Filed Pursuant to Rule 424(b)(3)
Registration No. 333-250964

PROSPECTUS SUPPLEMENT NO. 3
(to prospectus dated March 25, 2021)

Up to 42,437,330 Shares of Common Stock
166,333 Warrants to Purchase Common Stock

This prospectus supplement no. 3 (this "prospectus supplement") amends and supplements the prospectus dated March 25, 2021 (as supplemented or amended from time to time, the "Prospectus") which forms a part of our Registration Statement on Form S-1 (Registration Statement No. 333-250964). This prospectus supplement is being filed to update and supplement the information included or incorporated by reference in the Prospectus with the information contained in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (the "SEC") on May 17, 2021 (the "Form 10-Q"). Accordingly, we have attached the Form 10-Q to this prospectus supplement.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus and if there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

Our common stock and warrants are listed on The Nasdaq Capital Market under the symbols "CERE" and "CEREW", respectively. On May 14, 2021, the closing price of our common stock was $13.60 per share and the closing price of our warrants was $4.45 per share.

Investing in our securities involves risks that are described in the "*Risk Factors*" section beginning on page 10 of the Prospectus.

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

The date of this prospectus supplement is May 17, 2021.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

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 Capital Market
Warrants to purchase one share of common stock at an exercise price of $11.50	CEREW	The Nasdaq Capital Market

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 12, 2021, the registrant had 127,459,087 shares of common stock, par value $0.0001 per share, outstanding.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Quarterly Report on Form 10-Q, or this Quarterly Report, may constitute "forward-looking statements" for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Quarterly Report may include, for example, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding our plans for clinical development of our product candidates, the initiation and completion of clinical trials and related preparatory work and the expected timing of the availability of results of clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the potential attributes and benefits of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete further development, approval and, if approved, commercialization of our product candidates;
- the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expense and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to identify, in-license or acquire additional product candidates;
- our ability to maintain the Pfizer License Agreement underlying our product candidates;
- our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we are pursuing for our product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection;
- our ability to contract with and rely on third parties to assist in conducting its clinical trials and manufacture our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- the impact of laws, regulations, accounting standards, regulatory requirements, judicial decisions and guidance issued by authoritative bodies;
- our ability to attract and retain key scientific, medical, commercial or management personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the ability to recognize the anticipated benefits of the Business Combination and the tavapadon financing transaction; and
- the effect of COVID-19 on the foregoing.

The forward-looking statements contained in this Quarterly 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 that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "Risk Factors" of this Quarterly 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. Some of these risks and uncertainties may in the future be amplified by the COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

You should read this Quarterly 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.

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 successful development of pharmaceutical products is highly uncertain.
- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.
- Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.
- Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Business interruptions resulting from the COVID-19 outbreak or similar public health crises could cause a disruption of the development of our product candidates and adversely impact our business.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- We depend heavily on our executive officers, third-party consultants and others and our ability to compete in the biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of their services or our inability to hire and retain such personnel would materially harm our business.
- Bain Investor and Pfizer have significant influence over us.
- We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- We depend and expect in the future to continue to depend on in-licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose license rights, which would substantially harm our business.

The risks described above should be read together with the text of the full risk factors described below in the section entitled "*Risk Factors*" and the other information set forth in this Quarterly Report, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities Exchange Commission, or the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts and per share data)
(Unaudited)

	As of	
	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 343,287	$ 383,623
Prepaid expenses and other current assets	6,524	6,937
Total current assets	349,811	390,560
Property and equipment, net	27,597	24,165
Operating lease assets	24,187	24,459
Restricted cash	4,200	4,200
Other long-term assets	2,309	1,889
Total assets	$ 408,104	$ 445,273
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,755	$ 4,993
Accrued expenses and other current liabilities	24,257	22,519
Operating lease liabilities, current portion	2,139	2,036
Total current liabilities	34,151	29,548
Operating lease liabilities, net of current portion	32,952	30,969
Other long-term liabilities	965	236
Total liabilities	68,068	60,753
Commitments and contingencies (Notes 11 and 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value: 500,000,000 shares authorized; 127,325,116 and 127,123,954 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	781,914	775,417
Accumulated deficit	(441,891)	(390,910)
Total stockholders' equity	340,036	384,520
Total liabilities and stockholders' equity	$ 408,104	$ 445,273

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

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share amounts and per share data)
(Unaudited)

	For the Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 36,561	$ 26,959
General and administrative	14,010	10,743
Total operating expenses	50,571	37,702
Loss from operations	(50,571)	(37,702)
Interest income, net	15	204
Other income (expense), net	(425)	(15,710)
Loss before income taxes	(50,981)	(53,208)
Income tax benefit (provision), net	—	—
Net loss and comprehensive loss	$ (50,981)	$ (53,208)
Net loss per share, basic and diluted	$ (0.40)	$ (0.87)
Weighted-average shares used in calculating net loss per share, basic and diluted	127,225,535	60,944,732

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

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY(1)
(In thousands, except share amounts)
(Unaudited)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2020	127,123,954	$ 13	$ 775,417	$ (390,910)	$ 384,520
Issuance of common stock under equity incentive plans related to vesting of RSUs	14,270	—	—	—	—
Issuance of common stock under equity incentive plans related to exercise of options	186,892		742		742
Reclassification of private placement warrants from equity to other long-term liabilities	—	—	(305)	—	(305)
Equity-based compensation expense	—	—	6,060	—	6,060
Net loss	—	—	—	(50,981)	(50,981)
Balance at March 31, 2021	127,325,116	$ 13	$ 781,914	$ (441,891)	$ 340,036

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2019	60,930,932	$ 6	$ 322,115	$ (244,298)	$ 77,823
Issuance of common stock under equity incentive plans related to vesting of RSUs	14,270	—	—	—	—
Equity-based compensation expense	—	—	2,970	—	2,970
Net loss	—	—	—	(53,208)	(53,208)
Balance at March 31, 2020	60,945,202	$ 6	$ 325,085	$ (297,506)	$ 27,585

(1) Historical share and capital amounts were retroactively restated for reverse recapitalization as described in Note 1, *Nature of Operations*.

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

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	For the Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (50,981)	$ (53,208)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	63	95
Non-cash rent expense under operating leases	(184)	508
Equity-based compensation	6,137	2,970
Change in fair value of Equity Commitment and Share Purchase Option	—	15,710
Change in fair value of private placement warrants	424	—
Changes in operating assets and liabilities, net:		
Prepaid expenses and other current assets	426	940
Operating lease asset	(14)	(459)
Other assets	3	(1,167)
Accounts payable	3,176	4,806
Accrued expenses and other liabilities	1,975	351
Operating lease liability	2,557	—
Net cash flows used in operating activities	(36,418)	(29,454)
Cash flows from investing activities:		
Purchases of property and equipment	(4,660)	(2,556)
Net cash flows used in investing activities	(4,660)	(2,556)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	742	—
Net cash flows provided by financing activities	742	—
Net decrease in cash, cash equivalents and restricted cash	(40,336)	(32,010)
Cash, cash equivalents and restricted cash, beginning of the period	387,823	83,682
Cash, cash equivalents and restricted cash, end of the period	$ 347,487	$ 51,672
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 343,287	$ 47,541
Restricted cash	4,200	4,131
Total cash, cash equivalents and restricted cash	$ 347,487	$ 51,672
Supplemental cash flow disclosures from non-cash operating, investing, and financing activities:		
Fixed asset additions included in accounts payable and other current liabilities	$ 3,252	$ 3,357
Deferred unpaid transaction costs related to financing activities	$ 461	$ 1,047

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

1. Nature of Operations

Unless the context otherwise requires, references in these notes to "Cerevel," "the company," "we," "us" and "our" and any related terms are intended to mean Cerevel Therapeutics Holdings, Inc. and its consolidated subsidiaries.

We are a clinical-stage biopharmaceutical company pursuing a targeted approach to neuroscience that combines a deep understanding of disease-related biology and neurocircuitry of the brain with advanced chemistry and central nervous system, or CNS, target receptor selective pharmacology to discover and design new therapies. We seek to transform the lives of patients through the development of new therapies for neuroscience diseases, including schizophrenia, epilepsy and Parkinson's disease.

On October 27, 2020, ARYA Sciences Acquisition Corp II (ARYA) completed the acquisition of Cerevel Therapeutics, Inc. (Old Cerevel), a private company and our predecessor, pursuant to the Business Combination Agreement dated July 29, 2020, as amended on October 2, 2020 (Business Combination Agreement). ARYA was incorporated as a Cayman Islands exempted company on February 20, 2020, and was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. Cerevel Therapeutics, Inc. was incorporated in Delaware on July 23, 2018, under the name Perception Holdco, Inc., which was subsequently changed to Cerevel Therapeutics, Inc. on October 23, 2018.

Our principal operations commenced on September 24, 2018 (Formation Transaction Date), when Old Cerevel licensed technology to a portfolio of pre-commercial neuroscience assets from Pfizer Inc. (Pfizer) in exchange for the issuance of Series A-2 Preferred Stock of Old Cerevel and obtained a $350.0 million equity commitment (the Equity Commitment), from BC Perception Holdings, LP (Bain Investor), an affiliate of Bain Capital, to develop the in-licensed assets in exchange for the issuance of Series A-1 Preferred Stock and Series A Common Stock of Old Cerevel. Bain Investor also received the option to purchase up to an additional 10.0 million shares of Old Cerevel at $10.00 per share, subject to Pfizer's participation rights (the Share Purchase Option). On the Formation Transaction Date, we received an initial investment of $115.0 million in equity funding from Bain Investor to begin operations. During 2019 we received an additional investment of $60.1 million in equity funding from Bain Investor. Bain Investor contributed an additional $25.0 million in equity funding in July 2020 (the Additional Financing Shares).

