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 June 30, 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: 001-38085

Ovid Therapeutics Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-5270895**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
1460 Broadway, Suite 15044 **New York, New York**	**10036**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (646) 661-7661

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 $0.001 per share	OVID	The Nasdaq Stock Market LLC

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

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 the 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 August 6, 2021, the registrant had 67,931,996 shares of common stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "project," "should," "target," "will," "would" or the negative or plural of those terms, and similar expressions.

Forward-looking statements include, but are not limited to, statements about:

- statements regarding the impact of the COVID-19 pandemic and its effects on our operations, access to capital, research and development and clinical trials and potential disruption in the operations and business of third-party manufacturers, contract research organizations, or CROs, other service providers, and collaborators with whom we conduct business;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to identify additional novel compounds with significant commercial potential to acquire or in-license;
- our ability to successfully acquire or in-license additional drug candidates on reasonable terms;
- our ability to obtain regulatory approval of our current and future drug candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such drug candidates;
- our ability to fund our working capital requirements;
- the implementation of our business model and strategic plans for our business and drug candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our ability to establish and maintain collaborations or obtain additional funding;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- the factors that may impact our financial results.

Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part I, Item 1A, "Risk Factors," herein and for the reasons described elsewhere in this Quarterly Report on Form 10-Q. Any forward-looking statement in this Quarterly Report on Form 10-Q reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs and consumer products, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources and we have not independently verified the data from third party sources. In some cases, we do not expressly refer to the sources from which these data are derived.

In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context otherwise requires, references to "Ovid," "the Company," "we," "us," "our" and similar references refer to Ovid Therapeutics Inc. and its wholly owned subsidiaries. This Quarterly Report on Form 10-Q also contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, including those discussed at length in the section titled “Risk Factors.” These risks include, among others, the following:

- Historically, we have incurred significant operating losses and expect to continue to incur substantial operating losses for the foreseeable future.
- Our operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We will require additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our drug development efforts or other operations.
- We are very early in our development efforts and all our drug candidates are in preclinical development. If we are unable to successfully develop, receive regulatory approval for and commercialize our drug candidates for these or any other indications, or successfully develop any other drug candidates, or experience significant delays in doing so, our business will be harmed.
- Our future success is dependent on the successful clinical development, regulatory approval and commercialization of our current and future drug candidates. If we, or our licensees, are not able to obtain the required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be adversely affected.
- Because the results of preclinical studies or earlier clinical trials are not necessarily predictive of future results, our drug candidates may not have favorable results in planned or future preclinical studies or clinical trials, or may not receive regulatory approval.
- It is difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval for our gene therapy candidates.
- Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain marketing approvals for our product candidates.
- Interim topline and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes in the final data.
- Preclinical studies and clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes. Further, we may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy in our preclinical studies and clinical trials to the satisfaction of applicable regulatory authorities.
- If we are not successful in discovering, developing and commercializing additional drug candidates, our ability to expand our business and achieve our strategic objectives would be impaired.
- Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.
- Even if our current or future drug candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- Under the Takeda License and Termination Agreement, we are entitled to receive royalty and milestone payments in connection with the development and commercialization of soticlestat. If Takeda fails to progress or discontinues the development of soticlestat, we may not receive some or all of such payments, which would materially harm our business.
- Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- Coverage and adequate reimbursement may not be available for our current or any future drug candidates, which could make it difficult for us to sell profitably, if approved.
- If we are unable to obtain and maintain patent protection for our current or any future drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our current and any future drug candidates.

- We intend to rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- COVID-19 could adversely impact our business, including our preclinical studies, clinical trials and access to capital.
- We may need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.
- We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

OVID THERAPEUTICS INC.
Condensed Consolidated Balance Sheets

		June 30, 2021		December 31, 2020
Assets		(unaudited)		
Current assets:				
Cash and cash equivalents	$	212,166,565	$	72,033,930
Related party receivable		-		141,763
Prepaid expenses and other current assets		3,705,972		2,667,508
Total current assets		215,872,537		74,843,201
Long-term equity investment		1,607,946		-
Long-term prepaid expenses		-		477,171
Security deposit		177,726		150,626
Property and equipment, net		113,663		135,620
Other assets		227,427		318,900
Total assets	$	217,999,299	$	75,925,518
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$	909,523	$	5,446,206
Accrued expenses		10,380,263		12,032,685
Deferred revenue, current		-		2,212,892
Related party payable		-		2,370,992
Total current liabilities		11,289,786		22,062,775
Deferred revenue, net of current portion		-		10,169,887
Related party payable - noncurrent		-		61,200
Total liabilities		11,289,786		32,293,862
Stockholders' equity:				
Preferred stock, $0.001 par value; 10,000,000 shares authorized; Series A convertible preferred stock, 10,000 shares designated, 1,250 and 3,250 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively		1		3
Common stock, $0.001 par value; 125,000,000 shares authorized; 67,833,947 and 65,743,170 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively		67,834		65,743
Additional paid-in-capital		340,614,895		337,758,007
Accumulated other comprehensive income		-		-
Accumulated deficit		(133,973,217)		(294,192,097)
Total stockholders' equity		206,709,513		43,631,656
Total liabilities and stockholders' equity	$	217,999,299	$	75,925,518

