offerings, or the ATM Program. As of December 31, 2023, no sales had been made pursuant to the ATM Program.

In August 2022, we completed a follow-on public offering of our common stock pursuant to which we issued and sold 7,250,000 shares of our common stock at a price to the public of $35.00 per share. The aggregate net proceeds from this offering totaled approximately $238.3 million, after deducting underwriting discounts and commissions of $14.6 million and offering expenses of approximately $0.9 million.

In August 2022, we completed the offering of $345.0 million aggregate principal amount of the 2027 Notes pursuant to, and which are governed by, an indenture, or the Indenture, between us and U.S. Bank Trust Company, National Association, as trustee, or the Trustee, in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The aggregate net proceeds from the 2027 Notes offering totaled approximately $334.8 million, after deducting the initial purchasers' discounts of $9.5 million and other offering expenses of approximately $0.7 million.

In October 2023, we completed a follow-on public offering of our common stock pursuant to which we issued and sold an aggregate of 22,687,417 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $22.81 per share. The aggregate net proceeds from this offering totaled approximately $498.9 million, after deducting underwriting discounts and commissions of $18.3 million and offering expenses of approximately $0.3 million.

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.

Our future funding requirements will depend on many factors, including:

- the timing and ability to consummate the Merger;
- 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 under the Funding Agreements;
- the settlement method used for the outstanding 2027 Notes;

- our headcount growth and associated costs as we expand our research and development and market development and pre-commercial planning activities;
- 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 are 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.

The announcement of, or a failure to consummate, the Merger could negatively impact our business, financial condition, results of operations or our stock price. For additional information on risks associated with our substantial capital requirements, please read the sections entitled "—*Risks and Liquidity*" and "*Risk Factors*" included elsewhere in this Annual Report.

Working Capital

The following table summarizes our total working capital, defined as current assets less current liabilities as of December 31, 2023 and 2022:

(In thousands)	As of December 31, 2023	As of December 31, 2022	Change
Current assets	$ 1,006,938	$ 905,651	11 %
Current liabilities	(92,179)	(72,564)	27 %
Total working capital	$ 914,759	$ 833,087	10 %

The increase in working capital at December 31, 2023, from December 31, 2022, reflects a net increase in total current assets of $101.3 million partially offset by a net increase in total current liabilities of $19.6 million.

The net increase in total current assets was primarily driven by the net proceeds received from our financing activities, partially offset by cash used in operations and for purchases of property and equipment and non-current marketable securities.

The net increase in current liabilities was due to increases in accrued expenses and other current liabilities primarily related to external research and development services.

Cash Flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2023, 2022 and 2021:

(In thousands)	For the Year Ended December 31, 2023	2022	2021	Change 2023 vs. 2022	Change 2022 vs. 2021
Net cash flows used in operating activities	$ (342,301)	$ (293,187)	$ (178,546)	17 %	64 %
Net cash flows provided by (used in) investing activities	73,722	(388,834)	(435,661)	(119)%	(11)%
Net cash flows provided by financing activities	548,616	623,191	423,602	(12)%	47 %
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 280,037	$ (58,830)	$ (190,605)	(576)%	(69)%

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.

Net cash flows used in operating activities is derived by adjusting our net loss for:

- non-cash items such as depreciation and amortization, adjustments to operating lease expense, equity-based compensation, amortization of debt issuance costs, amortization of premiums and accretion of discounts on marketable securities and changes in the fair value remeasurement of our financing liabilities and private placement warrants; and
- changes in operating assets and liabilities reflecting timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations.

For 2023, net cash used in operating activities reflects our net loss for the period of $432.8 million, adjusted for net non-cash charges totaling $74.4 million and a net change of $16.1 million in our net operating assets and liabilities. Our non-cash adjustments primarily consisted of $69.4 million of equity-based compensation expense, $18.3 million of losses recognized from the fair value remeasurement of our financing liabilities and $5.6 million related to depreciation and amortization, partially offset by $19.7 million related to the net amortization of premiums and accretion of discounts on our marketable securities. The net changes in our operating assets and liabilities primarily reflects an increase in accrued expenses and other liabilities primarily driven by increases in accruals related to external research and development services.

For 2022, net cash used in operating activities reflects our net loss for the period of $351.5 million, adjusted for net non-cash charges totaling $30.3 million and a net change of $28.1 million in our net operating assets and liabilities. Our non-cash adjustments primarily consisted of $38.8 million of equity-based compensation expense and $4.9 million related to depreciation and amortization, partially offset by $6.9 million of gains recognized from the fair value remeasurement of our financing liabilities and $6.5 million from the amortization of premiums and accretion of discounts on marketable securities. The net changes in our operating assets and liabilities primarily reflects an increase in accrued expenses and other liabilities primarily driven by increases in accruals related to external research and development services, compensation and personnel costs and interest payable on the 2027 Notes.

For 2021, net cash used in operating activities reflects our net loss for the period of $225.3 million, adjusted for net non-cash charges totaling $31.2 million and a net change of $15.5 million in our net operating assets and liabilities. Our non-cash charges primarily consisted of $23.9 million of equity-based compensation expense, $3.9 million related to the final fair value remeasurement of private placement warrants through their cashless exercise and settlement, $2.7 million of depreciation and amortization and $1.5 million related to the fair value remeasurement of our financing liabilities. The net changes in our operating assets and liabilities primarily reflect an increase in operating lease liabilities resulting from landlord reimbursement for tenant improvements, an increase in accounts payable related to increased operating activities and the timing of payments, and an increase in accrued expenses related to increased operating activities. These increases are partially offset by a reduction in amounts accrued for property and equipment, an increase in prepaids and other current assets primarily due to advances related to clinical trials and other research activities, and the prepayment of insurance premiums and software licenses.

Cash Flows Provided by (Used in) Investing Activities

For 2023, net cash provided by investing activities reflects $942.8 million in maturities and redemptions of marketable securities, partially offset by $865.3 million used for purchases of marketable securities and $3.8 million used for purchases of property and equipment.

For 2022, net cash used in investing activities reflects $887.7 million used for purchases of marketable securities and $4.0 million used for purchases of property and equipment, partially offset by $502.9 million in maturities and redemptions of marketable securities.

For 2021, net cash used in investing activities reflects $425.2 million used for purchases of marketable securities and $10.5 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 2023, net cash provided by financing activities primarily reflects $498.9 million of net proceeds received from our October 2023 follow-on public offering of common stock, $31.3 million of proceeds received under the Funding Agreements and $18.6 million of proceeds received from the exercise of stock options and purchases of stock under our employee stock purchase plan.

For 2022, net cash provided by financing activities primarily reflects $238.3 million of net proceeds received from our August 2022 follow-on public offering of common stock, $334.8 million of net proceeds received from the issuance of the 2027 Notes, $37.5 million of proceeds received under the Funding Agreements and $13.1 million of proceeds received from the exercise of stock options and purchases of stock under our employee stock purchase plan.

For 2021, net cash provided by financing activities primarily reflects $328.3 million of net proceeds received from our follow-on offering, $55.5 million of net proceeds received from exercises of public warrants, $31.3 million of proceeds received under the Funding Agreements and $9.0 million of proceeds received from stock option exercises and purchases of stock under our ESPP.

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.

Contractual Obligations and Other Commitments

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, convertible debt obligations, contracts and other purchase obligations.

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 potential amounts related to uncertain tax positions. The timing and amount of such obligations are unknown or uncertain as of December 31, 2023.

Pfizer License Agreement

In August 2018, we entered into a license agreement with Pfizer, or 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 substantially all 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.

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 have been made or become due under this agreement.

For additional information related to the Pfizer License Agreement, please read Note 6, *Pfizer License Agreement*, to our audited consolidated financial statements included elsewhere in this Annual Report.

Funding Agreements

In April 2021, we entered into the Funding Agreements, pursuant to which we will receive a combined total of up to $125.0 million to support our development of tavapadon for the treatment of Parkinson's disease, of which approximately $31.1 million (25% of the Total Funding Commitment, net of $0.2 million of fees incurred by Bain and NovaQuest) was received in April 2021, $37.5 million (30% of the Total Funding Commitment) was received in April 2022, $31.3 million (25% of the Total Funding Commitment) was received in April 2023 and $25.0 million (20% of the Total Funding Commitment) is expected to be received in April 2024, subject to certain customary funding conditions. In return, we agreed to pay NovaQuest and Bain significant regulatory milestone, sales milestone and royalty payments upon approval of tavapadon by the FDA that collectively will not exceed $531.3 million. In addition, 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 an initial factor of 3.00x. This factor will increase ratably over time up to a maximum of 4.25x, less amounts previously paid to NovaQuest and Bain.

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.

For additional information related to our Funding Agreements, please read Note 8, *Financing Liabilities*, to our audited consolidated financial statements included elsewhere in this Annual Report.

2027 Convertible Senior Notes

In August 2022, we completed the offering of $345.0 million aggregate principal amount of the 2027 Notes pursuant to, and which are governed by the Indenture between us and the Trustee, in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act.

The 2027 Notes accrue interest at a rate of 2.50% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on February 15, 2023. The 2027 Notes mature on August 15, 2027, unless earlier converted, redeemed or repurchased. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

The 2027 Notes are our senior, unsecured obligations and are (i) equal in right of payment with our existing and future senior, unsecured indebtedness; (ii) senior in right of payment to our existing and future indebtedness that is expressly subordinated to the 2027 Notes in right of payment; (iii) effectively subordinated to our future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.

For additional information related to the 2027 Notes, please read Note 9*, 2027 Convertible Senior Notes*, to our audited consolidated financial statements included elsewhere in this Annual Report.

Management Agreement

In connection with the Business Combination, we entered into a management agreement with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP, providing for the expense reimbursement and indemnification of such entities. To date, no amounts have been incurred under the management agreement.

Contract Research and Manufacturing Organizations

As of December 31, 2023 and 2022, we recorded accrued expenses of approximately $45.0 million and $30.8 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 December 31, 2023 and 2022, we had no accrued interest or penalties related to uncertain tax positions.

Obligations Contingent upon Merger

We will be obligated to make significant contingent payments upon the consummation of the Merger. As the Merger was not deemed to be probable of being achieved as of December 31, 2023, we have not accrued any liabilities related to such contingent obligations in our consolidated financial statements as of December 31, 2023.

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 accounting principles generally accepted in the United States of America, 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 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 Annual Report.

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.

Fair Value Option for Funding Agreements

We elected to account for our funding agreements and related financing liabilities described in Note 8, *Financing Liabilities*, in accordance with the fair value option permitted under ASC 825-10, *Financial Instruments*. A liability associated with each of our funding agreements was initially recognized at their estimated fair value in our consolidated balance sheets. We revalue our financing liabilities on a recurring basis each reporting period with subsequent changes in fair value, excluding the impact of the change in fair value attributable to instrument-specific credit risk, separately presented as a component of other income (expense), net in our consolidated statements of operations and comprehensive loss. The portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized and separately presented as a component of other comprehensive income (loss).

We determined the estimated fair values using a Monte Carlo simulation model under the income approach determined by utilizing probability assessments of the expected future cash receipts and expected future cash payments. Changes in the fair value of our financing liabilities can result from changes to one or multiple inputs, including changes to discount rates, changes in the expected achievement or timing of any sales-based, development or regulatory milestones, changes in the amount or timing of expected net cash flows, changes in the probability or timing of certain clinical events and changes in the assumed probability or timing associated with regulatory approval. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

Upfront, direct costs and fees related to the instruments for which we have elected the fair value option were recognized in general and administrative expense in earnings as incurred.

The decision to elect the fair value option is determined on an instrument-by-instrument basis, and must be applied to an entire instrument and is irrevocable once elected, but need not be applied to all similar instruments. Assets and liabilities measured at fair value pursuant to ASC 825-10 are required to be reported separately from those instruments measured using another accounting method.

If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. For additional information on our qualifying instruments that we have elected to account for under the fair value option, please read Note 8, *Financing Liabilities*, and Note 10, *Fair Value Measurements,* to our audited consolidated financial statements included elsewhere in this Annual Report.

Recent Accounting Pronouncements

For a discussion of new accounting standards and their expected impact on our consolidated financial statements or disclosures, please read Note 5, *Recent Accounting Guidance*, to our audited consolidated financial statements included elsewhere in this Annual Report.

Item 7A. 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, which are affected by changes in the general level of U.S. interest rates.

We had cash, cash equivalents and marketable securities of $1,176.2 million and $950.2 million as of December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, these balances consisted of bank deposits, highly liquid money market funds and investment grade short to intermediate-term fixed income securities.

Interest Rate Sensitivity

The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2023, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $4.8 million to our interest rate sensitive instruments. As of December 31, 2022, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $3.6 million to our interest rate sensitive instruments.

The 2027 Notes bear interest at a fixed rate and therefore have minimal exposure to changes in interest rates. However, because these interest rates are fixed, we may be paying a higher interest rate, relative to market, in the future if our credit rating improves or other circumstances change. Our cash flows on this debt obligation are not subject to variability as a result of changes in interest rates.

Equity Price Risk

The 2027 Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or maturity of the 2027 Notes. The number of shares of common stock and/or amount of cash we may be required to pay upon conversion or maturity of the 2027 Notes is determined by the price of our common stock. The fair value of the 2027 Notes is dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes.

For additional information related to the 2027 Notes, please read Note 9, *2027 Convertible Senior Notes,* to our audited consolidated financial statements included elsewhere in this Annual Report.

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. Fluctuations in exchange rates have not been significant for us in any periods presented.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those financial statements is found in Item 15, Exhibit and Financial Statement Schedules, of this Annual Report.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

Internal Control Over Financial Reporting

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company’s principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company’s board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company’s assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company’s receipts and expenditures are being made only in accordance with authorizations of the company’s management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of a company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Ernst & Young LLP, our independent registered public accounting firm, has issued an auditor's report on management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023. This report is included below.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the fiscal quarter ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Cerevel Therapeutics Holdings, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Cerevel Therapeutics Holdings, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Cerevel Therapeutics Holdings, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 27, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2024

Item 9B. Other Information.

(a) None.

(b) Insider Trading Arrangements and Policies.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference or will be set forth in an amendment to this Annual Report to be filed on Form 10-K/A with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference or will be set forth in an amendment to this Annual Report to be filed on Form 10-K/A with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference or will be set forth in an amendment to this Annual Report to be filed on Form 10-K/A with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference or will be set forth in an amendment to this Annual Report to be filed on Form 10-K/A with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference or will be set forth in an amendment to this Annual Report to be filed on Form 10-K/A with the SEC no later than 120 days after the end of the fiscal year covered by this Annual Report.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) For a list of the financial statements included herein, see Index to the Financial Statements on page F-1 of this Annual Report.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

(b) Exhibit Index

Exhibit Number	Description
2.1†	Business Combination Agreement, dated as of July 29, 2020, by and among ARYA Sciences Acquisition Corp II, Cassidy Merger Sub 1, Inc. and Cerevel Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Annual Report on Form 10-K filed by the registrant on March 24, 2021).
2.2	Amendment No. 1 to Business Combination Agreement, dated as of October 2, 2020, by and between ARYA Sciences Acquisition Corp II and Cerevel Therapeutics, Inc. (incorporated by reference to Exhibit 2.2 to the Annual Report on Form 10-K filed by the registrant on March 24, 2021).
2.3†	Agreement and Plan of Merger, dated as of December 6, 2023, by and among AbbVie Inc., Symphony Harlan LLC, Symphony Harlan Merger Sub, Inc., and Cerevel Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by the registrant on December 7, 2023).
3.1	Certificate of Incorporation of Cerevel Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Annual Report on Form 10-K filed by the registrant on March 24, 2021).
3.2	Amended and Restated By-laws of Cerevel Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the registrant on June 15, 2022).
4.1	Description of the Registrant's securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934 (incorporated by reference to Exhibit 4.1 to the Annual Report on Form 10-K filed by the registrant on February 22, 2023).
4.2	Indenture, dated as of August 16, 2022, by and between Cerevel Therapeutics Holdings, Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the registrant on August 16, 2022).
4.3	Form of certificate representing the 2.50% Convertible Senior Notes due 2027 (incorporated by reference to Exhibit A to Exhibit 4.1 to the Current Report on Form 8-K filed by the registrant on August 16, 2022).
10.1	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Annual Report on Form 10-K filed by the registrant on March 24, 2021).
10.2	Subscription Agreement, by and between ARYA Sciences Acquisition Corp II and BC Perception Holdings, LP, dated July 29, 2020 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Registrant on July 30, 2020).
10.3	Amended and Restated Registration and Shareholder Rights Agreement, dated October 27, 2020, by and among Cerevel Therapeutics Holdings, Inc. and the stockholders party thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Registrant on November 2, 2020).
10.4	Waiver, dated January 20, 2021, by and among Cerevel Therapeutics Holdings, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on January 21, 2021).