Upon the closing of the transactions contemplated by the Business Combination Agreement (the Business Combination or the Business Combination Transaction), Old Cerevel became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc. and the Equity Commitment and the Share Purchase Option related to Old Cerevel were terminated. Upon completion of the Business Combination Transaction, and pursuant to the terms of the Business Combination Agreement, the existing shareholders of Old Cerevel exchanged their interests for shares of common stock of Cerevel Therapeutics Holdings, Inc. (New Cerevel). Net proceeds from this transaction totaled approximately $439.5 million.

We accounted for the Business Combination Transaction as a reverse recapitalization which is the equivalent of Old Cerevel issuing stock for the net assets of ARYA, with ARYA treated as the acquired company for accounting purposes. The net assets of ARYA were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Cerevel. The shares and corresponding capital amounts and loss per share related to Old Cerevel's outstanding redeemable convertible preferred stock, redeemable convertible common stock, and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the exchange ratio (the Exchange Ratio) established in the Business Combination Agreement (1.00 share of Old Cerevel for 2.854 shares of New Cerevel).

For additional information on the Business Combination Transaction and the Additional Financing Shares, please read Note 3, *Business Combination*, to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 (our Annual Report). For additional information on our license arrangement with Pfizer, please read Note 6, *Pfizer License Agreement*, to our audited consolidated financial statements included in our Annual Report. For additional information on the Equity Commitment and the Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included in our Annual Report.

2. Risks and Liquidity

We are subject to risks and uncertainties common to clinical-stage companies in the biopharmaceutical industry. These risks include, but are not limited to, the introduction of new products, therapies, standards of care or new technological innovations, our ability to obtain and maintain adequate protection for our licensed technology, data or other intellectual property and proprietary rights and compliance with extensive government regulation and oversight. In addition, we are dependent upon the services of our employees, including key personnel, consultants, third-party contract research organizations and other third-party organizations.

Our product candidates, currently under development or that we may develop, will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities. There can be no assurance that our research and development activities will be successfully completed, that adequate protection for our licensed or developed technology will be obtained and maintained, that products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable.

Our consolidated financial statements have been prepared on the basis of continuity of operations, the realization of assets and the satisfaction of liabilities in the ordinary course of business. Since our inception, we have incurred significant operating losses and, as of March 31, 2021, had an accumulated deficit of $441.9 million and had not yet generated revenues. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities to support our research, discovery and clinical development efforts and we expect to continue to incur significant expenses and operating losses for the foreseeable future.

Prior to the Business Combination Transaction, our operations were funded primarily from the issuance of convertible preferred stock, convertible common stock and common stock. Upon the closing of the Business Combination Transaction in October 2020, we received net proceeds totaling approximately $439.5 million, as described above in Note 1, *Nature of Operations*. We believe that our available cash resources as of March 31, 2021, of $343.3 million will enable us to fund our operating expense and capital expenditure requirements through at least twelve months from the issuance date of these financial statements.

Impact of the COVID-19 Pandemic

We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business, including how it will impact our operations and the operations of our customers, suppliers, vendors and business partners. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy and we cannot presently predict the scope and severity of any potential business shutdowns or disruptions. We have not incurred any significant impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that could have a material adverse impact on our business, results of operations and financial condition. The extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence. The estimates of the impact on our business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include those of the company and its subsidiaries, Cerevel Therapeutics Inc., Cerevel Therapeutics LLC and Cerevel MA Securities Corporation, after elimination of all intercompany accounts and transactions. The accompanying unaudited condensed consolidated financial statements and notes hereto have been prepared in conformity with the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting and, therefore, omit or condense certain footnotes and other information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) as set forth in the Financial Accounting Standards Board's (FASB) accounting standards codification. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the FASB.

In the opinion of management, all adjustments necessary for a fair statement of the financial information, which are of a normal and recurring nature, have been made for the interim periods reported. Results of operations for the three months ended March 31, 2021 and 2020, are not necessarily indicative of the results for the entire fiscal year or any other period. The condensed consolidated financial statements for the three months ended March 31, 2021 and 2020, have been prepared on the same basis as and should be read in conjunction with the audited consolidated financial statements and notes included in our Annual Report.

As a result of the Business Combination Transaction, the shares and corresponding capital amounts and loss per share related to Old Cerevel's outstanding redeemable convertible preferred stock, redeemable convertible common stock and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the Exchange Ratio established in the Business Combination Agreement. For additional information on the Business Combination Transaction and the Exchange Ratio, please read Note 3, *Business Combination*, to our audited consolidated financial statements included in our Annual Report.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to, the fair value of the Equity Commitment and Share Purchase Option, the fair value of stock options, the recoverability of our net deferred tax assets and the related valuation allowance and the accrual for research and development expense. The impact on accounting estimates and judgments on our financial condition and results of operations due to COVID-19 has introduced additional uncertainties. We evaluate our estimates and assumptions on an ongoing basis using historical experience and other factors and adjust those estimates and assumptions when facts and circumstances change. Actual results could differ materially from those estimates.

Restricted Cash

In connection with our entering into the lease agreement for our headquarters in Cambridge, MA, in July 2019 we were required to provide a security deposit in the form of a letter of credit. We have classified this amount as restricted cash within our consolidated balance sheet as of March 31, 2021 and December 31, 2020.

Common Stock Warrants and Derivative Financial Instruments

We review any common stock purchase warrants and other freestanding derivative financial instruments at each balance sheet date and account for them based on an assessment of the specific terms of the instrument and applicable authoritative guidance in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480).

Our assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

We classify freestanding derivative financial instruments that are indexed in our own stock as:

a) Equity if they (i) require physical settlement or net-share settlement, or (ii) give the company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement), or

b) Assets or liabilities if they (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the company's control), or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement)

We assess classification of our common stock warrants and other freestanding derivatives at each reporting date to determine whether a change in classification is required. Warrants to purchase an aggregate of 5,149,666 shares were issued by ARYA as part of the units sold in its IPO in June 2020. We determined that our 4,983,314 outstanding public warrants satisfied the criteria for classification as equity instruments as of March 31, 2021, and December 31, 2020, respectively.

We determined our 166,333 private placement warrants were immaterial as of December 31, 2020. In certain circumstances, the identity of the holder may result in different settlement amounts, and therefore our private placement warrants are not considered indexed in our own stock in the manner contemplated by ASC Section 815-40-15. Accordingly, we reclassified our private placement warrants as long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021.

Emerging Growth Company Status

We are an "emerging growth company" (EGC), as defined in the Jumpstart Our Business Startups Act (JOBS Act) and we may choose to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. We may take advantage of these exemptions until the company is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for complying with new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions until we no longer qualify as an EGC.

For additional information related to our other significant accounting policies, please read Note 4, *Summary of Significant Accounting Policies*, to our audited consolidated financial statements included in our Annual Report.

Recent Accounting Guidance

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the company as of the specified effective date. Unless otherwise discussed, the company believes that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Collaborative Arrangements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This standard clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. We adopted this standard on January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements as we have had no transactions applicable to this guidance; however, the standard may impact how we account for certain business transactions in the future.

Credit Losses

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements (ASU 2016-13).* The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. We adopted this standard on January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements.

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes*. The standard simplifies various aspects of the income tax accounting guidance in Topic 740, including the elimination of exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. We adopted this standard effective January 1, 2021. The adoption of this standard did not have a material impact on our consolidated financial statements.

4. Pfizer License Agreement

In August 2018, we entered into a license agreement with Pfizer (the Pfizer License Agreement) pursuant to which we were granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how to develop, manufacture and commercialize certain compounds and products, which currently constitute the entirety of our asset portfolio, subject to the terms and conditions of the Pfizer License Agreement.

Under the Pfizer License Agreement, we are solely responsible for the development, manufacture, regulatory approval and commercialization of compounds and products in the field and we will pay Pfizer tiered royalties on the aggregate net sales during each calendar year, determined on a product-by-product basis, with respect to products under the Pfizer License Agreement, and we may pay potential milestone payments to Pfizer, based on the successful achievement of certain regulatory and commercial milestones. To date, no regulatory or commercial approval milestone payments or royalty payments were made or became due under this agreement.

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

5. Fair Value Measurements

The following table presents information about our financial assets and liabilities measured at fair value on a recurring basis and indicates the level of fair value hierarchy utilized to determine such fair values:

As of March 31, 2021 *(In thousands)*	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents—money market funds	$ 343,287	$ —	$ —	$ 343,287
Restricted cash—money market funds	4,200	—	—	4,200
Total Assets	$ 347,487	$ —	$ —	$ 347,487
Liabilities:				
Private placement warrants	$ —	$ —	$ 729	$ 729
Total Liabilities	$ —	$ —	$ 729	$ 729

As of December 31, 2020 *(In thousands)*	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents—money market funds	$ 383,623	$ —	$ —	$ 383,623
Restricted cash—money market funds	4,200	—	—	4,200
Total Assets	$ 387,823	$ —	$ —	$ 387,823
Liabilities:				
Private placement warrants	$ —	$ —	$ —	$ —
Total Liabilities	$ —	$ —	$ —	$ —

There have been no impairments of our assets measured and carried at fair value during the three months ended March 31, 2021. In addition, there were no changes in valuation techniques, inputs utilized or transfers between fair measurement levels in the periods presented.

The carrying amounts reflected in our condensed consolidated balance sheets for our cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair value due to the short-term nature of these assets and liabilities.

The private placement warrants represent the only Level 3 assets and liabilities carried at fair market value as of March 31, 2021. The fair value measurement of the private placement warrants is sensitive to changes in the unobservable inputs used to value the financial instrument. Changes in the inputs could result in changes to the fair value of each financial instrument.

The following table provides a roll forward of the liability associated with our private placement warrants:

(In thousands)	Amount
Liability, December 31, 2020	$ —
Reclassification from equity	(305)
Change in fair value	(424)
Liability, March 31, 2021	$ (729)

We reclassified our private placement warrants from equity to other long-term liabilities as of March 31, 2021. Our estimate of the fair value of our private placement warrant liability was determined through a binomial lattice model utilizing a discount rate of 0.80%, an expected volatility implied by the market price of the public warrants of 37.7%, an expected dividend yield of 0% and the fair values of our common stock and public warrants as of March 31, 2021.