See accompanying notes to these unaudited condensed consolidated financial statements

OVID THERAPEUTICS INC.
Condensed Consolidated Statements of Operations
(unaudited)

	For The Three Months Ended June 30, 2021	For The Three Months Ended June 30, 2020	For The Six Months Ended June 30, 2021	For The Six Months Ended June 30, 2020
Revenue:				
License and other revenue	$ -	$ -	$ 12,382,779	$ -
License revenue - related party	-	-	196,000,000	-
Total revenue	-	-	208,382,779	-
Operating expenses:				
Research and development	$ 7,683,668	$ 16,032,945	$ 23,932,581	$ 30,658,313
General and administrative	6,629,158	7,108,742	22,205,707	12,777,759
Total operating expenses	14,312,826	23,141,687	46,138,288	43,436,072
(Loss) income from operations	(14,312,826)	(23,141,687)	162,244,491	(43,436,072)
Other (expenses) income, net	(2,517)	590,491	(52,250)	854,786
(Loss) income before provision for income taxes	(14,315,343)	(22,551,196)	162,192,241	(42,581,286)
Provision for income taxes	1,473,084	-	1,973,361	-
Net (loss) income	$ (15,788,427)	$ (22,551,196)	$ 160,218,880	$ (42,581,286)
Net (loss) income per share, basic	$ (0.23)	$ (0.41)	$ 2.32	$ (0.77)
Net (loss) income per share, diluted	$ (0.23)	$ (0.41)	$ 2.30	$ (0.77)
Weighted-average common shares outstanding, basic	67,818,366	55,607,110	66,953,431	55,161,360
Weighted-average common shares outstanding, diluted	67,818,366	55,607,110	67,565,761	55,161,360

See accompanying notes to these unaudited condensed consolidated financial statements

OVID THERAPEUTICS INC.
Condensed Consolidated Statements of Comprehensive (Loss) Income
(unaudited)

	For The Three Months Ended June 30, 2021	For The Three Months Ended June 30, 2020	For The Six Months Ended June 30, 2021	For The Six Months Ended June 30, 2020
Net (loss) income	$ (15,788,427)	$ (22,551,196)	$ 160,218,880	$ (42,581,286)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	-	(65,704)	-	(2,469)
Comprehensive (loss) income	$ (15,788,427)	$ (22,616,900)	$ 160,218,880	$ (42,583,755)

See accompanying notes to these unaudited condensed consolidated financial statements

OVID THERAPEUTICS INC.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
Balance, December 31, 2020	3,250	$ 3	65,743,170	$ 65,743	$ 337,758,007	$ -	$ (294,192,097)	$ 43,631,656
Stock-based compensation expense	-	-	-	-	1,320,002	-	-	1,320,002
Issuance of common stock from employee stock purchase plan	-	-	34,256	34	130,139	-	-	130,173
Issuance of common stock from exercise of stock options	-	-	10,400	11	20,791	-	-	20,802
Conversion of series A convertible preferred stock to common stock	(2,000)	(2)	2,000,000	2,000	(1,998)	-	-	-
Net income	-	-	-	-	-	-	176,007,307	176,007,307
Balance, March 31, 2021	1,250	1	67,787,826	67,788	339,226,941	-	(118,184,790)	221,109,940
Stock-based compensation expense	-	-	-	-	1,257,344	-	-	1,257,344
Issuance of common stock from exercise of stock options	-	-	46,121	46	130,610	-	-	130,656
Net loss	-	-	-	-	-	-	(15,788,427)	(15,788,427)
Balance, June 30, 2021	1,250	$ 1	67,833,947	$ 67,834	$ 340,614,895	$ -	$ (133,973,217)	$ 206,709,513