10.5††	License Agreement, by and between Cerevel Therapeutics, LLC (f/k/a Perception OpCo, LLC) and Pfizer Inc., dated August 13, 2018 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-4 filed by the Registrant on October 2, 2020).
10.6	Lease Agreement, by and between Cerevel Therapeutics, LLC and DW Propco JK, LLC, dated July 3, 2019, as amended on September 1, 2020 (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed by the Registrant on November 2, 2020).
10.7	Second Amendment to Lease, by and between Cerevel Therapeutics, LLC and DW Propco JK, LLC, dated November 17, 2022 (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K filed by the registrant on February 22, 2023).
10.8#	Cerevel Therapeutics Holdings, Inc. 2020 Equity Incentive Plan. (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K filed by the registrant on March 24, 2021).
10.9#	Forms of Award Agreements under the Cerevel Therapeutics Holdings, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed by the Registrant on November 2, 2020).
10.10#	Cerevel Therapeutics Holdings, Inc. 2020 Amended and Restated Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.3 to the Registration Statement on Form S-8 filed by the Registrant on January 4, 2021).
10.11#	Senior Executive Cash Annual Incentive Plan (incorporated by reference to Exhibit 10.13 to the Current Report on Form 8-K filed by the registrant on November 2, 2020).
10.12#*	Severance Benefits Policy for Specified C-Suite Executives.
10.13#	Non-Employee Director Compensation Policy, as amended (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed by the registrant on August 2, 2023).
10.14#	Form of Indemnification Agreement (Directors) (incorporated by reference to Exhibit 10.16 to the Current Report on Form 8-K filed by the registrant on November 2, 2020).
10.15#	Form of Indemnification Agreement (Officers) (incorporated by reference to Exhibit 10.17 to the Current Report on Form 8-K filed by the registrant on November 2, 2020).
10.16#	Employment Agreement, dated November 23, 2018, by and between Cerevel Therapeutics, LLC and N. Anthony Coles, and amendments thereto (incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K filed by the registrant on November 2, 2020).
10.17#	Employment Agreement, dated April 20, 2021, by and between Cerevel Therapeutics, LLC and Scott M. Akamine (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed by the registrant on May 17, 2021).
10.18#	Offer Letter, dated August 18, 2019, by and between Cerevel Therapeutics, LLC and Mark Bodenrader (incorporated by reference to Exhibit 10.18 to the Quarterly Report on Form 10-Q filed by the registrant on November 16, 2020).
10.19#	Employment Agreement, dated April 1, 2019, by and between Cerevel Therapeutics, LLC and Kenneth DiPietro (incorporated by reference to Exhibit 10.19 to the Quarterly Report on Form 10-Q filed by the registrant on November 16, 2020).
10.20#	Employment Agreement, dated March 16, 2019, by and between Cerevel Therapeutics, LLC and John Renger (incorporated by reference to Exhibit 10.12 to the Current Report on Form 8-K filed by the registrant on November 2, 2020).
10.21#	Employment Agreement, dated November 26, 2018, by and between Cerevel Therapeutics, LLC and Ramiro Sanchez, and amendment thereto (incorporated by reference to Exhibit 10.11 to the Current Report on Form 8-K filed by the registrant on November 2, 2020).
10.22#	Employment Agreement, dated July 7, 2020, by and between Cerevel Therapeutics, LLC and Kathleen Tregoning (incorporated by reference to Exhibit 10.22 to the Quarterly Report on Form 10-Q filed by the registrant on November 16, 2020).
10.23††	Funding Agreement, dated as of April 12, 2021, by and between Cerevel Therapeutics, Inc. and NovaQuest Co-Investment Fund XVI, L.P. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed by the registrant on May 17, 2021).

10.24††	Funding Agreement, dated April 12, 2021, by and between Cerevel Therapeutics, Inc., and BC Pinnacle Holdings, LP (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed by the registrant on May 17, 2021).
10.25#	Separation Agreement, by and between Abraham Ceesay and Cerevel Therapeutics, LLC, dated as of February 21, 2023 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed by the registrant on May 3, 2023).
10.26	Waiver, dated as of April 27, 2023, by and among Cerevel Therapeutics Holdings, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed by the registrant on August 2, 2023).
10.27#	Form of Performance Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed by the registrant on August 2, 2023).
10.28#	Employment Agreement, dated as of May 1, 2023, between Cerevel Therapeutics, LLC and Ronald Renaud (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed by the registrant on August 2, 2023).
10.29#	Employment Agreement, dated as of April 14, 2023, between Cerevel Therapeutics, LLC and Susan Altschuller (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q filed by the registrant on August 2, 2023).
10.30#	Employment Agreement, dated as of June 12, 2023, between Cerevel Therapeutics, LLC and Paul Burgess (incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q filed by the registrant on August 2, 2023).
10.31	Support Agreement, dated as of December 6, 2023, by and among AbbVie Inc., Symphony Harlan, LLC, Symphony Harlan Merger Sub, Inc. and BC Perception Holdings, LP. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the registrant on December 7, 2023).
10.32#*	Form of Restricted Stock Unit Award Agreement
10.33#*	Severance Benefits Policy for Senior Vice Presidents and Vice Presidents
10.34#*	Form of Repayment Agreement
21.1	List of subsidiaries of the registrant (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form S-1 filed by the registrant on November 25, 2020).
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1#*	Amended and Restated Clawback Policy.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted in Inline XBRL and included in Exhibit 101)

* Filed or furnished herewith.

# Indicates a management contract, compensatory plan or arrangement.

† Schedules, exhibits or similar attachments to this Exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule, exhibit or similar attachment to the SEC upon request.

†† Portions (indicated by brackets and asterisks) have been omitted from this exhibit pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and the registrant customarily and actually treats such information as private or confidential.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

CEREVEL THERAPEUTICS HOLDINGS, INC.

Date: February 27, 2024

By: /s/ Ron Renaud

Ron Renaud
President and Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

Each person whose individual signature appears below hereby authorizes and appoints each of Ron Renaud, Scott Akamine and Susan Altschuller with full power of substitution and resubstitution and full power to act as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Exchange Act, this Annual Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ron Renaud **Ron Renaud**	Director, President and Chief Executive Officer *(Principal Executive Officer)*	February 27, 2024
/s/ Susan Altschuller **Susan Altschuller, Ph.D.**	Chief Financial Officer *(Principal Financial Officer)*	February 27, 2024
/s/ Mark Bodenrader **Mark Bodenrader**	Senior Vice President, Finance and Chief Accounting Officer *(Principal Accounting Officer)*	February 27, 2024
/s/ N. Anthony Coles **N. Anthony Coles**	Chairperson and Director	February 27, 2024
/s/ Deborah Baron **Deborah Baron**	Director	February 27, 2024
/s/ Marijn Dekkers **Marijn Dekkers**	Director	February 27, 2024
/s/ Doug Giordano **Doug Giordano**	Director	February 27, 2024
/s/ Christopher Gordon **Christopher Gordon**	Director	February 27, 2024
/s/ Adam Koppel **Adam Koppel**	Director	February 27, 2024
/s/ Ruth McKernan **Ruth McKernan**	Director	February 27, 2024
/s/ Deval Patrick **Deval Patrick**	Director	February 27, 2024
/s/ Norbert Riedel **Norbert Riedel**	Director	February 27, 2024
/s/ Gabrielle Sulzberger **Gabrielle Sulzberger**	Director	February 27, 2024
/s/ Suneet Varma **Suneet Varma**	Director	February 27, 2024

INDEX TO FINANCIAL STATEMENTS

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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 27, 2024 expressed an unqualified opinion thereon.

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 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. 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

	Accrued and Prepaid Research and Development Expenses
Description of the Matter	The Company's total accrued expenses and other current liabilities were $76.9 million at December 31, 2023, which included the estimated obligation for research and development expenses incurred as of December 31, 2023 but not paid as of the date. In addition, the Company's total prepaid expenses and other current assets were $16.0 million and other long-term assets were $3.4 million at December 31, 2023, which included amounts that were paid in advance of services incurred pursuant to research and development activities. As discussed in Note 4 to the consolidated financial statements, research and development expenses are expensed as incurred. The Company estimates and accrues the value of goods and services received from clinical research organizations and other third-party vendors each reporting period based on estimates of the level of services performed and progress in the period when an invoice has not been received from such organizations, which results in an accrual or prepayment at period end. Auditing the Company's accrued and prepaid research and development expenses was especially challenging due to the significant judgment required to estimate the services provided but not yet invoiced. Specifically, the amount of research and development expenses recognized is sensitive to assumptions, including estimates of the progress of the studies or clinical trials, including the phase or completion of events, and the associated cost of

such services. Additionally, due to the long duration of clinical trials and the timing of invoicing received from third parties, the actual amounts incurred are not always known at the time the financial statements are issued.

How We Addressed the Matter in Our Audit

We obtained an understanding of, evaluated the design and tested the operating effectiveness of internal controls that addressed the identified risks related to the Company's process for estimating accrued and prepaid research and development expenses.

To evaluate the Company's estimate of services incurred as of period end pursuant to its research and development activities, our audit procedures included, among others, testing the completeness and accuracy of the data and evaluating the significant assumptions, described above, that are used by management to estimate the recorded amounts. For example, to assess the reasonableness of the significant assumptions, we obtained information regarding the nature and extent of progress of clinical trials and other activities from the Company's research and development personnel that oversee the clinical trials and compared it to information obtained directly from third parties which indicated the third parties' estimate of costs incurred to date. Further, to evaluate the completeness and valuation of the accrued or prepaid research and development expenses, we compared invoices received by the Company subsequent to December 31, 2023 to the amounts recognized by the Company as of that date. We also inspected the Company's contracts with these third parties and any pending change orders to assess the impact to the amounts recorded.

Valuation of Financing Liabilities

Description of the Matter

As discussed in Notes 8 and 10 to the consolidated financial statements, on April 12, 2021, the Company entered into funding agreements with NovaQuest Co-Investment Fund XVI, L.P. and BC Pinnacle Holdings, LP. The Company concluded that each funding agreement represents a financial instrument that was considered to be a debt host containing embedded redemption features due to certain contingencies related to repayment and elected to account for the financing liabilities using the fair value option. In order to determine the fair value of the financing liabilities, the Company is required to estimate the probability of future cash receipts and future cash payments, and the timing of expected future repayments based on achievement of any sales-based, development and regulatory milestones or sales-based royalties, subject to the capped amount, over the life of the arrangement. Management determined the fair value of the financing liabilities using the Monte Carlo simulation model. The fair value of the financing liabilities related to the funding agreements totaled $112.2 million as of December 31, 2023.

Auditing the Company's financing liabilities was especially complex and required significant auditor judgment due to the use of the Monte Carlo simulation model and the high degree of subjectivity required to evaluate assumptions regarding the probability of future cash receipts and timing of expected future repayments. In particular, the fair value of the financing liabilities was sensitive to the Company's estimates of the timing and likelihood of regulatory approvals and amount of future sales for which royalties will be paid and the related discount rate.

How We Addressed the Matter in Our Audit

We obtained an understanding of, evaluated the design and tested the operating effectiveness of internal controls that addressed the identified risks related to the Company's process for valuing the financing liabilities.

To test the Company's estimate of the fair value of the financing liabilities, our audit procedures included, among others, inspecting the terms of the funding agreements, involving our internal valuation specialists to assist in assessing the Monte Carlo simulation model used and evaluating the significant assumptions described above that were used to develop the prospective financial information, and testing the completeness and accuracy of the underlying data. We evaluated the assumptions regarding the probabilities related to the timing and likelihood of regulatory approvals and amount of future sales in light of available peer data and market research, external data sources, probability of success benchmarks, and regulatory factors. In addition, our procedures included evaluating the data sources used by management in determining its assumptions and, where necessary, included an evaluation of available information that either corroborated or contradicted management's conclusions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Boston, Massachusetts
February 27, 2024

CEREVEL THERAPEUTICS HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts and per share data)

	As of December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 416,465	$ 136,521
Marketable securities	574,500	755,509
Prepaid expenses and other current assets	15,973	13,621
Total current assets	1,006,938	905,651
Marketable securities	185,199	58,126
Property and equipment, net	25,647	27,467
Operating lease assets	20,125	21,820
Restricted cash	1,960	1,867
Other long-term assets	3,429	2,891
Total assets	$ 1,243,298	$ 1,017,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,863	$ 10,061
Accrued expenses and other current liabilities	76,912	59,604
Operating lease liabilities, current portion	3,404	2,899
Total current liabilities	92,179	72,564
Operating lease liabilities, net of current portion	27,786	31,190
Financing liability, related party (Notes 8, 10 and 20)	56,082	28,674
Financing liability (Notes 8 and 10)	56,082	28,674
2027 convertible senior notes, net (Note 9)	337,424	335,482
Total liabilities	569,553	496,584
Commitments and contingencies (Notes 12, 17 and 18)		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value: 500,000,000 shares authorized; 181,362,064 and 156,502,285 shares issued and outstanding as of December 31, 2023 and 2022, respectively	18	16
Additional paid-in capital	2,072,553	1,485,880
Accumulated other comprehensive income (loss)	1,771	3,097
Accumulated deficit	(1,400,597)	(967,755)
Total stockholders' equity	673,745	521,238
Total liabilities and stockholders' equity	$ 1,243,298	$ 1,017,822

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,		
	2023	**2022**	**2021**
Operating expenses:			
Research and development	$ 334,641	$ 280,259	$ 161,855
General and administrative	112,624	87,589	58,243
Total operating expenses	447,265	367,848	220,098
Loss from operations	(447,265)	(367,848)	(220,098)
Interest income, net	43,865	13,537	157
Interest expense	(10,567)	(3,918)	—
Other income (expense), net (including related party amounts), (Notes 8, 11 and 20)	(18,372)	6,878	(5,393)
Loss before income taxes	(432,339)	(351,351)	(225,334)
Income tax benefit (provision), net	(503)	(160)	—
Net loss	$ (432,842)	$ (351,511)	$ (225,334)
Net loss per share, basic and diluted	$ (2.67)	$ (2.32)	$ (1.65)
Weighted-average shares used in calculating net loss per share, basic and diluted	162,056,405	151,265,635	136,576,536
Comprehensive loss:			
Net loss	$ (432,842)	$ (351,511)	$ (225,334)
Other comprehensive income (loss):			
Changes in fair value attributable to instrument-specific credit risk (including related party amounts), (Notes 8, 10 and 20)	(5,220)	6,816	(788)
Unrealized gains (losses) on securities available-for-sale	3,894	(2,733)	(198)
Total other comprehensive income (loss)	(1,326)	4,083	(986)
Comprehensive loss	$ (434,168)	$ (347,428)	$ (226,320)

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)

	Common stock		Additional paid-in	Accumulated other comprehensive income	Accumulated	Total stockholders'
	Shares	**Amount**	**capital**	**(loss)**	**deficit**	**equity**
Balance at December 31, 2020	127,123,954	$ 13	$ 775,417	$ —	$ (390,910)	$ 384,520
Issuance of common stock related to follow-on offering, net of offering costs (refer to Note 13)	14,000,000	1	328,250	—	—	328,251
Issuance of common stock related to exercise of public warrants	4,822,947	1	55,462	—	—	55,463
Issuance of common stock related to cashless exercise of private placement warrants	111,426	—	4,186	—	—	4,186
Issuance of common stock under equity incentive plans related to vesting of restricted stock units (RSUs)	42,810	—	—	—	—	—
Issuance of common stock under equity incentive plans related to exercise of options	1,533,914	—	8,067	—	—	8,067
Issuance of common stock under employee stock purchase plan (ESPP)	84,472	—	926	—	—	926
Reclassification of private placement warrants from equity to other long-term liabilities	—	—	(305)	—	—	(305)
Equity-based compensation expense	—	—	23,941	—	—	23,941
Other comprehensive loss	—	—	—	(986)	—	(986)
Net loss	—	—	—	—	(225,334)	(225,334)
Balance at December 31, 2021	147,719,523	$ 15	$ 1,195,944	$ (986)	$ (616,244)	$ 578,729
Issuance of common stock related to follow-on offering, net of offering costs (refer to Note 13)	7,250,000	1	238,104	—	—	238,105
Issuance of common stock under equity incentive plans related to vesting of restricted stock units (RSUs)	28,540	—	—	—	—	—
Issuance of common stock under equity incentive plans related to exercise of options	1,443,897	—	11,697	—	—	11,697
Issuance of common stock under employee stock purchase plan (ESPP)	60,325	—	1,355	—	—	1,355
Equity-based compensation expense	—	—	38,780	—	—	38,780
Other comprehensive income	—	—	—	4,083	—	4,083
Net loss	—	—	—	—	(351,511)	(351,511)
Balance at December 31, 2022	156,502,285	16	$ 1,485,880	$ 3,097	$ (967,755)	$ 521,238
Issuance of common stock related to follow-on offering, net of offering costs (refer to Note 13)	22,687,417	2	498,702	—	—	498,704
Issuance of common stock under equity incentive plans related to vesting of restricted stock units (RSUs)	305,375	—	—	—	—	—
Issuance of common stock under equity incentive plans related to exercise of options	1,788,964	—	16,493	—	—	16,493
Issuance of common stock under employee stock purchase plan (ESPP)	78,023	—	2,068	—	—	2,068
Equity-based compensation expense	—	—	69,410	—	—	69,410
Other comprehensive loss	—	—	—	(1,326)	—	(1,326)
Net loss	—	—	—	—	(432,842)	(432,842)
Balance at December 31, 2023	181,362,064	$ 18	$ 2,072,553	$ 1,771	$ (1,400,597)	$ 673,745

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,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (432,842)	$ (351,511)	$ (225,334)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	5,627	4,903	2,731
Adjustments to operating lease expense	(1,189)	(1,012)	(830)
Equity-based compensation	69,410	38,780	23,941
Change in fair value of financing liabilities (including related party amounts), (Notes 8, 11 and 20)	18,346	(6,876)	1,502
Change in fair value of private placement warrants	—	—	3,881
Non-cash interest expense	1,942	708	—
Amortization of premiums and accretion of discounts on marketable securities	(19,700)	(6,549)	22
Other non-cash items	(8)	306	—
Changes in operating assets and liabilities, net:			
Prepaid expenses and other current assets	(1,993)	(1,139)	(5,271)
Other assets	(1,343)	(841)	(733)
Accounts payable	2,038	(763)	7,278
Accrued expenses and other liabilities	17,411	30,807	8,672
Operating lease liability	—	—	5,595
Net cash flows used in operating activities	(342,301)	(293,187)	(178,546)
Cash flows from investing activities:			
Purchases of marketable securities	(865,270)	(887,737)	(425,158)
Maturities and redemptions of marketable securities	942,800	502,857	—
Purchases of property and equipment	(3,808)	(3,954)	(10,503)
Net cash flows provided by (used in) investing activities	73,722	(388,834)	(435,661)
Cash flows from financing activities:			
Proceeds from issuance of common stock related to follow-on offering, net of offering costs	498,944	238,263	328,251
Proceeds from the Business Combination Transaction, net of offering costs	—	—	(140)
Proceeds from the exercise of public warrants	—	—	55,463
Proceeds from the exercise of stock options and ESPP purchases	18,561	13,052	8,993
Proceeds from financing liability, related party	15,625	18,750	15,625
Proceeds from financing liability	15,625	18,750	15,625
Proceeds from issuance of 2027 convertible senior notes, net of offering costs	—	334,774	—
Deferred costs related to financing activities	(139)	(398)	(215)
Net cash flows provided by financing activities	548,616	623,191	423,602
Net increase (decrease) in cash, cash equivalents and restricted cash	280,037	(58,830)	(190,605)
Cash, cash equivalents and restricted cash, beginning of the period	138,388	197,218	387,823
Cash, cash equivalents and restricted cash, end of the period	$ 418,425	$ 138,388	$ 197,218
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 8,601	$ —	$ —
Cash paid for income taxes	$ 614	$ —	$ —
Supplemental cash flow disclosures from non-cash investing and financing activities:			
Fixed asset additions included in accounts payable and other current liabilities	$ —	$ 329	$ 747
Offering costs included in accounts payable and other current liabilities	$ 75	$ 139	$ 270
Cashless exercise of private placement warrants	$ —	$ —	$ 4,186
Reclassification of deferred financing costs to additional paid-in capital	$ 165	$ 158	$ —

The accompanying notes are an integral part of these consolidated financial statements.