6. Financial Statement Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Prepaid clinical trial services	$ 807	$ 172
Prepaid research and development expenses	1,433	1,650
Prepaid insurance	2,678	3,675
Other prepaid expenses	1,444	1,280
Other current assets	162	160
Prepaid expenses and other current assets	$ 6,524	$ 6,937

Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Computer equipment	$ 881	$ 96
Furniture and fixtures	322	322
Laboratory equipment	545	101
Construction in progress	25,941	23,728
Less: Accumulated depreciation	(92)	(82)
Property and equipment, net	$ 27,597	$ 24,165

Construction-in-progress primarily relates to the build-out of our headquarters in Cambridge, Massachusetts.

Other Long-Term Assets

Other long-term assets consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Deferred expenses associated with financing activities	$ 461	$ —
Other prepaid expenses, net of current portion	1,363	1,389
Other	485	500
Other long-term assets	$ 2,309	$ 1,889

As of March 31, 2021 and December 31, 2020, other prepaid expenses, net of current portion, primarily consists of deposits paid under certain clinical research organization (CRO) agreements that will be held until the completion of the related clinical trials which are anticipated to end more than twelve months from the balance sheet date.

Deferred expenses associated with financing activities as of March 31, 2021, are comprised of costs incurred with third parties directly related to the Funding Agreements described in Note 14, *Subsequent Events*.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
External research and development services	$ 16,002	$ 8,893
Accrued compensation and personnel costs	4,483	9,489
Accrued construction-in-progress	1,930	2,618
Accrued deferred expenses associated with financing activities	424	96
Professional fees and consulting services	1,263	1,150
Other	155	273
Accrued expenses and other current liabilities	$ 24,257	$ 22,519

Other Long-Term Liabilities

Other long-term liabilities consisted of the following:

(In thousands)	As of March 31, 2021	As of December 31, 2020
Private placement warrants	$ 729	$ —
Other	236	236
Other long-term liabilities	$ 965	$ 236

Other Income (Expense), net

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

(In thousands)	For the Three Months Ended March 31, 2021	For the Three Months Ended March 31, 2020
Loss on fair value remeasurement of Equity Commitment	$ —	$ (15,760)
Gain on fair value remeasurement of Share Purchase Option	—	50
Loss on fair value remeasurement of private placement warrants	(424)	—
Other, net	(1)	—
Other income (expense), net	$ (425)	$ (15,710)

The Equity Commitment and Share Purchase Option were free-standing financial instruments that were recorded at fair value on the Formation Transaction Date. We revalued these financial instruments each reporting period and classified the fair value of the remaining Equity Commitment and the Share Purchase Option as an asset or a liability in our condensed consolidated balance sheets through their termination. We recognized the changes in fair value of the Equity Commitment and Share Purchase Option as a component of other income (expense), net in our condensed consolidated statements of operations and comprehensive loss.

For additional information on the Equity Commitment and Share Purchase Option and their related valuation, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included in our Annual Report.

7. Stockholders' Equity

The condensed consolidated statement of stockholders' equity has been retroactively adjusted for all periods presented to reflect the Business Combination and reverse recapitalization as discussed in Note 3, *Summary of Significant Accounting Policies*.

Preferred Stock

Upon closing of the Business Combination Transaction, pursuant to the terms of our Certificate of Incorporation, we authorized 10,000,000 shares of preferred stock with a par value of $0.0001 per share. Our board of directors has the authority, without further action by our stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, voting, and other rights, preferences and privileges of the shares. There were no issued and outstanding shares of preferred stock as of March 31, 2021 and December 31, 2020.

Common Stock

Pursuant to the terms of our Certificate of Incorporation, we authorized 500,000,000 shares of common stock with a par value of $0.0001 per share. There were 127,325,116 and 127,123,954 shares of common stock issued and outstanding as of March 31, 2021 and December 31, 2020, respectively.

Voting

The holders of our common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there is no cumulative voting.

Dividends

Common stockholders are entitled to receive dividends whenever funds are legally available and when declared by the board of directors. No dividends have been declared to date.

Warrants

ARYA issued public warrants and private placement warrants (collectively, the warrants) in its Initial Public Offering in June 2020. Upon the consummation of the Business Combination Transaction each outstanding warrant of ARYA become one warrant to purchase one share of Cerevel Therapeutics Holdings, Inc. Pursuant to the agreement, no fractional warrants were issued upon separation of the units and only whole warrants will trade. If a holder would be entitled to receive a fractional warrant, we rounded down to the nearest whole number of warrants to be issued to the warrant holder. None of the terms of the warrants were modified as a result of the Business Combination Transaction.

As of March 31, 2021 and December 31, 2020, we determined that our 4,983,314 public warrants outstanding satisfied the criteria for classification as equity instruments in our condensed consolidated balance sheet.

As of March 31, 2021 and December 31, 2020, there were 166,333 private placement warrants outstanding. The fair value of our private placement warrants as of March 31, 2021, totaled approximately $0.7 million. We reclassified our private placement warrants from equity to other long-term liabilities in our condensed consolidated balance sheet as of March 31, 2021. Upon establishment of this liability, we reclassified approximately $0.3 million from additional paid-in capital and recognized a charge of approximately $0.4 million to other income (expense), net, resulting from the change in fair value of these warrants. We did not recognize a liability in relation to our private placement warrants prior to March 31, 2021, as we previously determined that the fair value of these warrants was immaterial.

The warrants will become exercisable beginning on June 9, 2021. Each whole warrant entitles the holder to purchase one share of common stock at an exercise price of $11.50 per share. The warrants will expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

8. Equity-Based Compensation

Equity-based Compensation Expense

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

	For the Three Months Ended March 31,	
In thousands	**2021**	**2020**
Research and development	$ 1,797	$ 910
General and administrative	4,340	2,060
Total equity-based compensation expense included in total operating expense	$ 6,137	$ 2,970

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

In thousands	For the Three Months Ended March 31, 2021	2020
Stock options	$ 6,038	$ 2,948
Restricted stock units	22	22
Employee stock purchase plan	77	—
Total equity-based compensation expense included in total operating expense	$ 6,137	$ 2,970

Stock Options

The following table summarizes our stock option activity for the three months ended March 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life *(in years)*	Aggregate Intrinsic Value *(in thousands)*
Outstanding at December 31, 2020	12,464,668	$ 6.37	8.57	$ 127,301
Granted	4,423,523	$ 12.87		
Exercised	(186,892)	$ 3.97		
Forfeited	(617,107)	$ 7.02		
Outstanding at March 31, 2021	16,084,192	$ 8.14	8.48	$ 90,771
Options exercisable as of March 31, 2021	4,805,971	$ 5.36	7.59	$ 40,249

The aggregate intrinsic value represents the difference between the closing stock price of our common stock and the exercise price of in-the-money options. Our closing stock price as reported on Nasdaq as of March 31, 2021, was $13.73.

As of March 31, 2021, total unrecognized equity-based compensation expense relating to stock options was $60.0 million. This amount is expected to be recognized over a weighted average period of 3.5 years.

Stock options granted during the three months ended March 31, 2021, include awards granted in conjunction with our annual awards made in February 2021.

The weighted-average assumptions that we used to determine the fair value of stock options granted to employees and directors are summarized as follows:

	For the Three Months Ended March 31, 2021	2020
Risk free interest rate	0.65%	1.56%
Expected term (in years)	6.07	6.01
Expected volatility	95.0%	105.0%
Expected dividend yield	0.0%	0.0%
Weighted-average grant date fair value	$ 9.81	$ 2.54

9. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share:

(In thousands, except per share data)	For the Three Months Ended March 31, 2021	For the Three Months Ended March 31, 2020
Numerator:		
Net loss	$ (50,981)	$ (53,208)
Denominator:		
Weighted-average shares used in calculating net loss per share, basic and diluted	127,225,535	60,944,732
Net loss per share, basic and diluted	$ (0.40)	$ (0.87)

Since we were in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share as the inclusion of all potential dilutive securities would have been anti-dilutive. The shares in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	As of March 31, 2021	As of March 31, 2020
Stock options outstanding	16,084,192	14,922,159
Restricted stock units outstanding	57,080	99,890
Warrants outstanding	5,149,647	—
ESPP shares issuable	17,921	—
Shares to be issued upon settlement of remaining Equity Commitment	—	49,929,121
Shares to be issued upon exercise of Share Purchase Option	—	28,540,304
Total	21,308,840	93,491,474

10. Income Taxes

For the three months ended March 31, 2021 and 2020, we did not record income tax benefits for net operating losses incurred or for the research and development tax credits generated in each period due to the uncertainty of realizing a benefit from those items.

We have evaluated the positive and negative evidence bearing upon our ability to realize our deferred tax assets, which primarily consist of net operating loss carryforwards and research and development tax credits. We have considered our history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and have concluded that it is more likely than not that we will not realize the benefits of our deferred tax assets. As a result, as of March 31, 2021 and December 31, 2020, we have recorded a full valuation allowance against our net deferred tax assets.

11. Legal Proceedings

We, from time to time, may be party to litigation arising in the ordinary course of business. We were not subject to any material legal proceedings as of March 31, 2021, or December 31, 2020, and, to the best of our knowledge, no material legal proceedings are currently pending or threatened.

12. Commitments and Contingencies

As of March 31, 2021, we have several ongoing clinical studies in various clinical trial stages. Our most significant contracts relate to agreements with CROs for clinical trials and preclinical studies and contract manufacturing organizations (CMOs) for the manufacturing of drug substance, which we enter into in the normal course of business. The contracts with CROs and CMOs are generally cancellable, with notice, at our option.