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
Balance, December 31, 2019	7,762	$ 8	54,710,322	$ 54,711	$ 283,122,894	$ 2,469	$ (213,156,521)	$ 70,023,561
ATM offering costs	-	-	-	-	2,053	-	-	2,053
Stock-based compensation expense	-	-	-	-	1,302,931	-	-	1,302,931
Issuance of common stock from employee stock purchase plan	-	-	43,743	43	83,067	-	-	83,110
Other comprehensive income	-	-	-	-	-	63,235	-	63,235
Net loss	-	-	-	-	-	-	(20,030,090)	(20,030,090)
Balance, March 31, 2020	7,762	8	54,754,065	54,754	284,510,945	65,704	(233,186,611)	51,444,800
ATM offering costs	-	-		-	(61,260)	-	-	(61,260)
Stock-based compensation expense	-	-		-	1,555,332	-	-	1,555,332
Issuance of common stock from exercise of stock options	-	-	72,035	72	160,870	-	-	160,942
Conversion of series A convertible preferred stock to common stock	(2,256)	(2)	2,256,000	2,256	(2,254)	-	-	-
Other comprehensive loss	-	-	-	-	-	(65,704)	-	(65,704)
Net loss	-	-	-	-	-	-	(22,551,196)	(22,551,196)
Balance, June 30, 2020	5,506	$ 6	57,082,100	$ 57,082	$ 286,163,633	$ -	$ (255,737,807)	$ 30,482,914

See accompanying notes to these unaudited condensed consolidated financial statements

OVID THERAPEUTICS INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Cash flows from operating activities:		
Net income (loss)	$ 160,218,880	$ (42,581,286)
Adjustments to reconcile net income (loss) to cash used in operating activities:		
Stock-based compensation expense	2,577,346	2,858,263
Depreciation and amortization expense	127,950	144,889
Change in accrued interest and accretion of discount on short-term investments	-	(196,408)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,023,996)	(350,591)
Security deposit	(27,100)	(18,446)
Related party receivable	141,763	567,964
Long-term prepaid expenses	477,171	(239,506)
Accounts payable	(4,518,374)	1,535,514
Accrued expenses	(1,676,476)	2,674,502
Deferred revenue	(12,382,779)	-
Related party payable	(2,432,192)	-
Net cash provided by (used in) operating activities	141,482,193	(35,605,105)
Cash flows from investing activities:		
Purchases of short-term investments	-	(9,964,092)
Proceeds from maturities of short-term investments	-	45,000,000
Purchase of long-term equity investment	(1,583,893)	-
Purchase of property and equipment	(11,515)	(67,052)
Software development and other assets	-	(191,842)
Net cash (used in) provided by investing activities	(1,595,408)	34,777,014
Cash flows from financing activities:		
ATM offering costs	(21,314)	(59,207)
Proceeds from employee stock purchase plan	115,705	83,110
Proceeds from exercise of options	151,458	160,942
Net cash provided by financing activities	245,849	184,845
Net increase (decrease) in cash and cash equivalents	140,132,634	(643,246)
Cash and cash equivalents, at beginning of period	72,033,930	41,897,144
Cash and cash equivalents, at end of period	$ 212,166,564	$ 41,253,898
Non-cash investing and financing activities:		
Transaction costs related to purchase of long-term equity investment in accrued expenses	$ 24,054	$ -
Stock option exercise receivables in prepaid expenses and other current assets	$ 14,468	$ -
Purchase of property and equipment in accounts payable	$ 3,005	$ 7,121

See accompanying notes to these unaudited condensed consolidated financial statements

NOTE 1 – NATURE OF OPERATIONS

Ovid Therapeutics Inc. (the "Company") was incorporated under the laws of the state of Delaware on April 1, 2014 and maintains its principal executive office in New York, New York. The Company commenced operations on April 1, 2014 (date of inception). The Company is a biopharmaceutical company focused exclusively on developing impactful medicines for patients and families living with rare neurological disorders.

Since its inception, the Company has devoted substantially all of its efforts to business development, research and development, recruiting management and technical staff, and raising capital. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development and regulatory success, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations.

Historically, the Company's major sources of cash have been composed of proceeds from various public and private offerings of its capital stock, revenue from collaboration agreements, option exercises and interest income. As of June 30, 2021, the Company had approximately $212.2 million in cash and cash equivalents. Since inception, the Company has generated $221.0 million in revenue, which comprises $25.0 million received pursuant to the Company's license and collaboration agreement (the "Angelini License Agreement") with Angelini Pharma Rare Diseases AG ("Angelini") and a one-time, upfront payment of $196.0 million received pursuant to the Company's royalty, license and termination agreement (the "Takeda License and Termination Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"). Historically, the Company has incurred recurring losses, has experienced negative operating cash flows and requires significant cash resources to execute its business plans. The Company has an accumulated deficit of $134.0 million as of June 30, 2021, working capital of $204.6 million and had cash provided by operating activities of $141.5 million for the six months ended June 30, 2021.