CEREVEL THERAPEUTICS HOLDINGS, 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 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, Alzheimer’s disease psychosis, epilepsy, panic disorder and Parkinson’s disease. We are advancing our extensive and diverse pipeline with numerous clinical trials underway or planned, including three ongoing Phase 3 trials and an open-label extension trial for tavapadon in Parkinson’s, two ongoing Phase 2 trials and an open-label extension trial for emraclidine in schizophrenia, an ongoing Phase 2 proof-of-concept trial and an open-label extension trial for darigabat in focal epilepsy and an ongoing Phase 2 proof-of-concept trial for darigabat in panic disorder.

Our principal operations commenced on September 24, 2018 (Formation Transaction Date), when Cerevel Therapeutics, Inc. (Old Cerevel), a private company and our predecessor, in-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 (the Formation Transaction). In connection with the Formation Transaction, we entered into a stock purchase agreement with Pfizer and Bain Investor (the Stock Purchase Agreement), pursuant to which 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).

On October 27, 2020, ARYA Sciences Acquisition Corp II (ARYA) completed the acquisition of Old Cerevel pursuant to the Business Combination Agreement (the Business Combination Transaction or Business Combination). 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. Old Cerevel 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.

Upon closing of the Business Combination Transaction, Old Cerevel became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc. (New Cerevel) and the Equity Commitment, Share Purchase Option and Stock Purchase Agreement related to Old Cerevel were terminated and the remaining Equity Commitment immediately prior to the closing of $149.9 million was considered satisfied. In addition, the existing stockholders of Old Cerevel exchanged their equity interests of Old Cerevel for shares of common stock of 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.

On December 6, 2023, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with AbbVie Inc., a Delaware corporation, or AbbVie, Symphony Harlan LLC, a Delaware limited liability company and a wholly owned subsidiary of AbbVie, or Intermediate Holdco, and Symphony Harlan Merger Sub Inc., a Delaware corporation and a direct wholly owned subsidiary of Intermediate Holdco, or Merger Sub, pursuant to which, and on the terms and subject to the conditions thereof, at the effective time of the Merger, or the Effective Time, Merger Sub will merge with and into Cerevel, with Cerevel surviving as a wholly owned subsidiary of AbbVie, which we refer to as the Merger.

Under the terms of the transaction, among other things, AbbVie will acquire all outstanding shares of Cerevel for $45.00 per share in cash. The transaction values Cerevel at a total equity value of approximately $8.8 billion. The boards of directors of both companies have approved the transaction. This transaction is expected to close in the middle of 2024, subject to Cerevel stockholder approval, regulatory approvals and other customary closing conditions.

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 in-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 (CROs), third-party contract manufacturing organizations (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 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. We have incurred significant operating losses since our inception and, as of December 31, 2023, we have 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.

We have funded our operations primarily with the net proceeds received from the issuance of preferred stock, common stock and convertible senior notes, and the net proceeds from the consummation of the Business Combination and the Funding Agreements (as defined in Note 8, *Financing Liabilities*, to these consolidated financial statements). We believe that our available cash, cash equivalents and marketable securities as of December 31, 2023, will enable us to fund our operating expense and capital expenditure requirements through at least 12 months from the issuance date of these 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 stockholders 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 became one warrant to purchase one share of New Cerevel common stock. 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 held a majority of the voting power of the combined company, Cerevel comprised all of the ongoing operations of the combined entity, and a majority of the governing body of the combined company and Cerevel's senior management comprised 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 give effect to 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. The effect of the Exchange Ratio has been retroactively applied throughout our consolidated financial statements.

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 sheets. 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 Bain Investor (the Bain Subscription Agreement), Bain Investor, pre-funded a portion of its subscription amount by purchasing equity securities of Cerevel prior to the closing of the Business Combination Transaction, the proceeds of which were used to fund Cerevel's ongoing operations prior to completion of the transaction. 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 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. 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:

(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		(24,645)
Proceeds from Business Combination Transaction, net of offering costs paid per the Cash Flows from Financing Activities	$	442,477
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 Corp., 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 October 27, 2020, have been retroactively restated to give effect to 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 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 Chief Executive Officer and President. 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 consolidated 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 our financing liabilities, the fair value of equity-based awards and the accrual 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 contractual maturities of 90 days or less at the date of purchase to be cash equivalents. As of December 31, 2023 and 2022, our cash equivalents consisted of amounts invested in money market funds.

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 in our consolidated balance sheets as of December 31, 2023 and 2022. Restricted cash was classified as a non-current asset as the associated lease term expires more than 12 months from December 31, 2023.

A reconciliation of the cash, cash equivalents and restricted cash reported in our consolidated balance sheets that sum to the total of the amounts shown in the consolidated statements of cash flows is as follows:

	As of December 31,	
(In thousands)	2023	2022
Cash and cash equivalents	$ 416,465	$ 136,521
Restricted cash	1,960	1,867
Total cash, cash equivalents and restricted cash	$ 418,425	$ 138,388

Marketable Securities

We classify investments with original contractual maturities greater than 90 days at the date of purchase as marketable securities. Marketable securities with a remaining maturity date greater than one year are classified as non-current assets.

Marketable Debt Securities

Our investments in marketable debt securities are classified and accounted for as available-for-sale. Available-for-sale marketable debt securities are recorded at fair market value with unrealized gains and losses recognized in other comprehensive income (loss) unless the security has experienced a credit loss, or has experienced an unrealized loss and we have determined that we have the intent to sell the security or it is more likely than not that we will have to sell the security before its expected recovery. Realized gains and losses are reported in other income (expense), net, based on the specific identification method. Available-for-sale marketable securities are also adjusted for amortization of premiums and accretion of discounts to maturity, with such amortization and accretion included within interest income, net. Accrued interest receivable related to our available-for-sale marketable securities is presented within prepaid expenses and other current assets on our consolidated balance sheets.

Credit Losses

When the fair value of an available-for-sale debt security falls below the amortized cost basis it is evaluated to determine if any of the decline in value is attributable to a credit loss. Decreases in fair value attributable to credit losses are recorded directly to earnings with a corresponding allowance for credit losses, limited to the amount that the fair value is less than the amortized cost basis. If the credit quality subsequently improves the allowance is reversed up to a maximum of the previously recorded credit losses. If we intend to sell an impaired available-for-sale debt security, or if it is more likely than not that we will be required to sell the security prior to recovering the amortized cost basis, the entire fair value adjustment will immediately be recognized in earnings with no corresponding allowance for credit losses. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable debt security, duration and severity of the decline in value, and our strategy and intentions for holding the marketable debt security.

Concentration of Credit Risk

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities and restricted cash. All of these financial instruments are maintained at large, creditworthy and accredited financial institutions. Our cash 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 invest our excess cash primarily in money market funds, U.S. treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve capital and maintain liquidity. 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 to be held and used, such as property and equipment and other long-term assets, 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

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 in our consolidated balance sheets 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 consolidated 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 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 in a similar economic environment. 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.

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.

Fair Value Measurements

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. We have certain financial assets and liabilities recorded at fair value that have been classified and disclosed within one of the following three categories of the fair value hierarchy as described in the accounting standards for fair value measurements:

- 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.

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. 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 may require significant judgment and involve uncertainty. Changes in our fair value measurements could have a significant impact on our results of operations in any given period.

Fair Value Option for Funding Agreements

We elected to account for our funding agreements and related financing liabilities described in Note 8*, Financing Liabilities*, in accordance with the fair value option permitted under ASC 825-10, *Financial Instruments*. A liability associated with each of our funding agreements was initially recognized at their estimated fair value in our consolidated balance sheets. We revalue our financing liabilities on a recurring basis each reporting period with subsequent changes in fair value, excluding the impact of the change in fair value attributable to instrument-specific credit risk, separately presented as a component of other income (expense), net in our consolidated statements of operations and comprehensive loss. The portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized and separately presented as a component of other comprehensive income (loss). Changes in fair value attributable to instrument-specific credit risk are derived by benchmarking against the prior period credit spread to isolate the impact directly associated with the change in the credit spread utilized between periods.

Changes in the fair value remeasurement of our financing liabilities can result from changes in one or multiple inputs, including changes to discount rates, changes in the expected achievement or timing of any sales-based, development or regulatory milestones, changes in the amount or timing of expected net cash flows, changes in the probability or timing of certain clinical events, or changes in the assumed probability or timing associated with regulatory approval. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

The decision to elect the fair value option is determined on an instrument-by-instrument basis, and must be applied to an entire instrument and is irrevocable once elected, but need not be applied to all similar instruments. Assets and liabilities measured at fair value pursuant to ASC 825-10 are required to be reported separately from those instruments measured using another accounting method.

Upfront, direct costs and fees related to the instruments for which we have elected the fair value option are recognized in general and administrative expense in earnings as incurred.

For additional information on our qualifying instruments that we have elected to account for under the fair value option, please read Note 8*, Financing Liabilities*, and Note 10*, Fair Value Measurements,* 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. Costs directly associated with debt financings are amortized to interest expense using the effective interest method over the expected life of the related debt. Such debt issuance costs are presented on the consolidated balance sheets as a direct deduction from the related debt.

We have capitalized $0.3 million of deferred costs directly associated with our shelf registration statement on Form S-3 filed in November 2022. We reclassify such costs to additional paid-in capital on a pro-rata basis as we complete offerings under the shelf registration statement, with any remaining deferred costs charged to general and administration expense at the end of the life of the shelf registration. In October 2023, we reclassified $0.2 million of costs to additional paid-in capital as a result of the follow-on common stock offering under our shelf registration statement.

We had previously capitalized $0.5 million of deferred costs directly associated with our shelf registration statement on Form S-3 filed in November 2021. We reclassified $0.2 million of these costs to additional paid-in capital as a result of an offering under the shelf registration statement in August 2022 and charged the remaining $0.3 million of costs to general and administration expense in November 2022 upon the filing of the Form S-3 filed in November 2022.

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; expenses incurred with consultants and other third parties who supplement our internal capabilities; fees paid to other entities that conduct certain research and development activities on our behalf; costs associated with research materials and supplies and services associated with our laboratory; materials and supply costs associated with the manufacture of drug substance and drug product for preclinical testing and clinical trials; and 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, 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 or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the balances to be accrued 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.

Government Grants for Research and Development

We account for funds we receive from government grants based on specific facts and circumstances that best reflect the nature of the grant terms and conditions. To date, we have elected to account for funds received from government grants that are not in the form of an income tax credit, revenue from a contract with a customer or a loan, by analogy to International Accounting Standards (IAS) 20, *Accounting for Government Grants and Disclosure of Government Assistance.* We recognize funds we receive from government grants for qualifying reimbursable research and development activities in our consolidated statements of operations and comprehensive loss as an offset to research and development expense in the period in which the qualifying reimbursable research and development expenses are incurred and there is reasonable assurance that we will comply with the conditions attached to the grant and receive the funds.

Research and development expense for the years ended December 31, 2023, 2022 and 2021 was reduced by $3.1 million, $4.4 million and $0.9 million, respectively, related to the reimbursement of certain research and development costs received from the National Institute of Drug Abuse agency of the National Institutes of Health. Additionally, we have recognized a receivable in prepaid expenses and other current assets of $0.6 million and $1.4 million as of December 31, 2023 and 2022, respectively, for qualifying costs incurred but not yet reimbursed.

Concentration of Manufacturing Risk

We are dependent on third-party manufacturers for the manufacture and supply of all clinical supply of drug substances and drug products for research and development activities in our programs. In particular, we rely and expect to continue to rely on a small number of manufacturers to supply our requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

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 consolidated statements of operations and comprehensive loss.

Equity-Based Compensation

Our equity-based compensation programs grant awards that have included stock options, restricted stock units (RSUs), performance restricted stock units (PSUs) and shares issued under our employee stock purchase plan (ESPP). We determine the fair value of each employee and non-employee award issued under our equity-based compensation plan on the date of grant. Equity-based compensation expense is recognized based on the estimated fair value of the awards at the grant date.

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 and/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.

We 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 Fair Value – Preferred and Common Stock

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 Options

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 fair value of our common stock and the following assumptions:

- *Expected term* – We have opted to utilize 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 are granted "at-the-money."
- *Expected volatility* – We determine the volatility for options granted based on an analysis of reported data for a peer group of companies and our own internal volatility. The expected volatility of granted options has been determined by considering a weighted-average of the historical and implied volatility measures of the peer group of companies and our own historical and implied volatility measures. We will continue to apply this method until a sufficient amount of information regarding the volatility of our own stock price becomes available.
- *Risk-free interest rate* – 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.
- *Expected dividend* – 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 was based on a treasury instrument whose term is consistent with the expected life of the stock options. 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.

Determination of Fair Value – Restricted Stock Units (RSUs)

The fair value of our RSUs are determined based upon the fair value of our common stock on the date of grant.

Determination of Fair Value – Performance Restricted Stock Units (PSUs)

We utilized a Monte Carlo simulation model to determine the fair value of our PSU awards, which takes into consideration the possible outcomes pertaining to the market conditions of the PSUs.

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, 2023, 2022 and 2021, please read Note 14, *Equity-Based Compensation*, to these consolidated financial statements.

Common Stock Warrants and Derivative Financial Instruments

We accounted for our common stock purchase warrants and other freestanding derivative financial instruments 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)*, and reviewed our common stock purchase warrants and other freestanding derivative financial instruments at each balance sheet date to determine whether a change in classification was required.

Our assessment considered whether the warrants were freestanding financial instruments pursuant to ASC 480, whether the warrants met the definition of a liability pursuant to ASC 480, and whether the warrants met all of the requirements for equity classification under ASC 815, including whether the warrants were indexed to our own common stock and whether the warrant holders could have potentially required "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which required the use of professional judgment, was conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants were 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)

Upon the consummation of the Business Combination Transaction, there were 4,983,314 public warrants and 166,333 private placement warrants (collectively, the warrants) outstanding. Each outstanding warrant of ARYA became one warrant to purchase one share of New Cerevel common stock. We determined that the 4,983,314 public warrants satisfied the criteria for classification as equity instruments at each reporting period through their exercise or redemption. In certain circumstances, the identity of the holder may result in different settlement amounts, and therefore the private placement warrants were not considered indexed in our own stock in the manner contemplated by ASC Section 815-40-15. Accordingly, we recognized the liability associated with the 166,333 private placement warrants within other long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021, and revalued the liability on a recurring basis each reporting period through their cashless exercise and settlement in September 2021. We did not recognize a liability in relation to the private placement warrants prior to March 31, 2021, as we previously determined that the fair value of these warrants was immaterial. No warrants remained outstanding as of December 31, 2023 and 2022.

Changes in the fair value of the private placement warrants were recognized as an adjustment to other income (expense), net in our consolidated statements of operations and comprehensive loss, with such changes resulting 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.

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 we believe, 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 income (loss), which includes other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2023, 2022 and 2021, other comprehensive income (loss) consists of changes in fair value attributable to instrument-specific credit risk and net unrealized losses on our available-for-sale marketable securities.

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, common stock issuable upon conversion of convertible debt, 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 21, *Subsequent Events,* to these consolidated financial statements.