Guarantees and Indemnification Obligations

We enter into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, we indemnify and agree to reimburse the indemnified party for losses and costs incurred by the indemnified party in connection with any patent, copyright, trade secret or other intellectual property or personal right infringement claim by any third party with respect to our technology. The term of these indemnification agreements is generally perpetual after execution of the agreement. In addition, we have entered into indemnification agreements with members of our board of directors and our executive officers that will require us,

among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited. To date, we have not incurred any losses or any material costs related to these indemnification obligations and no claims with respect thereto were outstanding. We do not believe that the outcome of any claims under indemnification arrangements will have a material effect on our financial position, results of operations and cash flows, and we have not accrued any liabilities related to such obligations in our condensed consolidated financial statements as of March 31, 2021 and December 31, 2020.

13. Related Parties

As of March 31, 2021, and December 31, 2020, Pfizer held 27,349,211 shares of common stock and had nominated two members to our board of directors. For additional information on our license agreement with Pfizer, please read Note 4, *Pfizer License Agreement*, to these condensed consolidated financial statements.

As of March 31, 2021, and December 31, 2020, Bain Investor held 60,632,356 shares of common stock and had nominated four members to our board of directors.

Management Agreement

Following the closing of the Business Combination, we entered into a new management agreement with Bain Capital Private Equity, LP and Bain Capital Life Sciences, LP providing for the expense reimbursement and indemnification of such entities.

14. Subsequent Events

We have completed an evaluation of all subsequent events after the unaudited balance sheet date of March 31, 2021, through May 17, 2021, the issuance date of these financial statements, to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the condensed consolidated financial statements as of March 31, 2021, and events which occurred subsequently but were not recognized in the condensed consolidated financial statements. We have concluded that no subsequent events other than the following have occurred that require disclosure:

Funding Agreements

On April 12, 2021 (the Effective Date), we entered into a funding agreement with NovaQuest Co-Investment Fund XVI, L.P. (NovaQuest and the NovaQuest Funding Agreement) and a funding agreement with BC Pinnacle Holdings, LP (Bain, the Bain Funding Agreement and, together with the NovaQuest Funding Agreement, the Funding Agreements), pursuant to which NovaQuest and Bain will provide funding to support our development of tavapadon for the treatment of Parkinson’s disease.

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

In return, we agreed to pay to NovaQuest and Bain (1) upon approval of tavapadon by the FDA, a combined $187.5 million (1.5x of the Total Funding Commitment) (the Approval Milestone Payment), with 50% of the Approval Milestone Payment due within 30 days of FDA approval and 12.5% of the Approval Milestone Payment due on each of the first four anniversaries of FDA approval, (2) upon first reaching certain cumulative U.S. net sales thresholds, certain sales milestone payments and (3) combined tiered, mid-single digit to low-double digit royalties on annual net sales of tavapadon in the U.S.

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

Item 2. 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 unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report, and the consolidated financial statements and accompanying notes, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2020. Certain of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly 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, epilepsy and Parkinson's disease. Our "ready-made" pipeline of 11 small molecule programs, which includes five clinical-stage product candidates, was developed through over a decade of research and investment by Pfizer and was supported by an initial capital commitment from an affiliate of Bain Capital and a keystone equity position from Pfizer. We are advancing our broad and diverse pipeline with seven clinical trials underway or expected to start by the end of 2021 and up to eight clinical data readouts expected by the end of 2023. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with the proven expertise of large pharmaceutical company experience and capabilities in drug discovery and development.

Our portfolio of product candidates is based on a differentiated understanding of the neurocircuitry of CNS diseases, as well as the key pillars of our targeted approach to neuroscience: (1) receptor-drug interactions at the atomic level to achieve targeted receptor subtype selectivity, (2) orthosteric and allosteric chemistry to achieve ideal receptor pharmacology and (3) robust packages of preclinical and clinical data that elucidate the key points of differentiation for our compounds. Our rational design approach uses measured and calculated structural and surface charge information from the target protein combined with high-resolution crystallography data, computational homology models, screening of single-residue mutant proteins, indirect solution-phase imaging techniques and other biophysical measurements to glean key molecular-level information about the interaction between a target protein and our product candidates. These insights then drive structure-informed design of subsequent molecules. Due to our understanding of the specificity and dynamic range of neural networks and how to modulate them, we believe that our product candidates have the potential to achieve optimal therapeutic activity while minimizing unintended side effects of currently available therapies. Below are our five clinical-stage product candidates:

1. CVL-231 is a positive allosteric modulator, or PAM, that selectively targets the muscarinic acetylcholine 4 receptor subtype, or M4. We are currently conducting a Phase 1b trial of CVL-231 in patients with schizophrenia, consisting of Part A, a multiple ascending dose, or MAD, study and Part B, a pharmacodynamic, or PD, assessment. We initiated dosing in Part A of the trial in the second half of 2019 and initiated dosing in Part B of the trial in the second half of 2020, with data expected mid-year 2021.

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

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

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

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

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

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

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

Our Pipeline

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

Business Environment

The biopharmaceutical industry is extremely competitive. We are subject to risks and uncertainties common to clinical-stage companies in the biopharmaceutical industry. These risks include, but are not limited to, the introduction of new products, therapies, standards of care or technological innovations, our ability to obtain and maintain adequate protection for our licensed technology, data or other intellectual property and proprietary rights and compliance with extensive government regulation and oversight. We are also dependent upon the services of key personnel, including our Chief Executive Officer, executive team and other highly skilled employees. Demand for experienced personnel in the pharmaceutical and biotechnology industries is high and competition for talent is intense. Please read the section entitled "*Risk Factors*" for additional information.

We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies as well as public and private research institutions. Many of our competitors are working to develop or have commercialized products similar to those we are developing and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. Our competitors may also have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products. Other smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Risks and Liquidity

Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. We will not generate revenue from product sales unless and until we successfully complete clinical development, are able to obtain regulatory approval for and successfully commercialize the product candidates we are developing or may develop. We currently do not have any product candidates approved for commercial sale. In addition, we operate in an environment of rapid change in technology. We are also dependent upon the services of our employees, consultants, third-party CROs, CMOs and other third-party organizations.

Our product candidates, currently under development or that we may develop, will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities. There can be no assurance that our research and development activities will be successfully completed, that adequate protection for our licensed or developed technology will be obtained and maintained, that products developed will obtain necessary regulatory approval or that any approved products will be commercially viable.

Until such time, if ever, as we can generate substantial product revenue, we will need substantial additional funding to support our continuing operations and pursue our growth strategy, and we may finance our operations through a combination of additional private or public equity offerings, debt financings, collaborations, strategic alliances, marketing, distribution or licensing arrangements with third parties or through other sources of financing. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangement with collaborators on terms unfavorable to us or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

We have incurred significant operating losses since our inception and, as of March 31, 2021, we had an accumulated deficit of $441.9 million and had not yet generated revenues. We believe that our available cash resources as of March 31, 2021, of $343.3 million, will enable us to fund our operating expense and capital expenditure requirements through at least twelve months from the issuance date of the unaudited condensed consolidated financial statements included in this Quarterly Report.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- advance our clinical-stage product candidates CVL-231, darigabat, tavapadon, CVL-871 and CVL-936 through clinical development, including as we advance these candidates into later-stage clinical trials;
- advance our preclinical stage product candidates into clinical development including CVL-354 and our CVL-047;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increase personnel to support our operations;
- meet the requirements and demands of being a public company;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Pfizer License Agreement and any future in-license or collaboration agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties.

Impact of the COVID-19 Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

We are closely monitoring the impact of the pandemic of COVID-19 on all aspects of our business, including how it will impact our operations and the operations of our suppliers, vendors and business partners. We have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address this pandemic; however, the spread of COVID-19 has caused us to modify our business practices, including implementing a temporary work-from-home policy for all employees who are able to perform their duties remotely and temporarily restricting all non-essential travel and discouraged employee attendance at industry events and in-person work-related meetings. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of COVID-19.

More specifically, the onset of the COVID-19 pandemic caused brief pauses in patient screening and enrollment in our Phase 3 trials of tavapadon for the treatment of Parkinson’s (which we subsequently resumed in the second half of 2020), and we remain particularly vigilant about patient safety given the elderly nature of this population. While we have taken measures to revise clinical trial protocols, the ultimate extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, including vaccination campaigns, among others.

In addition, recurrences or additional waves of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience prolonged business shutdowns or other disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operations and financial condition. The estimates of the impact on our business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

We have not incurred any significant impairment losses in the carrying values of our assets as a result of the pandemic and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our audited consolidated financial statements.

Business Combination Transaction

On October 27, 2020, ARYA Sciences Acquisition Corp II, or ARYA, completed the acquisition of Cerevel Therapeutics, Inc., or Old Cerevel, a private company, pursuant to the Business Combination Agreement dated July 29, 2020, as amended on October 2, 2020, or the Business Combination Agreement. ARYA was incorporated as a Cayman Islands exempted company on February 20, 2020 and was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. Cerevel Therapeutics, Inc. was incorporated in Delaware on July 23, 2018 under the name Perception Holdco, Inc. which was subsequently changed to Cerevel Therapeutics, Inc. on October 23, 2018.

Upon the closing of the transactions contemplated by the Business Combination Agreement, which we refer to as the Business Combination or the Business Combination Transaction, Old Cerevel became a wholly owned subsidiary of ARYA and ARYA was renamed Cerevel Therapeutics Holdings, Inc. Upon completion of the Business Combination Transaction, and pursuant to the terms of the Business Combination Agreement, the existing shareholders of Old Cerevel exchanged their interests for shares of common stock of Cerevel Therapeutics Holdings, Inc., or New Cerevel.

We accounted for the Business Combination Transaction as a reverse recapitalization which is the equivalent of Old Cerevel issuing stock for the net assets of ARYA, with ARYA treated as the acquired company for accounting purposes. The net assets of ARYA were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Cerevel. The shares and corresponding capital amounts and loss per share related to Old Cerevel's outstanding redeemable convertible preferred stock, redeemable convertible common stock, and common stock prior to the Business Combination Transaction have been retroactively restated to reflect the exchange ratio established in the Business Combination Agreement (1.00 share of Old Cerevel for 2.854 shares of New Cerevel), or the Exchange Ratio.