Although the Company recorded net income of $160.2 million during the six months ended June 30, 2021, the Company expects to incur losses in subsequent periods for at least the next several years and is highly dependent on its ability to find additional sources of funding through either equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or a combination of any such transactions. Management believes that the Company's existing cash and cash equivalents as of June 30, 2021 will be sufficient to fund its current operating plans through at least the next 12 months from the date of filing of the Company's Quarterly Report on Form 10-Q. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise capital as and when needed could have a negative impact on the Company's financial condition and ability to pursue its business strategy. The Company may be required to delay, reduce the scope of or eliminate research and development programs, or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain drug candidates that the Company might otherwise seek to develop or commercialize independently.

We have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our business. The extent to which the ongoing COVID-19 pandemic impacts our business, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are subject to other challenges and risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of our product candidates; delays or problems in the supply of our product candidates, loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; and the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2021. There have been no material changes to the significant accounting policies during the period ended June 30, 2021, except for items mentioned below.

(A) Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet at June 30, 2021, the condensed consolidated statements of operations, comprehensive (loss) income, cash flows, and stockholders' equity for the three and six months ended June 30, 2021 and 2020 are unaudited. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and following the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP are condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of its financial information. The results of operations for the three and six months ended June 30, 2021 and 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements as of and for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K.

(B) Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in conformity with GAAP and include the accounts of Ovid Therapeutics Inc. and its wholly owned subsidiary, Ovid Therapeutics Hong Kong Limited. All intercompany transactions and balances have been eliminated in consolidation.

(C) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ materially from those estimates.

(D) Long-Term Equity Investment

Long-term equity investment consists of an equity investment in a private company through preferred shares, which are not considered in-substance common stock, that is accounted for at cost, with adjustments for observable changes in prices or impairments, and is classified as long-term equity investment on our consolidated balance sheets with adjustments recognized in other (expenses) income, net on our consolidated statements of operations. The Company has determined that the equity investment does not have a readily determinable fair value and elected the measurement alternative. Therefore, the equity investment's carrying amount will be adjusted to fair value at the time of the next observable price change for the identical or similar investment of the same issuer or when an impairment is recognized. Each reporting period, the Company performs a qualitative assessment to evaluate whether the investment is impaired. The assessment includes a review of recent operating results and trends, recent sales/acquisitions of the investee securities, and other publicly available data. If the investment is impaired, the Company writes it down to its estimated fair value. As of June 30, 2021 and December 31, 2020, the equity investment had a carrying value of $1.6 million and zero, respectively.

(E) Fair Value of Financial Instruments

Financial Accounting Standards Board ("FASB") guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities. The Company's Level 1 assets consisted of money market funds and short-term investments totaling $210.6 million and $70.1 million as of June 30, 2021 and December 31, 2020, respectively.
- Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies. The Company had no Level 2 assets or liabilities as of June 30, 2021 and December 31, 2020.
- Level 3—Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. The Company had no Level 3 assets or liabilities as of June 30, 2021 and December 31, 2020.

The carrying amounts reported in the balance sheets for cash and cash equivalents, related party receivable, other current assets, accounts payable, accrued expenses, and current related party payable approximate their fair value based on the short-term maturity of these instruments.

(F) Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. In applying ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the promises and performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) it satisfies the performance obligations. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined using expected cost and comparable transactions. Revenue for performance obligations recognized over time is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure.

Non-refundable upfront fees allocated to licenses that are not contingent on any future performance and require no consequential continuing involvement by the Company, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. The Company defers recognition of upfront license fees if the performance obligations are not satisfied.

(G) Net (Loss) Income Per Share

Net (loss) income, basic per share is calculated by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding. The Company applies the two-class method to allocate earnings between common stock and participating securities.

Net (loss) income, diluted per share attributable to common stockholders adjusts the basic earnings per share attributable to common stockholders and the weighted-average number of shares of common stock outstanding for the potential dilutive impact of stock options, using the treasury-stock method.