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 do not believe that the impact of recently issued standards that are not yet effective will have a material impact on our consolidated financial statements or related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and by extending the disclosure requirements to entities with a single reportable segment. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. ASU 2023-07 is to be applied retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. We are currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which modifies the rules on income tax disclosures to require entities to disclose (1) specific categories in the rate reconciliation, (2) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (3) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. We are currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

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 substantially all 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 certain significant transactions 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 our 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 Formation Transaction. The fair value of the Series A-2 Preferred Stock was established using an income approach for the valuation of our 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 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. Intellectual property licensed to us under the Pfizer License Agreement is limited to those 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 $190.0 million. To date, no regulatory approval milestone payments were made or became due under this agreement.

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 $1.4 billion. To date, no Pfizer commercial milestone payments were made or became due under this agreement.

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 a valid claim included in the patents licensed to us under the Pfizer License Agreement and (3) 12 years following the first commercial sale of such product in such country. To date, no royalty payments were made or became due under this agreement.

Pfizer can terminate the Pfizer License Agreement in its entirety upon a material breach by us, 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 (the Additional Financing Shares). As a result of these transactions, the remaining Equity Commitment was $149.9 million, which was considered satisfied upon closing of the Business Combination Transaction. Immediately prior to the closing of the Business Combination Transaction, the Equity Commitment was adjusted 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 completing an IPO or 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 had 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 have increased the number of shares available under the Share Purchase Option.

Upon closing of the Business Combination Transaction, the Share Purchase Option was terminated. Immediately prior to the closing of the Business Combination Transaction, the Share Purchase Option was adjusted to its final fair value of zero.

8. Financing Liabilities

Funding Agreements

In April 2021, 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 (the Funding Investors) will provide funding to support our development of tavapadon for the treatment of Parkinson’s disease.

Under the terms of 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 $125.0 million in funding (the Total Funding Commitment), of which approximately $31.1 million (25% of the Total Funding Commitment, net of $0.2 million of fees incurred by Bain and NovaQuest) was received in April 2021, $37.5 million (30% of the Total Funding Commitment) was received in April 2022, $31.3 million (25% of the Total Funding Commitment) was received in April 2023 and $25.0 million (20% of the Total Funding Commitment) is expected to be received in April 2024, 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 an initial factor of 3.00x. This factor will increase ratably over time up to a maximum of 4.25x, less amounts previously paid to NovaQuest and Bain.

During the term of the Funding Agreements, we 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 (each, a Technical Failure), we 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 we suspend or terminate the development of tavapadon or fail to perform certain diligence obligations for any reason other than a Technical Failure, we 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. 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.

We determined that each funding agreement represents a financial instrument that is considered to be a debt host containing embedded redemption features due to certain contingencies related to repayment. We elected to account for the Funding Agreements in accordance with the fair value option as permitted under ASC 825, *Financial Instruments*.

As of December 31, 2023 and 2022, the estimated fair value of the financing liability related to potential amounts payable to Bain under the Bain Funding Agreement, which is reflected in our consolidated balance sheets as financing liability, related party, totaled approximately $56.1 million and $28.7 million, respectively. As of December 31, 2023 and 2022, the estimated fair value of the financing liability related to potential amounts payable to NovaQuest under the NovaQuest Funding Agreement, which is reflected in our consolidated balance sheets as financing liability, totaled approximately $56.1 million and $28.7 million, respectively.

Changes in estimated fair value of the financing liabilities in our consolidated statements of operations and comprehensive loss are summarized as follows:

	For the Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Financing liability, related party			
Change in fair value recognized in other income (expense), net	$ (9,173)	$ 3,438	$ (751)
Change in fair value attributable to instrument-specific credit risk recognized in other comprehensive income (loss)	(2,610)	3,408	(394)
Financing liability			
Change in fair value recognized in other income (expense), net	$ (9,173)	$ 3,438	$ (751)
Change in fair value attributable to instrument-specific credit risk recognized in other comprehensive income (loss)	(2,610)	3,408	(394)

In addition, we recognized a charge to general and administrative expense of $0.6 million in the second quarter of 2021 for direct costs and fees incurred related to the Funding Agreements that cannot be deferred as a result of our election to apply the fair value option to the agreements.

9. 2027 Convertible Senior Notes

In August 2022, we completed the offering of $345.0 million aggregate principal amount of 2.50% Convertible Senior Notes due 2027 (the 2027 Notes) pursuant to, and which are governed by, an indenture (the Indenture), between us and U.S. Bank Trust Company, National Association, as trustee, in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The $345.0 million aggregate principal amount issued includes the purchase of $45.0 million aggregate principal amount issued pursuant to the full exercise by the initial purchasers of the 2027 Notes of their option to purchase additional 2027 Notes. The aggregate net proceeds from the 2027 Notes offering totaled approximately $334.8 million, after deducting the initial purchasers' discounts of $9.5 million and other offering expenses of approximately $0.7 million.

The 2027 Notes accrue interest at a rate of 2.50% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on February 15, 2023. The 2027 Notes mature on August 15, 2027, unless earlier converted, redeemed or repurchased. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election subject to terms and conditions provided in the Indenture.

Holders of 2027 Notes may convert all or any portion of their Notes at their option at any time prior to the close of business on the business day immediately preceding May 15, 2027, in multiples of $1,000 only in the following circumstances:

- during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on December 31, 2022, if the last reported sale price per share of our common stock exceeds 130% of the conversion price for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
- during the five consecutive business days immediately after any 10 consecutive trading day period (the Measurement Period) in which the trading price per $1,000 principal amount of notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price per share of our common stock on such trading day and the conversion rate on such trading day;
- upon the occurrence of certain corporate events or distributions on our common stock, as defined in the Indenture; and
- if we call the 2027 Notes for redemption.

From and after May 15, 2027, noteholders may convert their notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date.

The initial conversion rate is 21.5633 shares of common stock per $1,000 principal amount of the 2027 Notes, which represents an initial conversion price of approximately $46.38 per share of common stock, or a total of approximately 7,439,338 shares. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain events outlined within the Indenture. In addition, if certain corporate events that constitute a “Make-Whole Fundamental Change” (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

We may not redeem the 2027 Notes at any time before August 20, 2025 and no sinking fund is required to be provided for the 2027 Notes. The 2027 Notes will be redeemable, in whole or in part (subject to certain limitations described below), at our option at any time, on or after August 20, 2025, and on or before the 50th scheduled trading day immediately before the maturity date, under certain circumstances defined within the Indenture. We may not redeem less than all of the outstanding notes unless at least $100.0 million aggregate principal amount of notes are outstanding and not called for redemption as of the time we send the related redemption notice. The redemption price will be a cash amount equal to the principal amount of the 2027 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. In addition, calling any of the 2027 Notes for redemption will constitute a Make-Whole Fundamental Change with respect to such notes, in which case the conversion rate applicable to the conversion of such notes will be increased in certain circumstances if it is converted after it is called for redemption.

The Indenture has customary provisions relating to the occurrence of “Events of Default” (as defined in the Indenture), which include the following: (i) certain payment defaults on the 2027 Notes (which, in the case of a default in the payment of interest on the 2027 Notes, requires a default for 30 consecutive days); (ii) our failure to send certain notices under the Indenture within specified periods of time; (iii) our failure to convert the 2027 Notes upon the exercise of the conversion right with respect to such notes, subject to a three business day cure period; (iv) our failure to comply with certain covenants in the Indenture relating to our ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of our assets, taken as a whole, to another person; (v) a default in our other obligations or agreements under the Indenture or the 2027 Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (vi) certain defaults by us or any of our significant subsidiaries with respect to indebtedness for money borrowed of at least $50,000,000; and (vii) certain events of bankruptcy, insolvency and reorganization involving us or any of our significant subsidiaries. If an Event of Default involving bankruptcy, insolvency or reorganization events with respect to us occurs, then the principal amount of, and all accrued and unpaid interest on, all of the 2027 Notes then outstanding will immediately become due and payable without any further action or notice. If any other Event of Default occurs and is continuing, then, the Trustee, by notice to us, or noteholders of at least 25% of the aggregate principal amount of the 2027 Notes then outstanding, by notice to us and the Trustee, may declare the principal amount of, and all accrued and unpaid interest on, all of the 2027 Notes then outstanding to become due and payable immediately. Notwithstanding the foregoing, we may elect, at our option, that the sole remedy for an Event of Default relating to certain failures by us to comply with certain reporting covenants in the Indenture consists exclusively of the right of the noteholders to receive special interest on the 2027 Notes.

The 2027 Notes are our senior, unsecured obligations and are (i) equal in right of payment with our existing and future senior, unsecured indebtedness; (ii) senior in right of payment to our existing and future indebtedness that is expressly subordinated to the 2027 Notes in right of payment; (iii) effectively subordinated to our future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.

We accounted for the issuance of the 2027 Notes under ASC Topic 470-20, *Debt: Debt with Conversion and Other Options*, after the adoption of ASU 2020-06, which became effective beginning January 1, 2022. All of the proceeds received from the issuance of the 2027 Notes were recorded as a liability in our consolidated balance sheet. In connection with the issuance of the 2027 Notes, we incurred approximately $10.2 million of debt issuance costs, which primarily consisted of initial purchasers' discounts and other offering expenses. We accounted for the debt issuance costs as a debt discount for accounting purposes, which was recorded as a reduction in the carrying value of the debt in our consolidated balance sheet and is being amortized to interest expense using the effective interest method over the expected life of the 2027 Notes or approximately their five-year term. As of December 31, 2023, accrued interest on the 2027 Notes of $3.2 million was included in accrued expenses and other current liabilities in our consolidated balance sheet.

The net carrying amount of the 2027 Notes included in our consolidated balance sheets consisted of the following:

	As of December 31,	
(In thousands)	**2023**	**2022**
Principal amount	$ 345,000	$ 345,000
Unamortized debt discount	(7,576)	(9,518)
Net carrying amount	$ 337,424	$ 335,482

The following table sets forth the total interest expense related to the 2027 Notes recognized in interest expense in our consolidated statements of operations and comprehensive loss for the periods presented:

	For the Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Contractual interest expense	$ 8,625	$ 3,210	$ —
Amortization of debt issuance costs	1,942	708	—
Total interest expense	$ 10,567	$ 3,918	$ —
Effective interest rate	3.1%	3.1%	—

Future minimum payments under the 2027 Notes as of December 31, 2023, are as follows (in thousands):

Fiscal year ended December 31, 2024	$ 8,625
Fiscal year ended December 31, 2025	8,625
Fiscal year ended December 31, 2026	8,625
Fiscal year ended December 31, 2027	353,625
Thereafter	—
Total future payments	$ 379,500
Less: amounts representing interest	(34,500)
Total principal amount	$ 345,000

10. Fair Value Measurements

The tables below present information about our assets and liabilities that are measured and carried at fair value on a recurring basis and indicate the level within the fair value hierarchy of the inputs we utilized to determine such fair values:

As of December 31, 2023 *(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	$ 415,681	$ —	$ —	$ 415,681
Marketable securities (current)				
U.S. government treasuries	43,538	—	—	43,538
U.S. government agencies	—	201,058	—	201,058
Corporate debt securities	—	9,982	—	9,982
Commercial paper	—	319,922	—	319,922
Marketable securities (non-current)				
U.S. government treasuries	125,040	—	—	125,040
U.S. government agencies	—	60,159	—	60,159
Restricted cash				
Money market account	1,960	—	—	1,960
Total assets	$ 586,219	$ 591,121	$ —	$ 1,177,340
Liabilities:				
Financing liability, related party	$ —	$ —	$ 56,082	$ 56,082
Financing liability	—	—	56,082	56,082
Total liabilities	$ —	$ —	$ 112,164	$ 112,164

As of December 31, 2022 *(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	$ 136,521	$ —	$ —	$ 136,521
Marketable securities (current)				
U.S. government treasuries	103,238	—	—	103,238
U.S. government agencies	—	165,555	—	165,555
Corporate debt securities	—	9,416	—	9,416
Commercial paper	—	477,300	—	477,300
Marketable securities (non-current)				
U.S. government agencies	—	58,126	—	58,126
Restricted cash				
Money market funds	1,867	—	—	1,867
Total assets	$ 241,626	$ 710,397	$ —	$ 952,023
Liabilities:				
Financing liability, related party	$ —	$ —	$ 28,674	$ 28,674
Financing liability	—	—	28,674	28,674
Total liabilities	$ —	$ —	$ 57,348	$ 57,348

We have not recognized any impairments of our assets measured and carried at fair value during the year ended December 31, 2023.

There have been no changes in valuation techniques, inputs utilized or transfers between fair measurement levels in the periods presented. The fair value of our Level 2 instruments were determined using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly. We validate the prices provided by our third-party pricing services by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2023 and 2022.

The carrying amounts reflected in our 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. As of December 31, 2023, our financing liabilities represented our only Level 3 assets or liabilities carried at fair market value. Changes in the fair value remeasurement of our financing liabilities can result from changes in one or multiple inputs, including Level 3 fair value inputs that are not readily observable.

We reclassified the fair value associated with the 166,333 outstanding private placement warrants from equity to other long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021, and revalued the liability on a recurring basis each reporting period through their cashless exercise and settlement in September 2021. The fair value of our private placement warrant liability was determined utilizing a binomial lattice model using Level 3 fair value inputs. For the year ended December 31, 2021, we recognized net losses totaling $3.9 million on the fair value remeasurement of the private placement warrants within other income (expense), net. No private placement warrants remained outstanding as of December 31, 2023 and 2022. For additional information on our private placement warrants, please read *Note 13, Stockholders' Equity*, to these consolidated financial statements.

Marketable Securities

The estimated fair value and amortized cost of our available-for-sale marketable debt securities, by contractual maturity and security type, are summarized as follows:

As of December 31, 2023 *(In thousands)*	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Due in one year or less				
U.S. government treasuries	$ 43,487	$ 71	$ (20)	$ 43,538
U.S. government agencies	201,217	74	(233)	201,058
Corporate debt securities	9,954	28	—	9,982
Commercial paper	319,713	239	(30)	319,922
Due after one year through two years				
U.S. government treasuries	124,581	459	—	125,040
U.S. government agencies	59,783	379	(3)	60,159
Total marketable securities	$ 758,735	$ 1,250	$ (286)	$ 759,699

As of December 31, 2022 *(In thousands)*	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Due in one year or less				
U.S. government treasuries	$ 103,800	$ —	$ (562)	$ 103,238
U.S. government agencies	166,327	15	(787)	165,555
Corporate debt securities	9,454	—	(38)	9,416
Commercial paper	478,657	71	(1,428)	477,300
Due after one year through two years				
U.S. government agencies	58,327	7	(208)	58,126
Total marketable securities	$ 816,565	$ 93	$ (3,023)	$ 813,635

We had no realized gains or losses recognized on the sale or maturity of marketable securities during the years ended December 31, 2023, 2022 and 2021. To date, we have not recognized any allowances for credit losses or impairments in relation to our available-for-sale marketable securities as these marketable securities are comprised of high credit quality, investment grade securities that we do not intend or expect to be required to sell prior to their anticipated recovery, and the decline in fair value of these securities is attributable to factors other than credit losses. All marketable securities with unrealized losses presented in the previous tables have been in a continuous unrealized loss position for less than 12 months or the loss is not material. Based on our evaluation, we determined credit losses related to marketable securities were immaterial for the years ended December 31, 2023 and 2022.

The weighted average maturity of our marketable securities as of December 31, 2023 and 2022, was approximately eight months and five months, respectively.

Financing Liabilities

Upon execution of the Funding Agreements, we determined that the agreements qualified for election under the fair value option and initially measured the financial instruments at their issue-date estimated fair value. We revalue the related financing liabilities on a recurring basis at each reporting period.

As of December 31, 2023, the financing liability, related party and financing liability each totaled approximately $56.1 million. We determined their respective estimated fair values using a Monte Carlo simulation model under the income approach determined by using probability assessments of the expected future cash receipts and expected future cash payments and discount rates ranging from approximately 9.0% to 11.0% for the year ended December 31, 2023. For the year ended December 31, 2022, we used discount rates ranging from approximately 10.0% to 11.0%. The probability assessments of the expected future cash receipts and expected future payments and the timing of expected future repayments are based on significant inputs that are not observable in the market and are subject to remeasurement at each reporting date.

The following table provides a rollforward of the estimated fair value associated with our total financing liabilities:

(In thousands)	For the Year Ended December 31, 2023
Beginning balance, total financing liabilities	$ 57,348
Funding commitment received	31,250
Change in fair value recognized in other (income) expense, net	18,346
Change in fair value attributable to instrument-specific credit risk recognized in other comprehensive (income) loss	5,220
Ending balance, total financing liabilities	$ 112,164

For additional information related to the fair value of our financing liability and financing liability, related party, please read Note 8, *Financing Liabilities*, to these consolidated financial statements.

2027 Convertible Senior Notes

The fair value of the 2027 Notes, which were issued in August 2022, may differ from the carrying value. The fair value is determined utilizing prices for the 2027 Notes observed in market trading. As the market for the trading of the 2027 Notes is not considered to be an active market, the estimate of fair value is considered a Level 2 measurement. As of December 31, 2023, the estimated fair value of the 2027 Notes, which have an aggregate carrying value of $337.4 million was $382.0 million. As of December 31, 2022, the 2027 Notes had an aggregate carrying value and estimated fair value of $335.5 million and $341.7 million, respectively.