For additional information on our operations, please read Note 1, *Nature of Operations*, to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, or our Annual Report. For additional information on the Business Combination Transaction, please read Note 3, *Business Combination*, to our audited consolidated financial statements included in our Annual Report.

Our Agreements with Licensors and Stockholders

Pfizer License Agreement

In August 2018, we entered into the Pfizer License Agreement pursuant to which we were granted an exclusive, sublicensable, worldwide license under certain Pfizer patent rights, and a non-exclusive, sublicensable, worldwide license under certain Pfizer know-how to develop, manufacture and commercialize certain compounds and products, which currently constitute the entirety of our asset portfolio, subject to the terms and conditions of the Pfizer License Agreement.

Under the Pfizer License Agreement, we are solely responsible for the development, manufacture, regulatory approval and commercialization of compounds and products in the field and we will pay Pfizer tiered royalties on the aggregate net sales during each calendar year, determined on a product-by-product basis, with respect to products under the Pfizer License Agreement, and we may pay potential milestone payments to Pfizer, based on the successful achievement of certain regulatory and commercial milestones. To date, no regulatory or commercial approval milestone payments or royalty payments were made or became due under this agreement.

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

Components of Operating Results

Revenues

We have not generated any revenues since our inception and do not expect to generate any revenues from the sale of products in the near future, if at all. If our development efforts for our current product candidates or additional product candidates that we may develop in the future are successful and can be commercialized, we may generate revenue in the future from product sales. Additionally, we may enter into collaboration and license agreements from time to time that provide for certain payments due to us. Accordingly, we may generate revenue from payments from such collaboration or license agreements in the future.

Research and Development

We support our drug discovery and development efforts through the commitment of significant resources to our preclinical and clinical development activities. Our research and development expense includes:

- employee-related expenses, consisting of salaries, benefits and equity-based compensation for personnel engaged in our research and development activities;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including costs incurred under agreements with clinical research organizations, or CROs, investigative clinical trial sites and consultants and other third-party organizations that conduct research and development activities on our behalf;
- costs associated with preclinical studies and clinical trials, including research materials;
- materials and supply costs associated with the manufacture of drug substance and drug product for preclinical testing and clinical trials;
- costs related to regulatory compliance requirements; and
- certain indirect costs incurred in support of overall research and development activities, including facilities, depreciation and technology expenses.

We expense research and development expenses as incurred. Payments we make for research and development services prior to the services being rendered are recorded as prepaid assets in our consolidated balance sheets and are expensed as the services are provided. We estimate and accrue the value of goods and services received from CROs, CMOs and other third parties each reporting period based on estimates of the level of services performed and progress in the period when we have not received an invoice from such organizations. When evaluating the adequacy of accrued liabilities, we analyze progress of the studies or clinical trials, including the phase of completion of events, invoices received and contracted costs. We reassess and adjust our accruals as actual costs become known or as additional information becomes available. Our historical accrued estimates have not been materially different from actual costs.

Our external research and development expenses for our clinical stage product candidates are tracked on a program-by-program basis and consist primarily of fees, reimbursed materials and other costs paid to consultants, contractors, CROs and CMOs. External research and developments costs that directly support our discovery activities and preclinical programs are classified within other research and development programs. Program costs for the periods presented do not reflect an allocation of expenses associated with personnel costs, equity-based compensation expense, activities that benefit multiple programs or indirect costs incurred in support of overall research and development, such as technology and facilities-related costs.

We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities both in the near-term and beyond as we continue to invest in activities to develop our product candidates and preclinical programs and as certain product candidates advance into later stages of development. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, scope and duration of later-stage clinical trials. Furthermore, the process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we cannot accurately estimate or know the nature, timing and costs that will be necessary to complete the preclinical and clinical development for any of our product candidates or when and to what extent we may generate revenue from the commercialization and sale of any of our product candidates or achieve profitability.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;

- the duration of patient follow-up; and
- the efficacy and safety profile of our product candidates.

Changes in any of these assumptions could significantly impact the cost and timing associated with the development of our product candidates. Additionally, future competition and commercial and regulatory factors beyond our control may also impact our clinical development programs and plans.

General and Administrative

We expense general and administrative costs as incurred. General and administrative expenses consist primarily of salaries, benefits, equity-based compensation and outsourced labor for personnel in executive, finance, human resources, legal and other corporate administrative functions. General and administrative expenses also include legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, insurance costs, facilities and depreciation expenses.

We estimate and accrue for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from our service providers. We reassess and adjust our accruals as actual costs become known or as additional information becomes available.

We expect that our general and administrative expenses will increase both in the near-term and beyond as we continue to build general corporate infrastructure to support organization; however, we expect that the rate at which these expenses grow will moderate throughout 2021.

Interest Income, Net

Interest income, net primarily consists of interest earned on our cash, cash equivalents and restricted cash.

Other Income (Expense), Net

Other income (expense), net consists of amounts for other miscellaneous income and expense unrelated to our core operations.

For the three months ending March 31, 2021, other income (expense), net primarily consisted of gains (losses) on the fair value remeasurement of the private placement warrants.

The private placement warrants were free-standing financial instruments that were reclassified from equity to other long-term liabilities on March 31, 2021. We revalue our private placement warrants each reporting period with increases or decreases in the fair value of these warrants recognized as an adjustment to other income (expense), net in our consolidated statements of operations and comprehensive loss. Changes in the fair value of our private placement warrants result from changes to one or multiple inputs, including adjustments to the discount rate, expected volatility and dividend yield as well as changes in the fair value of our common stock and public warrants.

For the three months ending March 31, 2020, other income (expense), net primarily consisted of gains (losses) on the fair value remeasurement of the Equity Commitment and Share Purchase Option, which were terminated upon the completion of the Business Combination Transaction. The Equity Commitment and Share Purchase Option were free-standing financial instruments that were recorded at their fair value on the Formation Transaction Date. We revalued these instruments each reporting period and recorded increases or decreases in their respective fair value as an adjustment to other income (expense), net in our consolidated statements of operations and comprehensive loss.

Changes in the fair value of these financial instruments resulted from changes to one or multiple inputs, including adjustments to the discount rates and expected volatility and dividend yield as well as changes in the amount and timing of the anticipated future funding required to settle these instruments and the fair value of our preferred and common stock that were expected to be exchanged to complete that additional funding. Discount rates in our valuation models represent a measure of the credit risk associated with settling the financial instruments. The expected dividend yield was assumed to be zero as we have never paid dividends, nor do we have current plans to do so in the future. Significant judgment was employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period.

Income Taxes Benefit (Provision), Net

To date, we have not recorded any significant amounts related to income tax expense, we have not recognized any reserves related to uncertain tax positions, nor have we recorded any income tax benefits for net operating losses incurred to date or for our research and development tax credits.

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of March 31, 2021, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

We file income tax returns in the U.S. federal tax jurisdiction and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our initial tax return period for U.S. federal income taxes was the 2018 period. We currently remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for this period and for the 2019 tax year. 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 taxes 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 three months ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 36,561	$ 26,959	36%
General and administrative	14,010	10,743	30%
Total operating expenses	50,571	37,702	34%
Loss from operations	(50,571)	(37,702)	34%
Interest income, net	15	204	(93%)
Other income (expense), net	(425)	(15,710)	(97%)
Loss before income taxes	(50,981)	(53,208)	(4%)
Income tax benefit (provision), net	—	—	—%
Net loss	$ (50,981)	$ (53,208)	(4)%

Research and Development

The following table summarizes the components of research and development expense for the three months ended March 31, 2021 and 2020:

(In thousands)	For the Three Months Ended March 31, 2021	2020	Change
Tavapadon	$ 10,871	$ 9,184	18%
CVL-231	7,115	3,606	97%
Darigabat	5,065	3,327	52%
CVL-871	1,167	399	192%
CVL-936	20	1,038	(98%)
Other research and development programs	2,146	1,073	100%
Unallocated	1,752	2,204	(21)%
Personnel costs	6,628	5,218	27%
Equity-based compensation	1,797	910	97%
Total research and development	$ 36,561	$ 26,959	36%

For the three months ended March 31, 2021, compared to the same period in 2020, the increase in research and development expense was primarily due to costs associated with the continued advancement of our tavapadon, CVL-231, darigabat and CVL-871 programs as well as increased investment in our preclinical and discovery research efforts. The increase in research and development expense for the three-month comparative periods also reflects an increase in personnel costs, including equity-based compensation, as we continue to develop our organizational infrastructure to advance our pipeline. These increases were partially offset by reduction in costs for the development of CVL-936 as we concluded dosing of Cohort 1 of the Phase 1 SAD trial in the first quarter of 2020 after receiving sufficient clinical data for the intended purposes for this trial.

General and Administrative

(In thousands)	For the Three Months Ended March 31, 2021	2020	Change
General and administrative	$ 14,010	$ 10,743	30%

For the three months ended March 31, 2021, compared to the same period in 2020, the increase in general and administrative expense was primarily due to increased public company costs and a $2.2 million net charge associated with the departure of certain executives. Cost savings from a reduction in outsourced labor were offset by increased personnel costs as we continued to grow our organization.

Interest Income, Net

(In thousands)	For the Three Months Ended March 31, 2021	2020	Change
Interest income, net	$ 15	$ 204	(93)%

Interest income, net primarily consists of interest earned on our cash, cash equivalents and restricted cash. The decrease in interest income, net, reflects a reduction in market interest rates.

Other Income (Expense), Net

The following table summarizes other income (expense), net for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,		
(In thousands)	**2021**	**2020**	**Change**
Loss on fair value remeasurement of Equity Commitment	$ —	$ (15,760)	**
Gain on fair value remeasurement of Share Purchase Option	—	50	**
Loss on fair value remeasurement of private placement warrants	(424)	—	**
Other, net	(1)	—	**
Other income (expense), net	$ (425)	$ (15,710)	**

** – Not meaningful

The Equity Commitment and Share Purchase Option were free-standing financial instruments that were recorded at fair value on the Formation Transaction Date. We revalued these financial instruments each reporting period until their termination upon the completion of our Business Combination Transaction in 2020.