(H) Recent Accounting Pronouncements

<u>Recent accounting standards which have been adopted</u>

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This new standard requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, including loans and trade and other receivables. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. The standard also amends the impairment model for available-for-sale debt securities and requires entities to determine whether all or a portion of the unrealized loss on an available-for-sale debt security is a credit loss. Under the new guidance, an entity recognizes an allowance for credit losses on available-for-sale debt securities as a contra-account to the amortized cost basis rather than as a direct reduction of the amortized cost basis of the investment, as was previously required. ASU 2016-13 is effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2019. As of June 30, 2021, the Company did not hold any debt securities with credit losses, nor does it have any trade receivables. The adoption of this standard effective January 1, 2020 did not have a material impact on the Company’s consolidated financial statements.

On August 29, 2018, the FASB issued ASU No. 2018-15, Intangibles – Goodwill and Other - Internal-Use Software (Subtopic 350-40) - which amends ASC 350-40 to address a customer’s accounting for implementation costs incurred in a cloud computing arrangement (“CCA”) that is a service contract. ASU No. 2018-15 aligns the accounting for costs incurred to implement a CCA that is a service arrangement with the guidance on capitalizing costs associated with developing or obtaining internal-use software. Specifically, the ASU amends ASC 350 to include in its scope implementation costs of a CCA that is a service contract and clarifies that a customer should apply ASC 350-40 to determine which implementation costs should be capitalized in a CCA that is considered a service contract. According to the standard the balance sheet line item for the presentation of capitalized implementation costs should be the same as that for the prepayment of fees related to the hosting arrangement and the manner in which an entity classifies the cash flows related to capitalized implementation costs should be the same as that in which it classifies the cash flows for the fees related to the hosting arrangement. ASU 2018-15 is effective for the Company for fiscal years beginning after December 15, 2019, including interim periods therein. Entities are permitted to apply either a retrospective or prospective transition approach to adopt the guidance. The adoption of this standard effective January 1, 2020 did not have a material impact on the Company’s consolidated financial statements and was adopted prospectively.

On November 5, 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808) - which amends ASC 808 to clarify when transactions between participants in a collaborative arrangement under ASC 808 are within the scope of the FASB’s new revenue standard, ASU 2014-09 (codified in ASC 606). The amendments require the application of ASC 606 existing guidance to determine the units of account that are distinct in a collaborative arrangement for purposes of identifying transactions with customers. If a unit of account within the collaborative arrangement is distinct and is with a customer, an entity shall apply the guidance in Topic 606 to that unit of account. In a transaction between collaborative participants, an entity is precluded by ASU 2018-18 from presenting a transaction together with “revenue from contracts with customers” unless the unit of account is within the scope of ASC 606 and the entity applies the guidance in ASC 606 to such unit of account. The amended guidance is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The retrospective adoption of this standard effective January 1, 2020 did not have a material impact on the Company’s consolidated financial statements.

In October 2020, the FASB issued ASU 2020-10, Codification Improvements, which updates various codification topics by clarifying or improving disclosure requirements. ASU 2020-10 is effective for annual and interim periods beginning after December 15, 2020. The Company early adopted ASU 2020-10 for the reporting period ending December 31, 2020. The adoption of this update did not have a material effect on the Company's consolidated financial statements.

NOTE 3 – CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

All short-term investments are classified as available-for-sale. The following tables summarize the fair value of cash, cash equivalents and short-term investments, as well as gross unrealized holding gains and losses as of June 30, 2021 and December 31, 2020:

	June 30, 2021			
	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
Cash	$ 1,520,708	$ -	$ -	$ 1,520,708
Money market funds	210,645,857	-	-	210,645,857
Total cash and cash equivalents	$ 212,166,565	$ -	$ -	$ 212,166,565

	December 31, 2020			
	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
Cash	$ 1,977,320	$ -	$ -	$ 1,977,320
Money market funds	70,056,610	-	-	70,056,610
Total cash and cash equivalents	$ 72,033,930	$ -	$ -	$ 72,033,930

The Company did not hold any securities that were in an unrealized loss position for more than 12 months as of June 30, 2021 and December 31, 2020.

There were no material realized gains or losses on available-for-sale securities during the three and six months ended June 30, 2021 and 2020.

NOTE 4 – PROPERTY AND EQUIPMENT AND INTANGIBLE ASSETS

Property and equipment is summarized as follows:

	June 30, 2021	December 31, 2020
Furniture and equipment	$ 335,477	$ 320,957
Less accumulated depreciation	(221,814)	(185,337)
Total property and equipment, net	$ 113,663	$ 135,620

Depreciation expense was $36,000 and $27,000 for the six months ended June 30, 2021 and 2020, respectively. Depreciation expense was $18,000 and $15,000 for the three months ended June 30, 2021 and 2020, respectively.