For additional information related to the 2027 Notes, please read Note 9, *2027 Convertible Senior Notes*, to these consolidated financial statements.

11. Financial Statement Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

(In thousands)	As of December 31, 2023	As of December 31, 2022
Prepaid clinical trial services	$ 1,717	$ 2,872
Prepaid research and development expenses	1,821	1,228
Prepaid insurance	2,608	2,460
Other prepaid expenses	3,973	3,556
Interest receivable	5,291	2,046
Other	563	1,459
Prepaid expenses and other current assets	$ 15,973	$ 13,621

Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	As of December 31, 2023	As of December 31, 2022
Computer equipment and software	$ 1,045	$ 996
Furniture and fixtures	459	459
Laboratory equipment	13,212	9,489
Leasehold improvements	23,481	23,461
Construction in progress	16	321
Less: Accumulated depreciation	(12,566)	(7,259)
Property and equipment, net	$ 25,647	$ 27,467

Depreciation expense totaled $5.3 million, $4.7 million and $2.5 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Other Long-Term Assets

Other long-term assets consisted of the following:

	As of December 31,	
(In thousands)	2023	2022
Other prepaid expenses, net of current portion	$ 1,886	$ 1,792
Deferred expenses associated with financing activities	122	286
Other	1,421	813
Other long-term assets	$ 3,429	$ 2,891

As of December 31, 2023 and 2022, other prepaid expenses, net of current portion, primarily consisted of deposits paid under certain CRO agreements that will be held until the completion and close-out of the related clinical trials with our CROs which are anticipated to end more than 12 months from the balance sheet date.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	As of December 31,	
(In thousands)	2023	2022
Accrued external research and development services	$ 51,300	$ 33,967
Accrued compensation and personnel costs	19,423	19,057
Accrued property and equipment	—	40
Accrued professional fees and consulting services	1,786	2,187
Accrued interest	3,234	3,210
Other	1,169	1,143
Accrued expenses and other current liabilities	$ 76,912	$ 59,604

Other Income (Expense), net

Other income (expense), net consisted of the following:

	For the Year Ended December 31,		
(In thousands)	2023	2022	2021
Gain (loss) on fair value remeasurement of financing liability, related party	$ (9,173)	$ 3,438	$ (751)
Gain (loss) on fair value remeasurement of financing liability	(9,173)	3,438	(751)
Loss on fair value remeasurement of private placement warrants	—	—	(3,881)
Other, net	(26)	2	(10)
Other income (expense), net	$ (18,372)	$ 6,878	$ (5,393)

12. Leases

We lease certain office space and equipment. 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. The lease allowed for a tenant improvement allowance of up to $200 per square foot, or approximately $12.2 million, which was fully reimbursed by the landlord by December 31, 2021.

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, or amounts owed to a lessor that are not fixed, such as property taxes, 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, 2023, 2022 and 2021:

(In thousands, except term and discount rate)	For the Year Ended December 31, 2023	2022	2021
Lease cost[1]			
Operating lease cost	$ 4,906	$ 4,906	$ 4,906
Variable lease cost	2,357	1,994	1,512
Total lease cost	$ 7,263	$ 6,900	$ 6,418
Other information			
Operating cash flows included in the measurement of operating lease liabilities	$ 6,095	$ 5,918	$ 5,736
Weighted-average remaining lease term (in years)	6.17	7.17	8.17
Weighted-average discount rate	9.90 %	9.90 %	9.90 %

(1) Short-term lease costs incurred for the years ended December 31, 2023, 2022 and 2021 were immaterial.

As of December 31, 2023, future minimum commitments under our operating leases were as follows:

(In thousands)	As of December 31, 2023
Maturity of lease liabilities	
Fiscal year ended December 31, 2024	$ 6,289
Fiscal year ended December 31, 2025	6,457
Fiscal year ended December 31, 2026	6,661
Fiscal year ended December 31, 2027	6,861
Fiscal year ended December 31, 2028	7,078
Thereafter	8,484
Total future lease payments	$ 41,830
Less: Effect of discounting	(10,640)
Present value of lease liabilities	$ 31,190

The following table summarizes the presentation of our operating leases in our consolidated balance sheets as of December 31, 2023 and 2022:

(In thousands)	As of December 31, 2023	2022
Assets		
Operating lease assets	$ 20,125	$ 21,820
Total lease assets	$ 20,125	$ 21,820
Liabilities		
Current lease liabilities	$ 3,404	$ 2,899
Noncurrent lease liabilities	27,786	31,190
Total lease liabilities	$ 31,190	$ 34,089

13. Stockholders' Equity

Preferred Stock

Pursuant to the terms of our certificate of incorporation, we have 10,000,000 authorized shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated. Our board of directors or any authorized committee thereof is expressly authorized, without further action by our stockholders, to issue such 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. There were no issued and outstanding shares of preferred stock as of December 31, 2023 and 2022.

Common Stock

Pursuant to the terms of our certificate of incorporation, we have 500,000,000 authorized shares of common stock, par value $0.0001 per share. There were 181,362,064 and 156,502,285 shares of common stock issued and outstanding as of December 31, 2023 and 2022, respectively.

Voting

The holders of our common stock are 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 our common stock are not entitled to vote on any amendment to our certificate of incorporation (or on any amendment to a certificate of designations of any series of preferred stock) 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, and there is no cumulative voting.

Dividends

Subject to any other provisions of our certificate of incorporation, holders of our 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. No dividends have been declared to date.

October 2023 Public Offering

In October 2023, we completed a follow-on public offering of our common stock pursuant to which we issued and sold an aggregate of 22,687,417 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $22.81 per share. The aggregate net proceeds from this offering totaled approximately $498.9 million, after deducting underwriting discounts and commissions of $18.3 million and offering expenses of approximately $0.3 million. Additionally, we reclassified $0.2 million of deferred offering costs to additional paid-in capital as a result of this offering related to our shelf registration statement on Form S-3, which was originally filed in November 2022. For additional information related to our accounting policies for offering costs, please read Note 4, *Summary of Significant Accounting Policies*, to these consolidated financial statements.

August 2022 Public Offering

In August 2022, we completed a follow-on public offering of our common stock pursuant to which we issued and sold 7,250,000 shares of our common stock at a price to the public of $35.00 per share. The aggregate net proceeds from this offering totaled approximately $238.3 million, after deducting underwriting discounts and commissions of $14.6 million and offering expenses of approximately $0.9 million. Additionally, we reclassified $0.2 million of deferred offering costs to additional paid-in capital as a result of this offering related to our shelf registration statement on Form S-3, which was originally filed in November 2021.

July 2021 Public Offering

In July 2021, we completed a follow-on public offering of our common stock pursuant to which we issued and sold 14,000,000 shares of our common stock at a price to the public of $25.00 per share. The aggregate net proceeds from this offering totaled approximately $328.3 million, after deducting underwriting discounts and commissions of $21.0 million and offering expenses of approximately $0.7 million.

ATM Program

In November 2021, we entered into an open market sales agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale of up to $250.0 million of our common stock from time-to-time in "at-the-market" offerings (the ATM Program). As of December 31, 2023, no sales had been made pursuant to the ATM Program.

Warrants

Upon the consummation of the Business Combination Transaction, there were 4,983,314 public warrants and 166,333 private placement warrants (collectively, the warrants) outstanding. Each outstanding warrant of ARYA became one warrant to purchase one share of New Cerevel common stock. Pursuant to the agreement, no fractional warrants were issued upon separation of the units and only whole warrants traded. If a holder would have been 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. The warrants became exercisable beginning on June 9, 2021.

Public Warrants

We determined that the 4,983,314 public warrants satisfied the criteria for classification as equity instruments in our consolidated balance sheets through their exercise or redemption.

On July 30, 2021, we announced the redemption of all of the outstanding public warrants with a redemption date of August 30, 2021 (the Redemption Date). Any public warrants that remained outstanding as of the Redemption Date became void and no longer exercisable and the holders of such public warrants became entitled to receive the redemption price of $0.01 per public warrant. At any time prior to the Redemption Date, the public warrants were able to be exercised by the holders to purchase shares of our common stock at the exercise price of $11.50 per share. An aggregate of 4,822,947 public warrants were exercised prior to the Redemption Date for an equal number of shares of our common stock, resulting in gross proceeds to us of approximately $55.5 million. The 160,367 public warrants that remained unexercised following the Redemption Date were redeemed for $0.01 per public warrant. No public warrants remained outstanding following the Redemption Date.

Private Placement Warrants

We reclassified the fair value associated with the 166,333 outstanding private placement warrants from equity to other long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021, and revalued the liability on a recurring basis each reporting period through their cashless exercise and settlement in exchange for the issuance of 111,426 shares of our common stock in September 2021. The fair value of the private placement warrants as of March 31, 2021, totaled approximately $0.7 million. 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, reflecting the net change in fair value of these warrants between October 27, 2020 and March 31, 2021. 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. No private placement warrants remained outstanding after their cashless exercise and settlement in September 2021.

For the year ended December 31, 2021, we recognized a net loss of $3.9 million as a component of other income (expense), net, related to the change in fair value of our private placement warrants. The change in the fair value of this liability was primary due to changes in the fair value of the underlying common stock.

14. 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 Year Ended December 31, 2023	2022	2021
Research and development	$ 27,895	$ 18,206	$ 9,220
General and administrative	41,515	20,574	14,721
Total equity-based compensation expense included in total operating expense	$ 69,410	$ 38,780	$ 23,941

The following table summarizes equity-based compensation expense by award type included in our consolidated statements of operations and comprehensive loss:

(In thousands)	For the Year Ended December 31, 2023	2022	2021
Stock options	$ 51,569	$ 38,089	$ 23,441
Restricted stock units	14,137	91	80
Performance restricted stock units	2,875	—	—
Employee stock purchase plan	829	600	420
Total equity-based compensation expense included in total operating expense	$ 69,410	$ 38,780	$ 23,941

Equity Incentive Plans

We have two share-based compensation plans pursuant to which awards are currently being granted: (1) the Cerevel Therapeutics Holdings, Inc. 2020 Equity Incentive Plan (the 2020 Plan); and (2) the Cerevel Therapeutics Holdings, Inc. Amended and Restated 2020 Employee Stock Purchase Plan (the ESPP).

Prior to the completion of the Business Combination Transaction, we had two share-based compensation plans under which awards were granted, but from which no further awards can or will be granted: (1) the Cerevel Therapeutics, Inc. Amended and Restated 2018 Equity Incentive Plan (the 2018 Plan); and (2) the Cerevel Therapeutics, Inc. 2020 Equity Incentive Plan (the Old 2020 Plan). Upon completion of the Business Combination Transaction, all awards under the 2018 Plan and Old 2020 Plan were converted into awards under the 2020 Plan with the same terms and conditions. As of the closing date of the Business Combination Transaction, 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 under the 2020 Plan upon completion of the Business Combination after giving effect to the Exchange Ratio. In addition, the 337,792 stock options awards outstanding under the Old 2020 Plan were converted into 964,051 stock options under the 2020 Plan upon completion of the Business Combination Transaction after effect of the Exchange Ratio.

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.

Cerevel Therapeutics Holdings, Inc. 2020 Equity Incentive Plan

On October 27, 2020, our board of directors approved the 2020 Plan, pursuant to which 24,050,679 shares of common stock were initially reserved for issuance. The 2020 Plan provides that the number of shares reserved and available for issuance under the 2020 Plan will automatically increase each January 1, beginning on January 1, 2021, by 4.0% 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. As of December 31, 2023, 14,334,620 shares remain available for future issuance under the 2020 Plan. The 2020 Plan provides for us to grant incentive stock options or nonqualified stock options to 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 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. Pursuant to the 2020 Plan, the exercise price of each award requiring exercise will be equal to 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 determines in connection with the grant, and the term of any stock option will not be greater than 10 years. We generally grant equity-based awards subject to service, market and performance conditions.

Stock Options

Stock options granted to employees under our plan 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 through the vesting dates.

Stock options granted to our non-employee directors generally vest, if at all, either in 36 monthly installments through the third anniversary of the grant date or 100% on the one-year anniversary of the grant date.

Stock options granted during the years ended December 31, 2023, 2022 and 2021 had a weighted average grant-date fair value of $25.11, $23.22 and $11.36, respectively. 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 Year Ended December 31,		
	2023	**2022**	**2021**
Risk free interest rate	3.82 %	2.23 %	0.80 %
Expected term (in years)	6.06	6.05	6.05
Expected volatility	89.2 %	96.2 %	93.5 %
Expected dividend yield	0.0 %	0.0 %	0.0 %

As of December 31, 2023, total unrecognized equity-based compensation expense relating to stock options outstanding was $105.2 million, which is expected to be recognized over a weighted average period of 2.5 years.

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 millions)*
Outstanding at December 31, 2022	17,178,861	$ 13.59	7.55	$ 309.9
Granted	2,842,487	33.12		
Exercised	(1,788,964)	9.22		
Forfeited, canceled or expired	(1,081,131)	23.90		
Outstanding at December 31, 2023	17,151,253	$ 16.64	6.92	$ 441.9
Options vested and expected to vest as of December 31, 2023	17,151,253	$ 16.64	6.92	$ 441.9
Options exercisable as of December 31, 2023	11,341,491	$ 11.38	6.19	$ 351.8

The intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 were $39.1 million, $33.5 million and $33.4 million, respectively. 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 29, 2023, the last trading day of the year, was $42.40.

Restricted Stock Units

Restricted stock unit awards granted under our plan generally vest in one or four equal annual installments beginning on the first anniversary of the vesting start date. The vesting of these awards is generally contingent upon the respective grantee’s continued service through the vesting date(s). The vesting for RSU Awards granted to certain executive officers in 2023 and 2022 was accelerated in December 2023 to mitigate the potential impact of Sections 280G and 4999 of the United States Internal Revenue Code of 1986, as amended, or the Code, in connection with the Merger, which resulted in incremental operating expense of $8.2 million recognized in the fourth quarter of 2023.

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, 2022	18,932	$ 26.41
Granted	1,065,944	31.87
Vested	(305,375)	32.61
Forfeited	(76,359)	34.41
Non-vested at December 31, 2023	703,142	$ 31.13

The total fair value of restricted stock units that vested was $12.6 million, $0.9 million and $0.9 million for the years ended December 31, 2023, 2022 and 2021, respectively. The weighted average grant date fair value of restricted stock units granted during the year ended December 31, 2022 was $26.41. There were no restricted stock units granted during the year ended December 31, 2021.

As of December 31, 2023, total unrecognized equity-based compensation expense relating to restricted stock unit awards was $17.5 million, which is expected to be recognized over a weighted average period of 3.3 years.

Performance Restricted Stock Units

During the year ended December 31, 2023, we granted 320,742 performance restricted stocks units (PSUs), all of which were granted in the second quarter of 2023. The number of PSUs granted represents the target number of units that are eligible to vest at the end of a four-year performance period, subject to the grantee's continued service through the end of the performance period. The PSUs will be settled in shares at the end of the four-year performance period and are equity-classified.

- 50% of the PSUs are eligible to vest based on our relative total shareholder return performance at the end of the performance period as compared against the constituent companies of the Nasdaq Biotech Index on the grant date, with a payout range of 0% to 250% of the target number of PSUs (relative PSUs).
- 50% of the PSUs are eligible to vest based on our absolute total shareholder return performance at the end of the performance period with a payout range of 0% to 250% of the target number of PSUs (absolute PSUs).

Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned.

We utilized a Monte Carlo simulation model to determine the fair value of the award, which takes into consideration the possible outcomes pertaining to the market conditions of the relative and absolute PSUs. The grant date fair value for the relative and absolute PSUs totaled $20.8 million, which is recognized as equity-based compensation expense on a straight-line basis over the requisite four-year service period. The absolute PSUs also provide for an alternate payout range of 50% to 275% of the target number of PSUs upon a Sale Event (as defined in the PSU award agreement). Equity-based compensation expense for the absolute PSUs does not contemplate the Sale Event as it is a performance condition that is not considered probable of being achieved.

The grant date fair value for the relative and absolute PSUs were $69.23 and $60.44, respectively, and included the following key assumptions:

Valuation date stock price	$	32.72
Term (in years)		4.00
Risk free interest rate		3.99 %
Volatility		86.3 %
Average peer group volatility[1]		78.8 %

[1] Assumption only utilized in the determination of fair value for the relative PSUs.

As of December 31, 2023, total unrecognized equity-based compensation expense relating to our PSUs was $17.9 million, which is expected to be recognized over a weighted average period of 3.4 years.

Cerevel Therapeutics Holdings, Inc. Amended and Restated 2020 Employee Stock Purchase Plan

At a special meeting of stockholders held on October 26, 2020, stockholders considered and approved 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. We received $2.1 million, $1.4 million and $0.9 million in cash and issued 78,023, 60,325 and 84,472 shares of common stock under the ESPP for the years ended December 31, 2023, 2022 and 2021, respectively.

15. 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 Year Ended December 31, 2023	2022	2021
Numerator:			
Net loss	$ (432,842)	$ (351,511)	$ (225,334)
Denominator:			
Weighted-average shares used in calculating net loss per share, basic and diluted	162,056,405	151,265,635	136,576,536
Net loss per share, basic and diluted	$ (2.67)	$ (2.32)	$ (1.65)

Since we were in a loss position for all periods presented, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders 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 attributable to common stockholders due to their anti-dilutive effect:

	For the Year Ended December 31,		
	2023	2022	2021
Stock options outstanding	17,151,253	17,178,861	16,066,064
Restricted stock units outstanding	703,142	18,932	28,540
Performance restricted stock units outstanding[1]	320,742	—	—
Common stock issuable upon conversion of the 2027 Notes	7,439,338	7,439,338	—
Total	25,614,475	24,637,131	16,094,604

[1] Performance restricted stock units reflect the target number of shares eligible to be earned at the time of grant.