For additional information on our Equity Commitment and Share Purchase Option, please read Note 7, *Equity Commitment and Share Purchase Option*, to our audited consolidated financial statements included in our Annual Report.

Liquidity and Capital Resources

Sources of Liquidity and Capital

We have incurred significant operating losses since our inception, and we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. Our net losses totaled $51.0 million and $53.2 million for the three months ended March 31, 2021 and 2020, respectively, and as of March 31, 2021, we had an accumulated deficit of $441.9 million. We have not yet generated revenues.

Prior to the Business Combination, our operations were funded primarily from the issuance of convertible preferred stock, convertible common stock and common stock. Upon the closing of the Business Combination Transaction in October 2020, we received net proceeds totaling approximately $439.5 million.

Our cash and cash equivalents totaled $343.3 million as of March 31, 2021. Until required for use in our business, we typically invest our cash in investments that are highly liquid, readily convertible to cash with original maturities of 90 days or less at the date of purchase. We attempt to minimize the risks related to our cash and cash equivalents by maintaining balances in accounts only with accredited financial institutions and, consequently, we do not believe we are subject to unusual credit risk beyond the normal credit risk associated with ordinary commercial banking relationships.

Future Funding Requirements

Our primary use of cash is to fund operating expenses, primarily related to our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We have incurred significant operating expenses since our inception, and we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. In the future, we will require additional capital to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities.

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

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments under the Pfizer License Agreement and the Funding Agreements;
- the royalty payments due under the Pfizer License Agreement and the Funding Agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the total amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and preclinical studies.

Our expectations with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to us and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate certain of our research, product development or future commercialization efforts, obtain funds through arrangements with collaborators on terms unfavorable to us, or pursue other merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

For additional information on risks associated with our substantial capital requirements, please read the section entitled "*Risk Factors*" included elsewhere in this Quarterly Report.

Warrants

ARYA issued public warrants and private placement warrants (collectively, the warrants) in its IPO in June 2020. The warrants will become exercisable beginning on June 9, 2021. Warrants may only be exercised for a whole number of shares. No fractional shares will be issued upon exercise of the warrants. Each whole warrant entitles the holder to purchase one share of common stock at an exercise price of $11.50 per share.

We will use our commercially reasonable efforts to maintain the effectiveness of our registration statement and a current prospectus relating to those common shares issuable upon exercise of the warrants until the warrants expire or are redeemed, as specified in the warrant agreement. If the common stock at the time of any exercise of a warrant is not listed on a national securities exchange, we may, at our option, require holders of the warrants who exercise their warrants to do so on a "cashless basis." We are not required to file or maintain in effect a registration statement. In no event will the company be required to net cash settle any warrant.

Except as described in the warrant agreement, the private placement warrants have terms and provisions that are identical to those of the public warrants. If the private placement warrants are held by holders other than the Sponsor or its permitted transferees, the private placement warrants will be redeemable by us and exercisable by the holders on the same basis as the public warrants.

Once the warrants become exercisable, we may call the warrants for redemption:

- in whole and not in part;
- upon not less than 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the closing price of our common stock equals or exceeds $18.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of the redemption is given to the warrant holder.

If and when the warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. If we call the public warrants for redemption, as described above, we will have the option to require any holder that wishes to exercise the public warrants to do so on a "cashless basis," as described in the warrant agreement.

Commencing ninety days after the warrants become exercisable, we may redeem the outstanding warrants:

- in whole and not in part;
- at $0.10 per warrant upon a minimum of 30 days' prior written notice of redemption, provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares determined by reference to the table included in the warrant agreement, based on the redemption date and the "fair market value" of our shares of common stock, except as otherwise described below;
- if, and only if, the closing price of the shares of common stock equals or exceeds $10.00 per share (as adjusted for share subdivisions, share dividends, reorganizations, reclassifications, recapitalizations and the like) on the trading day before we send the notice of redemption to the warrant holders;
- if, and only if, the private placement warrants are also concurrently called for redemption on the same terms as the outstanding public warrants, as described above; and
- if, and only if, there is an effective registration statement covering the issuance of common stock issuable upon exercise of the warrants and a current prospectus relating thereto available throughout the 30-day period after written notice of redemption is given.

The warrants will expire five years after the completion of the Business Combination Transaction, or earlier upon redemption or liquidation.

Working Capital

The following table summarizes our total working capital, defined as current assets less current liabilities as of March 31, 2021 and December 31, 2020:

	As of		
(In thousands)	**March 31, 2021**	**December 31, 2020**	**Change**
Current assets	$ 349,811	$ 390,560	(10)%
Current liabilities	(34,151)	(29,548)	16%
Total working capital	$ 315,660	$ 361,012	(13)%

The change in working capital at March 31, 2021 from December 31, 2020, reflects a net decrease in total current assets of $40.7 million and a net increase in total current liabilities of $4.6 million.

The net decrease in total current assets was primarily driven by a net decrease in our cash and cash equivalents primarily due to $36.4 million of net cash flows used in operations and $4.7 million of cash used for the purchase of property and equipment.

The net increase in current liabilities was primarily driven by an increase in accounts payable and increases in accrued expenses and other current liabilities related to increased external research and development services partially offset a decrease in the accrual for employee compensation and personnel costs.

Cash Flows

The following table summarizes our sources and uses of cash for the years ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,		
(In thousands)	**2021**	**2020**	**Change**
Net cash flows used in operating activities	$ (36,418)	$ (29,454)	24%
Net cash flows used in investing activities	(4,660)	(2,556)	82%
Net cash flows provided by financing activities	742	—	**
Net decrease in cash, cash equivalents and restricted cash	$ (40,336)	$ (32,010)	26%

Cash flows used in Operating Activities

Net cash flows used in operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided by financing activities will continue to be our primary source of funds to finance operating needs and capital expenditures for the foreseeable future.

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

- non-cash operating items such as depreciation and amortization, non-cash rent expense, equity-based compensation, impairments and write-offs of deferred charges;
- changes in operating assets and liabilities reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- changes in the fair value remeasurement of the Equity Commitment, Share Purchase Option and the private placement warrants.

For the three months ended March 31, 2021, cash used in operating activities primarily reflects our net loss for the period of $51.0 million, adjusted for net non-cash charges totaling $6.4 million and a net change of $8.1 million in our net operating assets and liabilities. Our non-cash charges primarily consisted of $6.1 million of equity-based compensation expense. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses and other liabilities related to increased external research and development services partially offset by a decrease in the accrual for employee compensation and personnel costs and an increase in operating lease liabilities resulting from landlord reimbursement for tenant improvements.

For the three months ended March 31, 2020, net cash used in operating activities primarily reflected our net loss for the period of $53.2 million, adjusted by non-cash charges totaling $19.3 million and a net change of $4.5 million in relation to our net operating assets and liabilities. Our non-cash charges primarily consisted of net losses totaling $15.7 million recognized related to the Equity Commitment and Share Purchase Option, $3.0 million of equity-based compensation expense and $0.5 million of non-cash rent expense. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses and other current liabilities, and a decrease in prepaid expenses and other current assets.

Cash flows used in Investing Activities

For the three months ended March 31, 2021, cash used in investing activities reflected $4.7 million used for purchases of property and equipment, primarily related to the build-out of our Cambridge, Massachusetts headquarters.

For the three months ended March 31, 2020, cash used in investing activities reflected $2.6 million used for purchases of property and equipment, primarily related to the build-out of our Cambridge, Massachusetts headquarters.

Cash flows provided by Financing Activities

For the three months ended March 31, 2021, net cash provided by financing activities totaled $0.7 million, reflecting proceeds received from stock option exercises.

Contractual Obligations and Other Commitments

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, contracts and other purchase obligations. We did not have any debt obligations as of March 31, 2021 or December 31, 2020.

Our most significant contracts relate to agreements with CROs for clinical trials and preclinical studies, CMOs and other service providers for operating purposes, which we enter into in the normal course of business. These contracts are generally cancelable at any time by us following a certain period after notice and therefore, we believe that our non-cancelable obligations under these agreements are not material. In addition, we have obligations with respect to potential future royalties payable, contingent development, regulatory and commercial milestone payments and amounts related to uncertain tax positions. The timing and amount of such obligations are unknown or uncertain as of March 31, 2021. For additional information on potential royalties and milestone payments payable to Pfizer, see "*Our Agreements with Licensors and Stockholders—Pfizer License Agreement*."

As of March 31, 2021, our remaining obligations associated with expenditures expected to be incurred related to the build out of our corporate headquarters totaled $3.5 million. Other than the Funding Agreements, described in Note 14, *Subsequent Events*, to our accompanying unaudited condensed consolidated financial statements, there have been no other material changes to our contractual obligations and commitments since December 31, 2020.

Contract Research and Manufacturing Organizations

As of March 31, 2021, and December 31, 2020, we recorded accrued expenses of approximately $14.5 million and $7.1 million, respectively, in our consolidated balance sheets for expenditures incurred by CROs and CMOs.

Tax Related Obligations

To date, we have not recognized any reserves related to uncertain tax positions. As of March 31, 2021, and December 31, 2020, we had no accrued interest or penalties related to uncertain tax positions.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements and do not have holdings in any variable interest entities.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP.

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our most critical accounting policies and estimates were described under the heading "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates*" in our Annual Report. There have been no material changes to our critical accounting policies and estimates described in our Annual Report.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year (a) in which we are deemed to be a "large accelerated filer" under the Exchange Act, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) following the fifth anniversary of the closing of ARYA's initial public offering; or (ii) the date on which we have issued more than $1 billion in non-convertible debt in the prior three-year period. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. We have elected to take advantage of this exemption and will therefore, for so long as we are an emerging growth company, delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We are also a "smaller reporting company" meaning that the market value of our voting and non-voting common equity held by non-affiliates was less than $700 million as of our most recently completed second fiscal quarter and our annual revenue was less than $100 million during our most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Pronouncements

For a discussion of new accounting standards and their expected impact on our consolidated financial statements or disclosures, please read Note 3, *Recent Accounting Guidance*, to our unaudited consolidated financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We had cash and cash equivalents of $343.3 million and $383.6 million as of March 31, 2021 and December 31, 2020, respectively, which consisted of bank deposits and highly liquid money market funds. Furthermore, we had no outstanding debt as of March 31, 2021 or December 31, 2020.