Intangible assets, net of accumulated amortization was $227,000 and $376,000 as of June 30, 2021 and December 31,2020, respectively, and are included in other assets. Amortization expense was $91,000 and $118,000 for the six months ended June 30, 2021 and 2020, respectively. Amortization expense was $35,000 and $63,000 for the three months ended June 30, 2021 and 2020, respectively.

NOTE 5 – ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30, 2021	December 31, 2020
Clinical trials accrual	$ 390,177	$ 4,175,497
Payroll and bonus accrual	3,308,874	3,845,441
Professional fees accrual	4,724,945	3,846,211
Other	1,956,267	165,536
Total	$ 10,380,263	$ 12,032,685

NOTE 6 – STOCKHOLDERS' EQUITY AND PREFERRED STOCK

The Company's capital structure consists of common stock and convertible preferred stock ("Preferred Stock"). Pursuant to the Company's amended and restated certificate of incorporation, as amended, the Company is authorized to issue up to 125,000,000 shares of common stock and 10,000,000 shares of Preferred Stock. The Company has designated 10,000 of the 10,000,000 authorized shares of Preferred Stock as non-voting Series A Convertible Preferred Stock ("Series A Preferred Stock").

The holders of common stock are entitled to one vote for each share held. The holders of common stock have no preemptive or other subscription rights, and there are no redemption or sinking fund provisions with respect to such shares. Subject to preferences that may apply to any outstanding series of Preferred Stock, holders of the common stock are entitled to receive ratably any dividends declared on a non-cumulative basis. Shares of Series A Preferred Stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock. The common stock is subordinate to all series of Preferred Stock with respect to rights upon liquidation, winding up and dissolution of the Company. The holders of common stock are entitled to liquidation proceeds after all liquidation preferences for the Preferred Stock are satisfied.

In November 2020, the Company entered into a sales agreement (the "2020 ATM agreement") with Cowen and Company, LLC ("Cowen"), under which the Company may offer and sell in "at the market offerings," from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $75.0 million through Cowen acting as sales agent. As of June 30, 2021, the Company has not sold any shares of its common stock under the 2020 ATM agreement.

There were 1,250 and 3,250 shares of Series A Preferred Stock outstanding as of June 30, 2021 and December 31, 2020, respectively. Each share of Series A Preferred Stock is convertible into 1,000 shares of common stock at any time at the holder's option. However, the holder will be prohibited, subject to certain exceptions, from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than, at the written election of the holder, either 9.99% or 14.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holder's election to any other number less than or equal to 19.99% upon 61 days' notice to the Company; provided, however, that effective 61 days after delivery of such notice, such beneficial ownership limitations shall not be applicable to any holder that beneficially owns either 10.0% or 15.0%, as applicable based on the holder's initial written election noted above, of the total number of shares of common stock issued and outstanding immediately prior to delivery of such notice. In the event of a liquidation, dissolution, or winding up of the Company, holders of Series A Preferred Stock will receive a payment equal to $0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of common stock.

In March 2021, certain of the Company's stockholders elected to convert an aggregate of 2,000 shares of Series A Preferred Stock owned by such holders into an aggregate of 2,000,000 shares of the Company's common stock.

In August 2020, the Company sold 6,250,000 shares of its common stock at a public offering price of $8.00 per share, for net proceeds of $46.7 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company, (the "August 2020 Offering").

In May 2020, entities affiliated with Biotechnology Value Fund, L.P. elected to convert an aggregate of 2,256 shares of Series A Preferred Stock owned by such holders into an aggregate of 2,256,000 shares of the Company's common stock.

Dividends

Holders of Series A preferred stock are entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends (other than dividends in the form of the issuance of common stock) actually paid on shares of common stock. No dividends on the common stock shall be declared and paid unless dividends on the Preferred Stock have been declared and paid. Through June 30, 2021, the Company has not declared any dividends.