For additional information related to the performance restricted stock units, please read Note 14, *Equity-Based Compensation*, to these consolidated financial statements. For additional information related to the conversion of the 2027 Notes, please read Note 9, *2027 Convertible Senior Notes*, to these consolidated financial statements.

16. 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,		
	2023	2022	2021
Statutory tax rate	21.0%	21.0%	21.0%
State tax expense, net of federal benefit	7.1%	6.4%	6.4%
Executive compensation	(1.8)%	(1.2)%	(2.3)%
Non-deductible fair value adjustment	—	—	(0.4)%
Stock based compensation	1.4%	1.5%	2.7%
Tax credits	2.8%	3.0%	2.3%
Other	(0.1)%	(0.1)%	0.9%
Valuation allowance	(30.5)%	(30.6)%	(30.6)%
Effective tax rate	(0.1)%	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:

	As of December 31,	
(In thousands)	2023	2022
Deferred tax assets		
Net operating loss carryforwards	$ 146,495	$ 121,799
Capitalized research and development	136,090	67,283
Operating lease liabilities	8,513	9,145
Tax credits	37,165	23,864
Equity-based compensation	22,171	12,923
Accruals and reserves	4,592	4,253
Amortization	583	632
Financing liabilities	30,834	17,001
Other deferred tax assets	1,976	—
Total gross deferred tax assets	388,419	256,900
Valuation allowance	(376,948)	(245,392)
Total deferred tax assets	11,471	11,508
Deferred tax liabilities		
Depreciation	(2,725)	(2,940)
Operating lease assets	(5,493)	(5,854)
Prepaid expenses	(2,761)	(2,714)
Other deferred tax liabilities	(492)	—
Total deferred tax liabilities	(11,471)	(11,508)
Net deferred tax assets (liabilities)	$ —	$ —

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2023 and 2022, as we believe that it is more likely than not that these assets will not be realized. Our valuation allowance increased by approximately $131.6 million and $107.5 million during the years ended December 31, 2023 and 2022, respectively, primarily as a result of the increase in our unbenefited net operating loss, tax credits, and the capitalization of research and development expenditures under Section 174 of the Code for both periods. Beginning in 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenditures in the period incurred and requires capitalization and amortization of such expenditures over five or fifteen years, as applicable, pursuant to Section 174 of the Code.

Significant components of deferred income tax assets and liabilities include temporary differences related to net operating loss carryforwards, capitalized research and development expenditures, lease liabilities, stock compensation, tax credits and our financing liabilities. As of December 31, 2023, deferred tax assets include approximately $533.2 million of federal net operating loss carryforwards, all of which have an indefinite carryforward period. As of December 31, 2023, deferred tax assets also include approximately $549.0 million of state net operating loss carryforwards, with $542.2 million expiring at various dates between 2031 and 2043 and the remaining $6.8 million having an indefinite carryforward period. As of December 31, 2023, we also had federal and state research and development tax credits of $33.3 million and $4.9 million, respectively, which begin to expire in 2039 for federal purposes and 2034 for state purposes. Under the provisions of the 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 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 our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. We have not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

For financial reporting purposes, net losses before income taxes include $432.3 million, $351.4 million and $225.3 million for the years ended December 31, 2023, 2022 and 2021, respectively. We have no foreign operations and as such, the pretax loss is generated entirely in the United States.

Our income tax (benefit) provision, net consisted of the following:

(In thousands)	For the Year Ended December 31, 2023	2022	2021
Current tax expense			
Federal	$ —	$ —	$ —
State	503	160	2
Foreign	—	—	—
Deferred tax expenses			
Federal	—	—	(2)
State	—	—	—
Foreign	—	—	—
Income tax (benefit) provision, net	$ 503	$ 160	$ —

As of December 31, 2023 and 2022, we had no unrecognized tax benefits. As of and for the years ended December 31, 2023, 2022 and 2021, respectively, we had no accrued interest or penalties related to uncertain tax positions and no such amounts have been recognized in our consolidated statements of operations and comprehensive loss.

We will recognize interest and penalties related to uncertain tax positions in income tax expense. For the years ended December 31, 2023, 2022 and 2021, 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. We currently remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for the 2022, 2021, and 2020 tax years. To the extent we have loss and credit carryforwards, the tax years in which the carryforward was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

17. Legal Proceedings

We, from time to time, may be subject to various legal proceedings and claims that may arise in the ordinary course of business. Except as described below, we were not subject to any material legal proceedings as of December 31, 2023, and, to the best of our knowledge, no material legal proceedings are currently pending or threatened.

In January and February of 2024, in connection with the Merger, three purported stockholders of the Company commenced actions against the Company and its board members challenging the adequacy of disclosures in the Company’s proxy statement relating to the Merger in the United States District Courts for the Southern District of New York and District of Delaware. The three actions are captioned Travers v. Cerevel Therapeutics Holdings, Inc., et al., Case No. 1:24-cv-00493 (S.D.N.Y.), Scott v. Cerevel Therapeutics Holdings, Inc., et al., Case No. 1:24-cv-00099-UNA (D. Del.), and Dixon v. Cerevel Therapeutics Holdings, Inc., et al., Case No. 1:24-cv-00100-UNA (D. Del.). A number of other purported stockholders sent letters and/or draft complaints to the Company alleging similar deficiencies as those noted above, and one purported stockholder issued a demand letter seeking inspection of the Company’s books and records pursuant to 8 Del. C. § 220. The Company believes that the claims described above are without merit and intends to vigorously defend against them. An estimate of the possible loss or range of losses cannot be made at this time and no liability has been recorded as of December 31, 2023.

18. Commitments and Contingencies

As of December 31, 2023, 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 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 obligations in the ordinary course of business. Pursuant to these obligations, we indemnify and agree to reimburse the indemnified party for certain losses and costs incurred by the indemnified party. The term of these indemnification obligations is generally perpetual after execution of the agreement. In addition, we have entered into indemnification obligations 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 consolidated financial statements as of December 31, 2023 and 2022.

Obligations Contingent upon Merger

We will be obligated to make significant contingent payments upon the consummation of the Merger. As the Merger was not deemed to be probable of being achieved as of December 31, 2023, we have not accrued any liabilities related to such contingent obligations in our consolidated financial statements as of December 31, 2023.

19. 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 and 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 totaled $4.0 million, $3.1 million and $1.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

20. Related Party Transactions

As of December 31, 2023 and 2022, Pfizer held 27,349,211 shares of our common stock and had nominated two members to our board of directors. For information related to our license agreement with Pfizer, please read Note 6, *Pfizer License Agreement*, to these consolidated financial statements.

As of December 31, 2023 and 2022, Bain Investor held 65,679,781 and 60,632,356 shares of our common stock, respectively, and had nominated six members to our board of directors, with two such representatives that were required to be independent and were subject to Pfizer's prior written consent.

Research Collaboration and License Agreement

In June 2022, we entered into a research collaboration and license agreement with Pfizer, pursuant to which we will collaborate to identify, screen and evaluate compounds directed at certain targets for neuroscience diseases using Pfizer's chemical library. Under the terms of the agreement, we will be required to reimburse Pfizer for certain research services and make a contingent development milestone payment and single-digit royalty payments on net sales of products containing one or more compounds derived from the collaboration. No amounts have been incurred under the agreement to date.

Funding Agreement

In April 2021, we entered into a funding agreement with Bain, pursuant to which Bain will provide up to $62.5 million in funding (the Bain Funding Commitment) to support our development of tavapadon for the treatment of Parkinson's disease over four years, of which approximately $15.5 million (25% of the Bain Funding Commitment, net of $0.1 million of fees incurred by Bain) was received in April 2021, approximately $18.8 million (30% of the Bain Funding Commitment) was received in April 2022 and approximately $15.6 million (25% of the Bain Funding Commitment) was received in April 2023. For additional information related to our funding agreement with Bain, please read Note 8, *Financing Liabilities*, to these consolidated financial statements.

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 would 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 us 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 the Business Combination Transaction, 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 during the year ended December 31, 2020.

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. No amounts were incurred under the management agreement during the years ended December 31, 2023, 2022 and 2021.

21. Subsequent Events

We have completed an evaluation of all subsequent events after the balance sheet date of December 31, 2023 through February 27, 2024, the issuance date of these financial statements, to ensure that these consolidated financial statements include appropriate disclosure of material events both recognized in the consolidated financial statements as of December 31, 2023, and material 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.

CEREVEL THERAPEUTICS HOLDINGS, INC.
SEVERANCE BENEFITS POLICY FOR SPECIFIED C-SUITE EXECUTIVES

(Adopted October 27, 2020, as subsequently amended January 17, 2024)

I. Purpose

Cerevel Therapeutics Holdings, Inc. (the "Company") hereby establishes an unfunded severance benefits policy (the "Policy"). The purpose of this Policy is to provide Covered Employees with certain severance benefits if they experience a qualifying involuntary termination of employment in connection with a Sale Event of the Company, subject to the below terms and conditions. This Policy became effective on October 27, 2020 (the "Effective Date").

II. Certain Definitions

"Administrator" shall mean the Compensation Committee of the Board or, in the absence of a Compensation Committee, the Board or a committee thereof designated by the Board.

"Affiliates" shall mean all persons and entities directly or indirectly controlling, controlled by or under common control with the Company, where control may be by management authority, equity interest or otherwise.

"Base Salary" shall mean, for any Covered Employee, such Covered Employee's base salary or base rate of pay as in effect immediately before a Covered Termination (or base salary or base rate of pay as in effect immediately prior to the Sale Event, if greater), exclusive of any bonuses, overtime pay, shift differentials, "adders," any other form of premium pay, or other forms of compensation.

"Board" shall mean the Board of Directors of the Company.

"Cause" shall mean Cause as defined in the applicable employment agreement between the Covered Employee and the Company.

"COBRA" shall mean the Consolidated Omnibus Budget Reconciliation Act.

"Code" shall mean the Internal Revenue Code of 1986, as amended.

"Covered Employees" shall mean all employees of the Company that are senior executive officers who report directly to the Company's Chief Executive Officer on an other than temporary basis.

"Covered Termination" shall mean a termination of a Covered Employee's employment with the Company either (a) by the Company without Cause, or (b) by the Covered Employee for Good Reason. Notwithstanding the foregoing, and for the avoidance of doubt, a Covered Termination does not include a termination (i) due to a Covered Employee's death; and (ii) due to a Covered Employee's Disability (as defined in the applicable employment agreement between the Covered Employee and the Company).

"Date of Termination" means the last day of the Covered Employee's employment with the Company.

"Good Reason" shall mean Good Reason as defined in the applicable employment agreement between the Covered Employee and the Company.

"Plan" shall mean the Company's 2020 Equity Incentive Plan, as may be amended from time to time, including any successor plan.

"Sale Event" shall have the definition contained in the Plan.

"Sale Event Period" shall mean the period that commences three (3) months prior to, and ends twelve (12) months following, the occurrence of the first event constituting a Sale Event.

"Separation Agreement" shall mean a separation agreement in the form provided by the Company containing a general waiver and release, non-disparagement, post-employment noncompetition, statutorily required revocation period, and other provisions customary for such agreements.

III. Conditions to Receipt of Severance Benefits

A Covered Employee shall be entitled to receive Severance Benefits (as defined below) under this Policy only if the Covered Employee (i) experiences a Covered Termination during a Sale Event Period; (ii) executes and delivers a Separation Agreement that becomes nonrevocable and otherwise fully effective (the date when this occurs is the "Separation Agreement Effective Date") within the time period required by the Separation Agreement but in no event later than 60 days following the Covered Employee's Date of Termination; and (iii) complies fully at all times with the provisions of any applicable noncompetition, nonsolicitation, confidentiality, invention assignment and/or other agreement between the Covered Employee and the Company (subsection (iii), the "Employee Obligations").

IV. Severance Benefits

The "Severance Benefits" shall consist of (i) the Severance Pay; (ii) the Benefits Continuation; (iii) the Incentive Compensation and (iv) the Equity Acceleration, each as defined as follows:

(i) *Severance Pay*. The "Severance Pay" shall mean the continuation of the Covered Employee's Base Salary rate over the twelve (12) month period immediately following the Date of Termination (such period, the "Severance Period").

(ii) *Benefits Continuation*. The "Benefits Continuation" shall mean the Company's payment of the Company's portion of the contributions to the cost of COBRA coverage on behalf of the Covered Employee, and any applicable dependents under COBRA, over the Severance Period. A Covered Employee shall only receive the Benefits Continuation if the Covered Employee elects COBRA coverage, and only for so long as the Covered Employee remains eligible for such coverage under COBRA. The Company's contribution to costs of the Benefits Continuation shall be determined on the same basis as the Company's contribution to Company-provided health and dental insurance coverage, in effect on the Date of Termination, for an active employee with the same coverage elections. The Covered Employee shall be responsible for paying the remaining portion of the premiums for such COBRA coverage as if the Covered Employee remained employed. The Covered Employee authorizes the deduction of the portion for which the Covered Employee is responsible from the Covered Employee's Severance Pay. Notwithstanding this subsection (ii), if the Covered Employee commences new employment and is eligible for a new group health plan, the Benefits Continuation shall cease when the Covered Employee's new employment begins.

(iii) *Incentive Compensation*. The "Incentive Compensation" shall mean one (1) times the Covered Employee's target cash bonus for the calendar year in which the Date of Termination occurs.

(iv) *Equity Acceleration*. The "Equity Acceleration" means that, notwithstanding anything to the contrary in the Plan or any applicable award agreement and with respect to awards that are granted to the Covered Employee on or after the Effective Date, (A) all awards with conditions and restrictions relating to the attainment of performance goals (if any) and for which there is no assumption, continuation, substitution or cash-out provided in connection with the Sale Event, may become immediately vested and payable in the Administrator's discretion or to the extent specified in the applicable award agreement, and (B) all time-based stock options and other stock-based awards subject to time-based vesting (the "Post-Effective Date Time-Based Equity Awards") shall accelerate and become fully exercisable or nonforfeitable immediately as of the later of (i) the Date of Termination or (ii) the Separation Agreement Effective Date (in either case, the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Post-Effective Date Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Policy will be delayed until the Separation Agreement Effective Date and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Post-Effective Date Time-Based Equity Awards shall occur during the period between the Covered Employee's Date of Termination and the Accelerated Vesting Date.

For the avoidance of doubt: (a) if a Covered Termination occurs outside of the Sale Event Period, Covered Employees shall not be eligible for Severance Benefits under this Policy, but instead may be eligible for severance benefits under the Covered Employee's Employment Agreement with the Company (and subject to the terms thereof); and (b) any stock options or other stock-based award granted to the Covered Employee prior to the Effective Date shall not be eligible for the Equity Acceleration under this Policy.

V. Timing of Severance Pay and Incentive Compensation

The Severance Pay and Incentive Compensation shall be paid out in substantially equal installments in accordance with the Company's payroll practices over the Severance Period, commencing within 60 days after the Date of Termination; *provided*, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, amounts payable hereunder shall begin to be paid in the second calendar year by the last day of such 60-day period;

provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Policy is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

VI. Equity Awards

Except with respect to the Equity Acceleration, the treatment of a Covered Employee's equity awards with the Company shall be governed by the terms of the Plan and applicable award agreement(s) in all respects.

VII. Recoupment

Without limiting the Company's other remedies at law or equity in any respect, if a Covered Employee fails to comply with the terms of this Policy, the Covered Employee's Employee Obligations, or the terms of the Separation Agreement, the Company shall have the right to require repayment to the Company of any amounts paid hereunder, and/or cancel or cause the forfeiture of the Covered Employee's equity rights, in any such case to the extent permitted by applicable law, and with the value or amount of such repayment, forfeiture or cancellation determined in the sole discretion of the Administrator. If such recoupment is the form of cash, such payment is due in cash or by check within 10 days after the Company provides notice to a Covered Employee that it is enforcing this provision. Any amounts payable or to be accelerated hereunder but not yet received by such Covered Employee will be immediately forfeited in the event of a failure to comply with the terms of this Policy, the Covered Employee's Employee Obligations, or the terms of the Separation Agreement.

VIII. Death After Covered Termination

If a Covered Employee dies after the date of his or her Covered Termination but before all payments or benefits to which such Covered Employee is entitled pursuant to this Policy have been paid or provided, any remaining payments and benefits will be made to any beneficiary designated by the Covered Employee prior to or in connection with such Covered Employee's Covered Termination or, if no such beneficiary has been designated, to the Covered Employee's estate. For the avoidance of doubt, if a Covered Employee dies during such Covered Employee's applicable Severance Period, Benefits Continuation will continue for the Covered Employee's applicable dependents for the remainder of the Covered Employee's Severance Period, subject to applicable law.

IX. Withholding

The Severance Benefits shall be subject to applicable taxes. The Company has the right to withhold such other amounts as may be withheld under the Company's policies and procedures from time to time in effect, subject to applicable law.