Interest Rate Sensitivity

Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Foreign Currency Exchange Risk

We currently do not have significant exposure to foreign currencies as we hold no foreign exchange contracts, option contracts, or other foreign hedging arrangements. Further, our operating activities are predominately denominated in U.S. dollars.

We do not believe that inflation, interest rate changes or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. 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 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 Chief Executive Officer and Chief Financial Officer, who serve as our principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2021.

Changes in Internal Control Over Financial Reporting

There has been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the during the quarter ended March 31, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We, from time to time, may be party to litigation arising in the ordinary course of business. We were not subject to any material legal proceedings as of March 31, 2021 and December 31, 2020, and, to the best of our knowledge, no material legal proceedings are currently pending or threatened.

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 Quarterly Report, including our consolidated financial statements and the related notes included in this Quarterly 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 Quarterly 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 above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly 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 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 NDA preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

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

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

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

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

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

We have no products approved for commercial sale and have not generated any revenue from product sales to date, nor do we expect to generate any revenue from product sales for the next few years, if ever. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled $51.0 million and $53.2 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $441.9 million and had not yet generated revenues. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

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

- advance our clinical-stage product candidates CVL-231, darigabat, tavapadon, CVL-871 and CVL-936 through clinical development, including as we complete our registration-directed Phase 3 program for our most advanced product candidate, tavapadon;
- headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- advance our preclinical-stage product candidates into clinical development;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increase personnel to support our operations;
- meet the requirements and demands of being a public company;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Pfizer License Agreement and any future in-license or collaboration agreements;
- make milestone, royalty or other payments due under the Funding Agreements and any future financing or other arrangements with third parties;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties.

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

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

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

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, the product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

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

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

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

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments under the Pfizer License Agreement and the Funding Agreements;
- the royalty payments due under the Pfizer License Agreement and the Funding Agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our receipt of additional funding from NovaQuest and Bain, or the Investors, under the Funding Agreements;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

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

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

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

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

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

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

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

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

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

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

In April 2021, we entered into the Funding Agreements, pursuant to which the 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 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 Investors a combined amount equal to the total amount funded by the 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 Investors on a timely basis or at all. In conjunction with the Funding Agreements, we also entered into security agreements with the Investors pursuant to which we granted the 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 Investors may be able to foreclose on the collateral that was pledged to the Investors. Any of the foregoing events could significantly and adversely affect our financial condition and results of operations.

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

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

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry,
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of COVID-19;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

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

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

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

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

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an IND or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the EMA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities.

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

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

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

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

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

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

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

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

The general approach for FDA approval of a new drug is dispositive data from two or more well-controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our registration-directed Phase 3 program for tavapadon after receiving input and feedback from the FDA, there can be no assurance that the design of our planned clinical trials will be satisfactory to the FDA or that the FDA will not require us to modify our trials or conduct additional testing, or that completing these trials will result in regulatory approval. See the section entitled "*Business—Our Solution–Tavapadon—Ongoing Clinical Trials—Phase 3 Fixed-Dose Early-Stage Parkinson's Trial*" in our Annual Report for a description of our discussions with the FDA regarding the proposed primary endpoint of our Phase 3 trials of tavapadon in early-stage Parkinson's. Even if our Phase 3 clinical trials in early-stage Parkinson's achieve their primary endpoint, there can be no assurance

that the FDA will find them sufficient to support approval if, for example, FDA determines the contribution of the MDS-UPDRS Part II score to the primary endpoint results to be inadequate. Our Phase 2 early-stage Parkinson's trial of tavapadon did not use the MDS-UPDRS Part II score as a primary endpoint and was therefore not powered to show a statistically significant difference from placebo for this measure. In addition, based on our end-of-Phase 2 meeting with the FDA where we presented single-dose ECG, multiple-dose ECG and a model-based analysis of Phase 1 data, we plan to collect time-matched PK and ECG measures in a subset of patients as a sub-study in our planned Phase 3 fixed-dose early-stage Parkinson's trial. However, there can be no assurance that we will not be required to conduct additional testing on the safety and tolerability of tavapadon, including with respect to arrhythmia. Additionally, we are developing CVL-871 for the treatment of dementia-related apathy. There are no currently approved therapies for dementia-related apathy, and we may experience challenges in defining this indication. There are limited precedents for trial design, trial endpoints and regulatory pathway for this indication, which may make clinical development and regulatory approval of CVL-871 more challenging.

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

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

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

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

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

In addition, COVID-19 may impact our ability to retain principal investigators and site staff for our clinical trials as healthcare providers may have heightened exposure to COVID-19 if an outbreak occurred in their geography or may be impacted due to prioritization of hospital resources toward the outbreak and restrictions on travel. Our clinical trial sites may be located in geographies that are disproportionately affected by the COVID-19 pandemic or actions taken by governmental and health authorities to address the pandemic. Furthermore, COVID-19 may also negatively affect the operations of third-party contract research organizations that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. Any negative impact COVID-19 has on patient enrollment, site staffing or treatment or the timing and execution of our clinical trials could cause costly delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business and financial results. These measures could negatively affect our business. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

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

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

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

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

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

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, while darigabat demonstrated anti-epileptic activity similar to lorazepam, a commonly prescribed BZD, in a Phase 2 photoepilepsy trial, only seven patients were treated with darigabat in that trial and we may not be able to replicate the observed results from that trial in our ongoing Phase 2 proof-of-concept trial in focal epilepsy. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. For instance, although they both activate muscarinic receptors, CVL-231 may not be able to replicate the anti-psychotic benefit observed in prior clinical trials of xanomeline.

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

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

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

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

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

- regulators, IRBs or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which it may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries

have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

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

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

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

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

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

We intend to evaluate our product candidates in combination with other compounds. The use of our product candidates in combination with other compounds may subject us to risks that we would not face if our product candidates were being administered as a monotherapy. For instance, in our Phase 3 late-stage Parkinson’s trial, we are evaluating tavapadon in combination with L-dopa for the treatment of late-stage Parkinson’s, and L-dopa’s safety issues may be improperly attributed to tavapadon or the administration of tavapadon with L-dopa may result in safety issues that such other therapies or tavapadon would not have when used alone. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside our control. If we experience efficacy or safety issues in our clinical trials in which our product candidates are being administered with other compounds, we may not receive regulatory approval for our product candidates, which could prevent us from ever generating revenue or achieving profitability.

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

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

Patient enrollment is affected by many factors, including:

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

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

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

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

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

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

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

Undesirable side effects have been observed in our product candidates to date. For example, in clinical trials of tavapadon, a dose-dependent increase in the frequency of nausea and headache was observed, with nausea, vomiting, dyskinesia, fall, fatigue, sleep disorder and tremors being the most common adverse events leading to discontinuation of tavapadon. In clinical trials of CVL-231, some moderate treatment-emergent increases in heart rate and blood pressure were observed following single doses of CVL-231 (>10 mg), which may be due to CVL-231's activity on the M4 receptor subtype and its subsequent reduction of striatal dopamine levels. We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

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

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

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

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

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

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

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;

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

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

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

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

In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

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

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

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

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

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

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

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

We believe that a significant number of product candidates are currently under development for the same indications we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled "*Business—Competition*" in our 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, including tavapadon, is approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than tavapadon, our other product candidates or any other product candidates that we may develop, which could render our product candidates obsolete and noncompetitive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2020, we had U.S. federal net operating loss carryforwards totaling $213.9 million, all of which have an indefinite carryforward period. As of December 31, 2020, we had state net operating loss carryforwards totaling $206.2 million which begin to expire in 2038 and 2040. As of December 31, 2020, we also had U.S. federal and state research and development tax credit carryforwards of $5.7 million and $0.7 million, respectively, which expire at various dates through 2040 for federal purposes and 2035 for state purposes. The net operating losses which are limited in life and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with, or we undergo an ownership change following, the transactions contemplated hereby, 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 are subject to limitation by Sections 382 and 383 of the Code.

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.

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 2002, 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 financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

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

Upon completion of this transaction, we will become subject to certain reporting requirements of the Exchange Act. 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.

Risks Related to Managing our Business and Operations

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

As a public company, we are facing, and will continue to face, increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the Public Company Accounting Oversight Board and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of

those requirements mandate us to carry out activities we have not done previously. In addition, additional expenses associated with SEC reporting requirements are being incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if our auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It will also be more expensive to obtain director and officer liability insurance as a public company. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on the board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

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

We qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year (a) in which we are deemed to be a "large accelerated filer" under the Exchange Act, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) following the fifth anniversary of the closing of ARYA's initial public offering; or (ii) the date on which we have issued more than $1 billion in non-convertible debt in the prior three-year period. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. We have elected to take advantage of this exemption and will therefore, for so long as we are an emerging growth company, delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Therefore, we may not be subject to the same new or revised accounting standards as other public companies. Investors may find our common stock less attractive because we will rely on these exemptions, which may result in a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

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

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

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

As of December 31, 2020, we had 104 full-time employees. Our focus on the development of multiple initial product candidates requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop our product candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. If we are not able to effectively expand our organization by hiring new employees, our clinical trials may be delayed or terminated, we may not be able to successfully execute the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our development and commercialization goals.

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

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

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

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

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

We expect to experience significant growth in the number of our employees and the scope of our operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of their attention to managing these growth activities. For instance, the transition to and build-out of our new headquarters may divert our management’s time and attention. Due to our limited financial resources and the limited experience of our management team in

managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Risks Related to Our Organizational Structure

Bain Investor and Pfizer have significant influence over us.