NOTE 7 – STOCK-BASED COMPENSATION

The Company's Board of Directors adopted and the Company's stockholders approved the 2017 equity incentive plan ("2017 Plan"), which became effective immediately on May 4, 2017. The initial reserve of shares of common stock under the 2017 Plan was 3,052,059 shares. The 2017 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance-based stock awards, and other forms of stock-based awards. Additionally, the 2017 Plan provides for the grant of performance cash awards. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2017 Plan. Upon the adoption of the 2017 Plan, no further awards will be granted under the Company's prior plan. Pursuant to the terms of the 2017 Plan, on each January 1st, the plan limit shall be increased by the lesser of (x) 5% of the number of shares of common stock outstanding as of the immediately preceding December 31 and (y) such lesser number as the Board of Directors may determine in its discretion. On January 1, 2021 and January 1, 2020, respectively, an additional 3,287,158 and 2,735,516 shares were reserved for issuance under the 2017 Plan. As of June 30, 2021, there were 4,440,940 shares of the Company's common stock reserved and available for issuance under the 2017 Plan.

The Company's Board of Directors adopted, and the Company's stockholders approved the 2017 employee stock purchase plan (the "2017 ESPP"), which became effective immediately prior to the execution of the underwriting agreement related to the Company's initial public offering on May 4, 2017. The initial reserve of shares of common stock that may be issued under the 2017 ESPP was 279,069 shares. The ESPP allows employees to purchase common stock of the Company at a 15% discount to the market price on designated purchase dates. During the three months ended June 30, 2021 and 2020, no shares were purchased under the ESPP and the Company recorded expense of $38,000 and $52,000, respectively. The number of shares of common stock reserved for issuance under the 2017 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2018 and continuing through and including January 1, 2027, by the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (ii) 550,000 shares or (iii) such lesser number of shares determined by our Board. The Board acted prior to each of January 1, 2020 and January 1, 2021 to provide that there be no increase in the number of shares reserved for issuance under the 2017 ESPP on either such date. As of June 30, 2021, there were 519,296 shares of the Company's common stock reserved for issuance under the 2017 ESPP.

Unless specified otherwise in an individual option agreement, stock options granted under the prior plan and the 2017 Plan generally have a ten-year term and a four-year graded vesting period. The vesting requirement is generally conditioned upon the grantee's continued service with the Company during the vesting period. Once vested, all awards are exercisable from the date of grant until they expire. The option grants are non-transferable. Vested options generally remain exercisable for 90 days subsequent to the termination of the option holder's service with the Company. In the event of option holder's death or disability while employed by or providing service to the Company, the exercisable period extends to 12 months.

Performance-based option awards generally have similar terms, with vesting commencing on the date the performance condition is achieved and expire in accordance with the specific terms of the agreement. At June 30, 2021, there were 50,000 performance-based options outstanding and unvested that include options to be granted upon the achievement of certain research and development milestones.

The fair value of options granted during the six months ended June 30, 2021 and 2020 was estimated using the Black-Scholes option valuation model. The inputs for the Black-Scholes option valuation model require management's significant assumptions and are detailed in the table below. The risk-free interest rates were based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life was based on the simplified method in accordance with the SEC Staff Accounting Bulletin No. Topic 14D. The expected volatility was estimated based on historical volatility information of peer companies that are publicly available.

All assumptions used to calculate the grant date fair value of nonemployee options are generally consistent with the assumptions used for options granted to employees. In the event the Company terminates any of its consulting agreements, the unvested options underlying the agreements would also be canceled.

The Company granted 170,000 and 10,000 stock options to nonemployee consultants for services rendered during the six months ended June 30, 2021 and 2020, respectively. There were 191,875 and 144,375 unvested nonemployee options outstanding as of June 30, 2021 and 2020, respectively. Total expense recognized related to the nonemployee stock options for the three months ended June 30, 2021 and 2020, was $55,000 and $35,000, respectively. Total expense recognized related to the nonemployee stock options for the six months ended June 30, 2021 and 2020 was $91,000 and $71,000, respectively. Total unrecognized compensation expenses related to the nonemployee stock options was $519,000 as of June 30, 2021. The Company did not recognize any expense for nonemployee performance-based option awards during the six months ended June 30, 2021 and 2020.

The Company granted 836,600 and 1,116,860 stock options to employees during the six months ended June 30, 2021 and 2020 respectively. There were 4,749,550 and 4,240,051 unvested employee options outstanding as of June 30, 2021, and 2020, respectively. Total expense recognized related to the employee stock options for the three months ended June 30, 2021 and 2020 was $1.2 million and $1.5 million, respectively. Total expense recognized related to the employee stock options for the six months ended June 30, 2021 and 2020 was $2.4 million and $2.8 million, respectively. Total unrecognized compensation expense related to employee stock options was $10.8 million as of June 30, 2021. During the six months ended June 30, 2021 and 2020, the Company recognized zero and $277,000 respectively, in expenses for employee performance-based option awards.