X. Section 409A

The payments under this Policy are intended either to be exempt from Section 409A of the Code ("Section 409A") under the short-term deferral, separation pay, or other applicable exception, or to otherwise comply with Section 409A. This Policy shall be administered in a manner consistent with such intent. For purposes of Section 409A, all payments under this Policy shall be considered separate payments. To the extent that any payment or benefit described in this Policy constitutes "non-qualified deferred compensation" under Section 409A, and to the extent that such payment or benefit is payable upon a Covered Employee's termination of employment, then such payments or benefits shall be payable only upon such Covered Employee's "separation from service" (determined in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h)). Notwithstanding any provision to the contrary, to the extent an Covered Employee is considered a specified "covered employee" under Section 409A and would be entitled, during the six-month period beginning on such Covered Employee's separation from service, to a payment that is not otherwise excluded under Section 409A, such payment will not be made until the earlier of (i) the date six months and one day after the Covered Employee's separation from service, or (ii) the Covered Employee's death. This Policy may be amended as may be necessary to fully comply with Section 409A and all related rules and regulations in order to preserve the payments and benefits provided hereunder. The Company makes no representation or warranty and shall have no liability to any Covered Employee or any other person if any provisions of this Policy are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, such Section.

XI. Section 280G

Notwithstanding anything herein to the contrary, in the event that the Severance Benefits to be provided to a Covered Employee pursuant to this Policy calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments") would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Covered Employee becomes subject to the excise tax imposed by Section 4999 of the Code; *provided* that such reduction shall only occur if it would result in the Covered Employee receiving a higher After Tax Amount (as defined below) than the Covered Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (i) cash payments not subject to Section 409A of the Code; (ii) cash payments subject to Section 409A of the Code; (iii) equity-based payments and acceleration; and (iv) non-cash forms of benefits; *provided* that in the case of all the foregoing Aggregate Payments, all amounts or payments that are not subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c). For purposes of this Policy, the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Covered Employee as a result of the Covered Employee's receipt of the Aggregate

Payments. For purposes of determining the After Tax Amount, the Covered Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to the Policy shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Covered Employee within fifteen (15) business days of the termination date, if applicable, or at such earlier time as is reasonably requested by the Company or the Covered Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Covered Employee.

XII. Administration

The Administrator shall be responsible for administering this Policy, and shall have all necessary authority to discharge such responsibilities, which include, but are not limited to, interpretation and construction of this Policy, the determination of all questions of fact and disputes, including, without limit, with respect to eligibility, participation and benefits, the resolution of any ambiguities and all other related or incidental matters. The Administrator may adopt rules and regulations in its interpretation and implementation of the Policy. The Administrator's determinations under this Policy shall be conclusive, final and binding on Covered Employees and the Company.

XIII. Not an Employment Contract

The Policy is not a contract between the Company and any employee, nor is it a condition of employment of any employee. Covered Employees remain employees at-will. Nothing contained in the Policy gives, or is intended to give, any employee the right to be retained in the service of the Company, or to interfere with the right of the Company to discharge or terminate the employment of any employee at any time and for any reason.

XIV. Severability

In case any one or more of the provisions of this Policy (or part thereof) shall be held to be invalid, illegal or unenforceable in any respect: (i) such provision(s) shall be reformed and enforced to its/their fullest permissible extent; (ii) any such invalidity, illegality or unenforceability shall not affect the other provisions hereof, and (iii) this Policy shall be construed as if such invalid, illegal or unenforceable provisions (or part thereof) never had been contained herein.

XV. Non-Assignability by Employees; Assignability by the Company

No right or interest of any Covered Employee in this Policy shall be assignable or transferable in whole or in part either directly or by operation of law or otherwise, including, but not limited to, execution, levy, garnishment, attachment, pledge or bankruptcy. The Company may assign or otherwise transfer this Policy to any other person or entity without any Covered Employee's consent.

XVI. Integration with Other Pay or Benefits Requirements

The terms of this Policy supersede any (i) severance plans and separation policies applicable to Covered Employees and (ii) provisions of any agreement between any Covered Employee and the Company, in either case ((i) or (ii)) to the extent such plans, policies or provisions provide for severance benefits in connection with a Covered Termination during a Sale Event Period. To avoid doubt, this Policy does not supersede (i) any severance benefits provided under the Employment Agreement between the Covered Employee and the Company with respect to any termination of the Covered Employee's employment occurring outside the Sale Event Period; and (ii) any right of the Covered Employee to garden leave pay under the Massachusetts Noncompetition Agreement Act ("Garden Leave Pay"). To the extent that the Company owes any amounts in the nature of severance benefits under any other program, policy plan or agreement of the Company that is not otherwise superseded by this Policy, or to the extent that any federal, state or local law, including, without limitation, so-called "plant closing" laws, requires the Company to give advance notice or make a payment of any kind to an employee because of that employee's involuntary termination due to a layoff, reduction in force, plant or facility closing, sale of business, or similar event, the benefits provided under this Policy or the other arrangement shall either be reduced or eliminated to avoid any duplication of payment. To the extent that the Covered Employee is entitled to any payments pursuant to any restrictive covenant agreement with the Company, including without limitation any Garden Leave Pay, the Severance Pay received by the Covered Employee in any calendar year shall be reduced by the amount the Covered Employee is paid in the same such calendar year (including Garden Leave Pay paid in such calendar year) pursuant to such restrictive covenant agreement. The terms of this Policy supersede any prior representations, communications or agreements regarding the subject matter hereof, i.e. Severance Benefits resulting from a Covered Termination within the Sale Event Period.

XVII. Amendment or Termination

The Board may amend, modify, or terminate the Policy at any time in its sole discretion prior to the Sale Event Period. Following the occurrence of a Sale Event, the Policy may not be amended in any respect that adversely affects the rights of any Covered Employee and may not be terminated until all obligations under the Policy have been satisfied.

XVIII. Governing Law

This Policy and the rights of all persons hereunder shall be construed in accordance with the laws of the Commonwealth of Massachusetts (without regard to conflict of laws provisions), and the Company and the Covered Employee waive the right to any jury with respect to any dispute under this Policy.

RESTRICTED STOCK UNIT AWARD AGREEMENT UNDER THE CEREVEL THERAPEUTICS HOLDINGS, INC. 2020 EQUITY INCENTIVE PLAN

(Employees)

Name of Grantee:	
No. of Restricted Stock Units:	
Grant Date:	

Pursuant to the Cerevel Therapeutics Holdings, Inc. 2020 Equity Incentive Plan as amended through the date hereof (the "Plan"), Cerevel Therapeutics Holdings, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.00001 per share (the "Stock") of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee maintains a continuous Service Relationship with the Company or a Subsidiary on such Dates, subject to Paragraph 3 of this Agreement. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

Incremental Number of Restricted Stock Units Vested	Vesting Date
_____________ (___%)	_______________
_____________ (___%)	_______________
_____________ (___%)	_______________
_____________ (___%)	_______________

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

3. Termination of Service.

(a) Subject to Paragraph 3(b) of this Agreement, if the Grantee's Service Relationship with the Company and its Subsidiaries terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such termination date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

(b) Notwithstanding Paragraph 3(a) of this Agreement, if the Grantee's Service Relationship with the Company and its Subsidiaries is terminated by the Company without Cause or by Grantee for Good Reason (each as defined in the Grantee's employment agreement with the Company or the Company's severance benefits policy or plan covering the Grantee, as applicable and as in effect on the date hereof) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, the Restricted Stock Units that have not vested as of such termination date shall accelerate and fully vest as of such date.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding. The Grantee shall, not later than the date as of which the receipt of this Award becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by (i) withholding from shares of Stock to be issued to the Grantee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; or (ii) causing its transfer agent to sell from the number of shares of Stock to be issued to the Grantee, the number of shares of Stock necessary to satisfy the Federal, state and local taxes required by law to be withheld from the Grantee on account of such transfer.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

8. No Obligation to Continue Service. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee in employment or any other Service Relationship and neither the Plan nor this Agreement shall interfere in any

way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Grantee at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file

with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

CEREVEL THERAPEUTICS HOLDINGS, INC.

By: ____
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: ____ ____

Grantee's Signature

Grantee's name and address:

____

____

____

CEREVEL THERAPEUTICS HOLDINGS, INC.
SEVERANCE BENEFITS POLICY FOR SENIOR VICE PRESIDENTS AND VICE PRESIDENTS

(Adopted September 28, 2022, as subsequently amended January 17, 2024)

I. Purpose

Cerevel Therapeutics Holdings, Inc. (the "Company") hereby establishes an unfunded severance benefits policy (the "Policy"). The purpose of this Policy is to provide Covered Employees with certain severance benefits if they experience a qualifying involuntary termination of employment, subject to the below terms and conditions. This Policy became effective on October 27, 2020 (the "Effective Date").

II. Certain Definitions

"Administrator" shall mean the Compensation Committee of the Board or, in the absence of a Compensation Committee, the Board or a committee thereof designated by the Board.

"Affiliates" shall mean all persons and entities directly or indirectly controlling, controlled by or under common control with the Company, where control may be by management authority, equity interest or otherwise.

"Base Salary" shall mean, for any Covered Employee, such Covered Employee's base salary or base rate of pay as in effect immediately before a Covered Termination (or base salary or base rate of pay as in effect immediately prior to the Sale Event, if greater), exclusive of any bonuses, overtime pay, shift differentials, "adders," any other form of premium pay, or other forms of compensation.

"Board" shall mean the Board of Directors of the Company.

"Cause" shall mean the occurrence of any of the following, as determined by the Administrator in its reasonable judgment: (i) the Covered Employee's failure to comply with a material directive of the executive to whom the Covered Employee directly reports, the Company's Chief Executive Officer or the Board, or the Covered Employee's gross negligence in the performance of the Covered Employee's duties and responsibilities to the Company or any of its Affiliates; (ii) the Covered Employee's material breach of the Covered Employee's offer letter or employment agreement with the Company, or any other written agreement between the Covered Employee and the Company or any of its Affiliates; (iii) the Covered Employee's indictment for, or plea of nolo contendere to, a felony or other crime involving moral turpitude that causes or could reasonably be expected to cause material harm to the business interests or reputation of the Company or any of its Affiliates; or (iv) fraud, theft, embezzlement or other intentional misconduct by the Covered Employee that is or could reasonably be expected to be materially harmful to the business interests or reputation of the Company or any of its Affiliates. Cause shall not exist hereunder, in the case of (i) or (ii) above, unless the Company has provided the Covered Employee with written notice of the event(s) alleged to constitute Cause thereunder and, if such event(s) are susceptible to cure, a 15 day period to cure following the receipt of such notice in which the Covered Employee has failed to cure such event(s).

"COBRA" shall mean the Consolidated Omnibus Budget Reconciliation Act.

"Code" shall mean the Internal Revenue Code of 1986, as amended.

"Covered Employees" shall mean all employees of the Company that are (a) at the Senior Vice President level or who are otherwise graded as "C-12" in the Company's pay grade system or (b) at the Vice President level or who are otherwise graded as "C-11" in the Company's pay grade system.

"Covered Termination" shall mean a termination of a Covered Employee's employment with the Company either (a) by the Company without Cause, or (b) by the Covered Employee for Good Reason. Notwithstanding the foregoing, and for the avoidance of doubt, a Covered Termination does not include a termination (i) due to a Covered Employee's death; or (ii) due to a Covered Employee's Disability.

"Date of Termination" means the last day of the Covered Employee's employment with the Company.

"Disability" shall mean that a Covered Employee becomes disabled during his or her employment through any illness, injury, accident or condition of either a physical or psychological nature and, as a result, is unable to perform substantially all of his or her duties and responsibilities, even with a reasonable accommodation, for a period of ninety (90) consecutive days or one hundred and twenty (120) days (whether or not consecutive) during any period of three hundred sixty-five (365) consecutive days.

"Good Reason" shall mean, without a Covered Employee's consent, (i) any diminution in the Covered Employee's Base Salary or target bonus, unless applied across-the-board to all similarly-situated Covered Employees of the Company and not more than five percent (5%); (ii) any material diminution in the Covered Employee's titles, authority, duties or responsibilities, provided that a reduction in titles, authority, duties or responsibilities solely by virtue of the Company being acquired and made part of a larger entity, whether as a subsidiary, business unit or otherwise (as, for example, when a Vice President of the Company remains a Vice President of the Company following a Sale Event where the Company becomes a wholly owned subsidiary of the acquiror, but is not made the Vice President of the acquiring corporation), will not in and of itself constitute Good Reason; (iii) a permanent reassignment of the Covered Employee's primary office to a location more than 35 miles from the Company's offices in Massachusetts; or (iv) a material failure of the Company to comply with this Policy or any material breach by the Company of any other written agreement with the Covered Employee; provided, however, that Good Reason shall not exist hereunder unless: (A) the Covered Employee has provided the Company with written notice of the event(s) alleged to constitute Good Reason within 30 days after the initial occurrence of such event(s), (B) the Company fails to cure such event(s) within 30 days following its receipt of such notice (the "Good Reason Cure Period") and (C) the Covered Employee terminates the Covered Employee's employment for Good Reason at any time within the 30-day period immediately following the last day of the Cure Period.

"Plan" shall mean the Company's 2020 Equity Incentive Plan, as may be amended from time to time, including any successor plan.

"Sale Event" shall have the definition contained in the Plan.

"Sale Event Period" shall mean the period that commences three (3) months prior to, and ends twelve (12) months following, the occurrence of the first event constituting a Sale Event.

"Separation Agreement" shall mean a separation agreement in the form provided by the Company containing a general waiver and release, non-disparagement, post-employment noncompetition, statutorily required revocation period, and other provisions customary for such agreements.

III. Conditions to Receipt of Severance Benefits

A Covered Employee shall be entitled to receive Severance Benefits (as defined below) under this Policy only if the Covered Employee (i) experiences a Covered Termination; (ii) executes and delivers a Separation Agreement that becomes nonrevocable and otherwise fully effective (the date when this occurs is the "Separation Agreement Effective Date") within the time period required by the Separation Agreement but in no event later than 60 days following the Covered Employee's Date of Termination; and (iii) complies fully at all times with the provisions of any applicable noncompetition, nonsolicitation, confidentiality, invention assignment and/or other agreement between the Covered Employee and the Company (subsection (iii), the "Employee Obligations").

IV. Severance Benefits

The "Severance Benefits" shall consist of (i) the Severance Pay and (ii) the Benefits Continuation. If the Covered Termination occurs during the Sale Event Period, the Severance Benefits shall also include (iii) the Incentive Compensation and (iv) the Equity Acceleration, each as defined as follows:

(i) *Severance Pay*. The "Severance Pay" shall mean the continuation of the Covered Employee's Base Salary rate over the nine (9) month period immediately following the Date of Termination (such period, the "Severance Period").

(ii) *Benefits Continuation*. The "Benefits Continuation" shall mean the Company's payment of the Company's portion of the contributions to the cost of COBRA coverage on behalf of the Covered Employee, and any applicable dependents under COBRA, over the Severance Period. A Covered Employee shall only receive the Benefits Continuation if the Covered Employee elects COBRA coverage, and only for so long as the Covered Employee remains eligible for such coverage under COBRA. The Company's contribution to costs of the Benefits Continuation shall be determined on the same basis as the Company's contribution to Company-provided health and dental insurance coverage, in effect on the Date of Termination, for an active employee with the same coverage elections. The Covered Employee shall be responsible for paying the remaining portion of the premiums for such COBRA coverage as if the Covered Employee remained employed. The Covered Employee authorizes the deduction of the portion for which the Covered Employee is responsible from the Covered Employee's Severance Pay. Notwithstanding this subsection (ii), if the Covered Employee commences new employment and is eligible for a new group health plan, the Benefits Continuation shall cease when the Covered Employee's new employment begins.

(iii) *Incentive Compensation*. The "Incentive Compensation" shall mean 0.75 times the Covered Employee's target cash bonus for the calendar year in which the Date of Termination occurs.

(iv) *Equity Acceleration*. The "Equity Acceleration" means that, notwithstanding anything to the contrary in the Plan or any applicable award agreement and with respect to awards that are granted to the Covered Employee on or after the Effective Date, (A) all awards with conditions and restrictions relating to the attainment of performance goals (if any) and for which there is no assumption, continuation, substitution or cash-out provided in connection with the Sale Event, may become immediately vested and payable in the Administrator's discretion or to the extent specified in the applicable award agreement, and (B) all time-based stock options and other stock-based awards subject to time-based vesting (the "Post-Effective Date Time-Based Equity Awards") shall accelerate and become fully exercisable or nonforfeitable immediately as of the later of (i) the Date of Termination or (ii) the Separation Agreement Effective Date (in either case, the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Post-Effective Date Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Policy will be delayed until the Separation Agreement Effective Date and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Post-Effective Date Time-Based Equity Awards shall occur during the period between the Covered Employee's Date of Termination and the Accelerated Vesting Date.

For the avoidance of doubt, any stock options or other stock-based award granted to the Covered Employee prior to the Effective Date shall not be eligible for the Equity Acceleration under this Policy.

V. Timing of Severance Pay and Incentive Compensation

The Severance Pay and Incentive Compensation shall be paid out in substantially equal installments in accordance with the Company's payroll practices over the Severance Period, commencing within 60 days after the Date of Termination; *provided*, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, amounts payable hereunder shall begin to be paid in the second calendar year by the last day of such 60-day period; *provided, further*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Policy is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

VI. Equity Awards

Except with respect to the Equity Acceleration, the treatment of a Covered Employee's equity awards with the Company shall be governed by the terms of the Plan and applicable award agreement(s) in all respects.