As of March 15, 2021, Bain Investor and Pfizer own, collectively, approximately 69.1% of the outstanding shares of our common stock. Furthermore, as discussed in the section entitled "*Certain Relationships and Related Person Transactions, and Director Independence*" in our Annual Report, so long as they own certain specified amounts of our equity securities, Bain Investor and Pfizer have certain rights to nominate our directors. As long as such persons each own or control a significant percentage of outstanding voting power, they will have the ability to strongly influence all corporate actions requiring stockholder approval, including the election and removal of directors and the size of our board of directors, any amendment of our certificate of incorporation or bylaws, or the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at other shareholders have purchased share or have held their shares for a longer period, they may be more interested in selling the company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders.

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

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

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

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

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

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

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

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

Our warrant agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of our warrants, which could limit the ability of warrant holders to obtain a favorable judicial forum for disputes with our company.

Our warrant agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the warrant agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. We will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, these provisions of the warrant agreement do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of our warrants will be deemed to have notice of and to have consented to the forum provisions in our warrant agreement.

If any action, the subject matter of which is within the scope of the forum provisions of the warrant agreement, is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York, or a foreign action, in the name of any holder of our warrants, such holder will be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions, or an enforcement action, and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder's counsel in the foreign action as agent for such warrant holder.

This choice-of-forum provision may limit a warrant holder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our company, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our warrant agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

Delaware law and our Governing Documents 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.

The Governing Documents and the Delaware General Corporation Law, 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, the Governing Documents include provisions regarding:

- the ability of our board of directors to issue shares of preferred stock, including "blank check" preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the limitation of the liability of, and the indemnification of, our directors and officers;
- a prohibition on 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;

- the requirement 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;
- the ability of our board of directors to amend the bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our board of directors.

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs.

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

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

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

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

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

Under the Funding Agreements, the 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 Investors agreed to provide up to an additional $37.5 million, approximately $31.3 million and $25.0 million on the first, second and third anniversaries of the effective date of the Funding Agreements, respectively, such payments are subject to certain customary funding conditions, and, if those funding conditions are not satisfied or waived, we would not receive such payments. The 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 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 Investors may terminate their obligation to make any further development payments if such condition is not resolved or cured within 12 months. If the 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 Investors in the event we nonetheless receive FDA approval for tavapadon and commercialize tavapadon in the U.S. Our ability to receive payments under the Funding Agreements also depends on the ability of the Investors to meet their funding commitments. If we do not receive additional payments under the Funding Agreements, our business, results of operations, cash flows and financial condition could be adversely affected.

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

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

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

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

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

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

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

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

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

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

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

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

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

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

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

- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

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

Additionally, if any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. 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. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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 U.S. 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 U.S. 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. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

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

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

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

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

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

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

Risks Related to Government Regulation

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

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

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

In particular, the impact of the impending Brexit, whereby the United Kingdom is planning to leave the EEA, either with or without a “deal,” is uncertain and cannot be predicted at this time. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU. For instance, in November 2017, European Union member states voted to move the EMA, the European Union’s regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As a result of any funding from NIDA, or if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. On November 20, 2020, OIG finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, this rule will have on our business;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended, and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS within the HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal consumer protection laws, which broadly regulative marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and FCA which may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

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

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

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

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

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

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

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

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

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

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

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

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

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

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

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

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

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

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

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

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. For example, California recently passed the California Data Privacy Protection Act, which goes into effect in January 2020 and provides broad rights to California consumers with respect to the collection and use of their information by businesses. The new California law further expands the privacy and process enhancements and commitment of resources in support of compliance with California's regulatory requirements and may lead to similar laws in other U.S. states or at a national level.

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

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

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

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

On October 27, 2020, Cerevel Therapeutics, Inc., a private company and our predecessor, completed a business combination 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 license rights, which would substantially harm our business.

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

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

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

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

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

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

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

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

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the statutory expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. While various extensions such as patent term adjustments and/or extensions, may be available, the life of a patent, and the protection it affords, is limited. Our current composition of matter patents, and patents that may issue from our pending patent applications, covering new chemical entities, pharmaceutical compositions comprising those entities, and their use in methods of treating various diseases and/or disorders, which we licensed from Pfizer, in

connection with the formation of our company, are expected to expire between 2033 and 2039, not including any patent term extensions or adjustments. Our earliest patents may expire before, or soon after, our product candidates achieve marketing approval in the United States or foreign jurisdictions. Once the patent life has expired, we may be open to competition from competitive products, including generics. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The expiration of the patents covering our lead product candidates, and our inability to secure additional patent protection, could also have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents;
- the APIs in our current product candidates may eventually become commercially available in generic drug products, and no patent protection may be available with regard to their formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regard to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or design around any of our or our licensors' technologies;
- it is possible that pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable because such omissions or inclusions are held to be done with deceptive intent;
- we may engage in scientific collaborations with one or more third parties, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

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

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived or completed by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may, for example, not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Periodic maintenance fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent applications and patents. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result, if not cured, in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock and Warrants

An active trading market for our common stock or warrants may never develop or be sustained, which may make it difficult to sell the shares of our common stock or warrants you purchase.

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

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

If Nasdaq delists our shares of common stock or warrants 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 and warrants may be volatile.

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

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- actual or anticipated fluctuations in our quarterly or annual operating results;

- publication of research reports by securities analysts about us, our competitors or our industry;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism.

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

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 shares.

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.

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

Sales of a substantial number of shares of our shares of common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our shares of common stock. For instance, certain lock-up restrictions under the Registration and Shareholder Rights Agreement applicable to the Perceptive Shareholders, the Bain Investor and Pfizer expired in April 2021. As restrictions on resale end and the registration statements are available for use, the market price of our shares of common stock could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

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

Outstanding warrants to purchase an aggregate of 5,149,647 shares of our shares of common stock will become exercisable in accordance with the terms of the warrant agreement governing those securities. These warrants will become exercisable beginning on June 9, 2021. The exercise price of these warrants will be $11.50 per share. To the extent such warrants are exercised, additional shares of our shares of common stock will be issued, which will result in dilution to the holders of our shares of common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of our shares of common stock. However, there is no guarantee that the warrants will ever be in the money prior to their expiration, and as such, the warrants may expire worthless. See "*—Our warrants may never be in the money, and they may expire worthless and the terms of the warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding public warrants approve of such amendment*."

Our warrants may never be in the money, and they may expire worthless and the terms of the warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding warrants approve of such amendment.

The warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and ARYA. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, but requires the approval by the holders of at least 50% of the then-outstanding public warrants to make any change that adversely affects the interests of the registered holders of public warrants. Accordingly, we may amend the terms of the public warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding public warrants approve of such amendment and, solely with respect to any amendment to the terms of the private placement warrants or any provision of the warrant agreement with respect to the private placement warrants, 50% of the number of the then outstanding private placement warrants. Although our ability to amend the terms of the public warrants with the consent of at least 50% of the then-outstanding public warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, convert the warrants into cash, shorten the exercise period or decrease the number of shares of our shares of common stock purchasable upon exercise of a warrant.

We may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

We have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of our shares of common stock equals or exceeds $18.00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date we send the notice of redemption to the warrant holders. If and when the warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding warrants could force you to: (i) exercise your warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so; (ii) sell your warrants at the then-current market price when you might otherwise wish to hold your warrants; or (iii) accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants.

In addition, we may redeem your warrants at any time after they become exercisable and prior to their expiration at a price of $0.10 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their warrants prior to redemption for a number of shares of common stock determined based on the redemption date and the fair market value of our common stock.

The value received upon exercise of the warrants (1) may be less than the value the holders would have received if they had exercised their warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the warrants, including because the number of ordinary shares received is capped at 0.365 shares of common stock per warrant (subject to adjustment) irrespective of the remaining life of the warrants.

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

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

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

We have no current plans to pay cash dividends on our common stock. The declaration, amount and payment of any future dividends will be at the sole discretion of our board of directors. Our board of directors may take into account general and economic conditions, our financial condition and operating results, our available cash, current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders or by our subsidiary to us and such other factors as our board of directors may deem relevant. In addition, the terms of our existing financing arrangements restrict or limit our ability to pay cash dividends. Accordingly, we may not pay any dividends on our common stock in the foreseeable future.

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Equity Securities

The information required by Item 701 of Regulation S-K was previously included in Quarterly Reports on Form 10-Q filed on August 14, 2020 and November 16, 2020.

Use of Proceeds from our Initial Public Offering

Of the gross proceeds received from the IPO and the full exercise of the option to purchase additional units, $149.5 million was placed in ARYA's trust account. The net proceeds of the IPO were applied to fund the Business Combination and related expenses.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

PART II

Item 6. Exhibits.

Exhibit Number	Description
10.1*†++	Funding Agreement, dated as of April 12, 2021, by and between Cerevel Therapeutics, Inc. and NovaQuest Co-Investment Fund XVI, L.P.
10.2*†++	Funding Agreement, dated as of April 12, 2021, by and between Cerevel Therapeutics, Inc. and BC Pinnacle Holdings, LP.
10.3*#	Employment Agreement, dated April 20, 2021, by and between Cerevel Therapeutics, LLC and Scott M. Akamine.
10.4†#	Employment Agreement, dated April 13, 2021, by and between Cerevel Therapeutics, LLC and Abraham N. Ceesay (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on April 21, 2021).
10.5*#	Non-Employee Director Compensation Policy, as amended on April 8, 2021.
10.6	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).
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

\+ This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

++ Schedules and exhibits to this Exhibit are omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Securities and Exchange Commission upon request.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CEREVEL THERAPEUTICS HOLDINGS, INC.

Date: May 17, 2021

By: /s/ N. Anthony Coles

N. Anthony Coles
Chief Executive Officer
(Principal Executive Officer)

Date: May 17, 2021

By: /s/ Kathy Yi

Kathy Yi
Chief Financial Officer
(Principal Financial Officer)