VII. Recoupment

Without limiting the Company's other remedies at law or equity in any respect, if a Covered Employee fails to comply with the terms of this Policy, the Covered Employee's Employee Obligations, or the terms of the Separation Agreement, the Company shall have the right to require repayment to the Company of any amounts paid hereunder, and/or cancel or cause the forfeiture of the Covered Employee's equity rights, in any such case to the extent permitted by applicable law, and with the value or amount of such repayment, forfeiture or cancellation determined in the sole discretion of the Administrator. If such recoupment is the form of cash, such payment is due in cash or by check within 10 days after the Company provides notice to a Covered Employee that it is enforcing this provision. Any amounts payable or to be accelerated hereunder but not yet received by such Covered Employee will be immediately forfeited in the event of a failure to comply with the terms of this Policy, the Covered Employee's Employee Obligations, or the terms of the Separation Agreement.

VIII. Death After Covered Termination

If a Covered Employee dies after the date of his or her Covered Termination but before all payments or benefits to which such Covered Employee is entitled pursuant to this Policy have been paid or provided, any remaining payments and benefits will be made to any beneficiary designated by the Covered Employee prior to or in connection with such Covered Employee's Covered Termination or, if no such beneficiary has been designated, to the Covered Employee's estate. For the avoidance of doubt, if a Covered Employee dies during such Covered Employee's applicable Severance Period, Benefits Continuation will continue for the Covered Employee's applicable dependents for the remainder of the Covered Employee's Severance Period, subject to applicable law.

IX. Withholding

The Severance Benefits shall be subject to applicable taxes. The Company has the right to withhold such other amounts as may be withheld under the Company's policies and procedures from time to time in effect, subject to applicable law.

X. Section 409A

The payments under this Policy are intended either to be exempt from Section 409A of the Code ("Section 409A") under the short-term deferral, separation pay, or other applicable exception, or to otherwise comply with Section 409A. This Policy shall be administered in a manner consistent with such intent. For purposes of Section 409A, all payments under this Policy shall be considered separate payments. To the extent that any payment or benefit described in this Policy constitutes "non-qualified deferred compensation" under Section 409A, and to the extent that such payment or benefit is payable upon a Covered Employee's termination of employment, then such payments or benefits shall be payable only upon such Covered Employee's "separation from service" (determined in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h)). Notwithstanding any provision to the contrary, to the extent an Covered Employee is considered a specified "covered employee" under Section 409A and would be entitled, during the six-month period beginning on such Covered Employee's separation from service, to a payment that is not otherwise excluded under Section 409A, such payment will not be made until the earlier of (i) the date six months and one day after the Covered Employee's separation from service, or (ii) the Covered Employee's death. This Policy may be amended as may be necessary to fully comply with Section 409A and all related rules and regulations in order to preserve the payments and benefits provided hereunder. The Company makes no representation or warranty and shall have no liability to any Covered Employee or any other person if any provisions of this Policy are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, such Section.

XI. Section 280G

Notwithstanding anything herein to the contrary, in the event that the Severance Benefits to be provided to a Covered Employee pursuant to this Policy calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments") would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Covered Employee becomes subject to the excise tax imposed by Section 4999 of the Code; *provided* that such reduction shall only occur if it would result in the Covered Employee receiving a higher After Tax Amount (as defined below) than the Covered Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (i) cash payments not subject to Section 409A of the Code; (ii) cash payments subject to Section 409A of the Code; (iii) equity-based payments and acceleration; and (iv) non-cash forms of benefits; *provided* that in the case of all the foregoing Aggregate Payments, all amounts or payments that are not subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c). For purposes of this Policy, the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Covered Employee as a result of the Covered Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Covered Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to the Policy shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Covered Employee within fifteen (15) business days of the termination date, if applicable, or at such earlier time as is reasonably requested by the Company or the Covered Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Covered Employee.

XII. Administration

The Administrator shall be responsible for administering this Policy, and shall have all necessary authority to discharge such responsibilities, which include, but are not limited to, interpretation and construction of this Policy, the determination of all questions of fact and disputes, including, without limit, with respect to eligibility, participation and benefits, the resolution of any ambiguities and all other related or incidental matters. The Administrator may adopt rules and regulations in its interpretation and implementation of the Policy. The Administrator's determinations under this Policy shall be conclusive, final and binding on Covered Employees and the Company.

XIII. Not an Employment Contract

The Policy is not a contract between the Company and any employee, nor is it a condition of employment of any employee. Covered Employees remain employees at-will. Nothing contained in the Policy gives, or is intended to give, any employee the right to be retained in the service of the Company, or to interfere with the right of the Company to discharge or terminate the employment of any employee at any time and for any reason.

XIV. Severability

In case any one or more of the provisions of this Policy (or part thereof) shall be held to be invalid, illegal or unenforceable in any respect: (i) such provision(s) shall be reformed and enforced to its/their fullest permissible extent; (ii) any such invalidity, illegality or unenforceability shall not affect the other provisions hereof, and (iii) this Policy shall be construed as if such invalid, illegal or unenforceable provisions (or part thereof) never had been contained herein.

XV. Non-Assignability by Employees; Assignability by the Company

No right or interest of any Covered Employee in this Policy shall be assignable or transferable in whole or in part either directly or by operation of law or otherwise, including, but not limited to, execution, levy, garnishment, attachment, pledge or bankruptcy. The Company may assign or otherwise transfer this Policy to any other person or entity without any Covered Employee's consent.

XVI. Integration with Other Pay or Benefits Requirements

The terms of this Policy supersede any (i) severance plans and separation policies applicable to Covered Employees and (ii) provisions of any agreement between any Covered Employee and the Company, in either case ((i) or (ii)) to the extent such plans, policies or provisions provide for severance benefits in connection with a Covered Termination. To avoid doubt, this Policy does not supersede any right of the Covered Employee to garden leave pay under the Massachusetts Noncompetition Agreement Act ("Garden Leave Pay"). To the extent that the

Company owes any amounts in the nature of severance benefits under any other program, policy plan or agreement of the Company that is not otherwise superseded by this Policy, or to the extent that any federal, state or local law, including, without limitation, so-called "plant closing" laws, requires the Company to give advance notice or make a payment of any kind to an employee because of that employee's involuntary termination due to a layoff, reduction in force, plant or facility closing, sale of business, or similar event, the benefits provided under this Policy or the other arrangement shall either be reduced or eliminated to avoid any duplication of payment. To the extent that the Covered Employee is entitled to any payments pursuant to any restrictive covenant agreement with the Company, including without limitation any Garden Leave Pay, the Severance Pay received by the Covered Employee in any calendar year shall be reduced by the amount the Covered Employee is paid in the same such calendar year (including Garden Leave Pay paid in such calendar year) pursuant to such restrictive covenant agreement. The terms of this Policy supersede any prior representations, communications or agreements regarding the subject matter hereof.

XVII. Amendment or Termination

The Board may amend, modify, or terminate the Policy at any time in its sole discretion prior to the Sale Event Period. Following the occurrence of a Sale Event, the Policy may not be amended in any respect that adversely affects the rights of any Covered Employee and may not be terminated until all obligations under the Policy have been satisfied.

XVIII. Governing Law

This Policy and the rights of all persons hereunder shall be construed in accordance with the laws of the Commonwealth of Massachusetts (without regard to conflict of laws provisions), and the Company and the Covered Employee waive the right to any jury with respect to any dispute under this Policy.

Exhibit 10.34

[CEREVEL THERAPEUTICS HOLDINGS LETTERHEAD]

December ___, 2023

Re: Repayment Agreement

Dear ______:

In connection with the transactions contemplated by that certain Agreement and Plan of Merger by and among AbbVie Inc., Symphony Harlan LLC, Symphony Harlan Merger Sub Inc. and Cerevel Therapeutics Holdings, Inc. (the "Company"), dated as of December 6, 2023 (the "Merger Agreement"), you may become entitled to payments and benefits that may be treated as "excess parachute payments" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder (the "Code"). Pursuant to the Merger Agreement and associated Company Disclosure Letter, the Company is permitted to take certain steps to mitigate the potential impact of Sections 280G and 4999 of the Code (the "280G Mitigation").

In connection with the 280G Mitigation, the Company has determined to (i) advance the payment of your 2023 Annual Incentive Plan ("AIP") bonus in the amount of $______ (less applicable taxes and withholdings) based on an estimate of actual performance achievement, to be paid on _____ (the "2023 AIP Advance Bonus"), and (ii) accelerate the vesting of _____ shares subject to your time-based Restricted Stock Unit award granted on _____ under the Company's 2020 Equity Incentive Plan, with such acceleration effective as of _____ (the "Accelerated RSUs").

You and the Company hereby acknowledge and agree to the following:

1. If the amount of your 2023 AIP bonus based on actual achievement of the performance goals (as determined by the Company's Compensation Committee) (the "Actual AIP Bonus") exceeds the amount of the 2023 AIP Advance Bonus, the Company will pay such excess amount (less applicable taxes and withholdings) to you at the same time 2023 AIP bonuses are paid to the Company's employees generally. If the Actual AIP Bonus is less than the 2023 AIP Advance Bonus, you will repay to the Company the excess (if any) of the after-tax portion of the 2023 AIP Advance Bonus over the Actual AIP Bonus (with the Actual AIP Bonus calculated on an after-tax basis assuming the Actual AIP Bonus had actually been paid to you at the same time that 2023 AIP bonuses are ordinarily paid) within 20 business days following the date that the Company makes such determination and notifies you of the applicable repayment amount. In addition, you hereby agree that you will promptly repay the net after-tax amount of such 2023 AIP Advance Bonus in the event you resign from employment prior to year-end, with such repayment to occur within 20 business days following such termination.

2. If your employment terminates for any reason prior to the earlier of (i) the date on which the applicable portion of the Accelerated RSUs otherwise would have vested in accordance with their terms and (ii) the date of the consummation of the transactions contemplated by the Merger Agreement, then you agree that you shall promptly repay the net, after-tax amount of the income you received as a result of the settlement of the Unearned Accelerated RSUs with such repayment to occur within 20 business days following such termination.

   For purposes of this letter, "Unearned Accelerated RSUs" means any Accelerated RSUs that, as of any date of your termination of employment, would have remained unvested in accordance with the terms of (a) the applicable award agreement pursuant to which such Accelerated RSUs were granted, (b) your Employment Agreement with the Company dated as of _____ and (c) the Company's Severance Benefits Policy applicable to you (in each case, for the avoidance of doubt, after taking into account any accelerated vesting that would have occurred in connection with such termination of employment).

In the event of any default by you in the repayment obligations described above, to the extent permitted by applicable law, in addition to any other remedy which may be available at law or in equity, the Company reserves the right to reduce any payments due to you from the Company or any subsidiary following the termination of your employment to satisfy any such repayment obligations.

This letter may be delivered electronically and may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same document. This letter shall be governed by and construed and enforced in accordance with Massachusetts law without regard to the conflict of laws provisions thereof. This letter constitutes the entire agreement between you and the Company with regard to the subject matter hereof and supersedes any and all prior agreements, whether written or oral, between the parties with respect to the subject matter herein. This letter may be amended or modified only with the written consent of you and the Company.

Please indicate your acceptance and acknowledgement of, and agreement to, the foregoing by signing below.

Sincerely,

____
By:
Its:

Agreed and Acknowledged:

____
Name:

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-260945) of Cerevel Therapeutics Holdings, Inc.,
(2) Registration Statement (Form S-3 No. 333-250964) of Cerevel Therapeutics Holdings, Inc.,
(3) Registration Statement (Form S-3 No. 333-264812) of Cerevel Therapeutics Holdings, Inc.,
(4) Registration Statement (Form S-3 No. 333-268235) of Cerevel Therapeutics Holdings, Inc.,
(5) Registration Statement (Form S-8 No. 333-251881) pertaining to the 2020 Equity Incentive Plan and Amended and Restated 2020 Employee Stock Purchase Plan of Cerevel Therapeutics Holdings, Inc.,
(6) Registration Statement (Form S-8 No. 333-263158) pertaining to the 2020 Equity Incentive Plan and Amended and Restated 2020 Employee Stock Purchase Plan of Cerevel Therapeutics Holdings, Inc.; and
(7) Registration Statement (Form S-8 No. 333-269916) pertaining to the 2020 Equity Incentive Plan and Amended and Restated 2020 Employee Stock Purchase Plan of Cerevel Therapeutics Holdings, Inc.;

of our reports dated February 27, 2024, with respect to the consolidated financial statements of Cerevel Therapeutics Holdings, Inc. and the effectiveness of internal control over financial reporting of Cerevel Therapeutics Holdings, Inc. included in this Annual Report (Form 10-K) of Cerevel Therapeutics Holdings, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ron Renaud, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerevel Therapeutics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2024

By: /s/ Ron Renaud
Ron Renaud
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Susan Altschuller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerevel Therapeutics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2024

By: /s/ Susan Altschuller
Susan Altschuller, Ph.D.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cerevel Therapeutics Holdings, Inc. (the “Company”) for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2024

By: /s/ Ron Renaud
Ron Renaud
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Cerevel Therapeutics Holdings, Inc. (the "Company") for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2024

By: /s/ Susan Altschuller
Susan Altschuller, Ph.D.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 97.1

CEREVEL THERAPEUTICS HOLDINGS, INC.

AMENDED AND RESTATED CLAWBACK POLICY

Adopted as of June 7, 2023

Cerevel Therapeutics Holdings, Inc., a Delaware corporation (the "Company"), has adopted an Amended and Restated Clawback Policy (this "Policy") as described below. This Policy supersedes the Clawback Policy previously adopted by the Company on December 8, 2021 (the "Prior Policy"). Compensation received prior to the Effective Date (as defined below) is subject to the Prior Policy.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Incentive Compensation and, if applicable, Excess Other Compensation, from current and former Executive Officers and other employees of the Company in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934 (the "Exchange Act") and the Nasdaq Stock Market. Please refer to Section 3 below for definitions of capitalized terms used and not otherwise defined herein.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Material Financial Restatement, the Company shall reasonably promptly recover all Erroneously Awarded Incentive Compensation with respect to such Material Financial Restatement, and each Covered Person shall be required to take all actions necessary to enable such recovery (the "Mandatory Compensation Recovery").

In addition, in the event the Company is required to prepare an accounting restatement due to (1) the material non-compliance of the Company with any financial reporting requirement and (2) fraud or material misconduct by a Covered Person, then the Committee may require any Covered Person to repay to the Company any or all Excess Other Compensation; provided that, this paragraph shall not apply to any Excess Other Compensation that is deemed Erroneously Awarded Incentive Compensation subject to the Mandatory Compensation Recovery set forth above. In the event the Company requires a Covered Person to repay Excess Other Compensation pursuant to this Policy, the Committee may take into account factors it deems reasonable in determining whether to seek recoupment of previously paid Excess Other Compensation from such Covered Person and, if so, how much Excess Other Compensation to recoup from such Covered Person, as applicable (which need not be the same amount or proportion for every Covered Person).

3. Definitions

a. "Applicable Recovery Period" means with respect to a Material Financial Restatement, the three completed fiscal years immediately preceding the Restatement Date for such Material Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. A "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Incentive Compensation or Excess Other Compensation shall be determined as of the time of receipt of such Erroneously Awarded Incentive Compensation or Excess Other Compensation regardless of their current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Incentive Compensation or Excess Other Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Incentive Compensation or Excess Other Compensation received after the person began service as an Executive Officer where, if applicable, such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Incentive Compensation).

f. "Effective Date" means June 7, 2023.

g. "Erroneously Awarded Incentive Compensation" means, with respect to a Material Financial Restatement, the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in the Material Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Incentive Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Incentive Compensation is not subject to mathematical recalculation directly from the information in a Material Financial Restatement, shall be based on a reasonable estimate of the effect of the Material Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules.

h. "Excess Other Compensation" means that part of any annual performance-based cash bonus and equity incentive compensation (e.g., employee stock options, restricted stock units and/or restricted stock awards) (whether or not such compensation is Incentive-Based Compensation) received by a Covered Person during the current fiscal year or the three most recently completed fiscal years preceding the publication of the restated financial statement that the Committee determines was in excess of the amount that such Covered Person would have received had such compensation been calculated based on the financial results reported in the restated financial statement.

i. "Exchange" means The Nasdaq Stock Market LLC.

j. An "Executive Officer" means any person who served the Company in any of the following roles, received Incentive-Based Compensation or Excess Other Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation or Excess Other Compensation was received during or after such person's service in such role) and, if applicable, served in such role at any time during the performance period for such Incentive-Based Compensation: the president, the principal financial officer, the principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

k. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

l. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

m. A "Material Financial Restatement" means an accounting restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

n. "Restatement Date" means, with respect to a Material Financial Restatement, the earlier to occur of: (i) the date the Board, a committee of the Board or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare the Material Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Material Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Incentive Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Incentive Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Incentive Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Incentive Compensation and, if applicable, any Excess Other Compensation, hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation or annual performance-based bonus previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or setting-off against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person’s obligation to return Erroneously Awarded Incentive Compensation to the Company if such Erroneously Awarded Incentive Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law and shall otherwise be interpreted (including in the determination of amounts recoverable) in the business judgment of the Committee. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Material Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules. This Policy shall be deemed to be automatically amended, as of the date the Applicable Rules become effective with respect to the Company, to the extent required for this Policy to comply with the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Incentive Compensation or Excess Other Compensation recovered under this Policy and, to the extent any such agreement or organizational document purports to provide otherwise, Covered Persons hereby irrevocably agree to forego such indemnification.