The Company's stock-based compensation expense was recognized in operating expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Research and development	$ 430,638	$ 514,761	$ 888,673	$ 1,078,899
General and administrative	826,707	1,040,571	1,688,673	1,779,364
Total	$ 1,257,345	$ 1,555,332	$ 2,577,346	$ 2,858,263

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Stock options	$ 1,219,496	$ 1,503,491	$ 2,520,710	$ 2,786,662
Employee Stock Purchase Plan	37,849	51,841	56,636	71,601
Total	$ 1,257,345	$ 1,555,332	$ 2,577,346	$ 2,858,263

The fair value of employee options granted during the three and six months ended June 30, 2021 and 2020 was estimated by utilizing the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
Volatility	86.13 %	81.35 %	81.72 %	78.41 %
Expected term in years	5.91	5.60	6.04	5.96
Dividend rate	0.00 %	0.00 %	0.00 %	0.00 %
Risk-free interest rate	0.99 %	0.00 %	0.73 %	0.01 %
Fair value of option on grant date	$ 3.09	$ 3.45	$ 2.39	$ 2.73

The fair value of nonemployee options granted during the three and six months ended June 30, 2021 and 2020 was estimated by utilizing the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
Volatility	80.43 %	-	80.43 %	74.86 %
Expected term in years	6.23	-	6.23	5.38
Dividend rate	0.00 %	-	0.00 %	0.00 %
Risk-free interest rate	1.03 %	-	1.03 %	2.27 %
Fair value of option on measurement date	$ 2.49	-	$ 2.49	$ 1.21

The following table summarizes the number of options outstanding and the weighted average exercise price:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding December 31, 2020	10,403,420	$ 5.26	7.59	$ 652,438
Granted	1,006,600	3.47	9.01	
Exercised	(56,521)	2.68		$ 62,419
Forfeited or expired	(388,610)	3.60		
Options outstanding June 30, 2021	10,964,889	$ 5.17	6.75	$ 5,669,446
Vested and exercisable at June 30, 2021	6,023,464	$ 6.31	5.11	$ 2,450,587

At June 30, 2021 there was approximately $11.3 million of unamortized share–based compensation expense related to employee and nonemployee grants, which is expected to be recognized over a remaining average vesting period of 2.85 years.

NOTE 8 – INCOME TAXES

The Company’s interim income tax provision consists of U.S. federal and state income taxes based on the estimated annual effective tax rate that the Company expects for the full year together with the tax effect of discrete items. Each quarter the Company updates its estimate of the annual effective tax rate and records cumulative adjustments as necessary. As of June 30, 2021, the estimated annual effective tax rate for 2021, exclusive of discrete items, is approximately 1.22% of projected pre-tax income. The estimated annual tax expense consists of a provision for federal and state income taxes.

For the three months ended June 30, 2021, due to statutory limitations on our ability to utilize research and development credits and net operating losses to offset year to date taxable income, the Company recorded a tax expense of $1.5 million on a pre-tax loss of $14.3 million.

For the six months ended June 30, 2021, the Company recorded a tax expense of $2.0 million on a pre-tax income of $162.2 million.

For the three and six months ended June 30, 2020, the Company did not record a U.S. federal or state income tax provision due to current and historical net operating losses.

Under Section 382 of the Internal Revenue Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. On August 10, 2015 and February 22, 2019 the Company experienced an ownership change. Accordingly, our ability to utilize NOL and tax credit carryforwards attributable to periods prior to February 22, 2019 is subject to substantial limitations. Additionally, the net operating losses incurred in future years will be reduced by the recognized built-in loss of approximately $5 million.

In assessing the realizability of deferred tax assets, the Company's management evaluates whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income in those periods in which temporary differences become deductible and/or net operating losses can be utilized. Management assesses all positive and negative evidence when determining the amount of the net deferred tax assets that are more likely than not to be realized. This evidence includes, but is not limited to, prior earnings history, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Significant weight is given to positive and negative evidence that is objectively verifiable. Based on these factors, including cumulative losses in recent years, the Company continues to maintain a full valuation allowance against its net deferred tax assets as of June 30, 2021.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

License Agreements

In December 2016, the Company entered into a license agreement with Northwestern University ("Northwestern"), pursuant to which Northwestern granted the Company an exclusive, worldwide license to patent rights in certain inventions (the "Northwestern Patent Rights") which relate to a specific compound and related methods of use for such compound, along with certain Know-How related to the practice of the inventions claimed in the Northwestern Patents.

Under the Northwestern agreement, the Company was granted exclusive rights to research, develop, manufacture and commercialize products utilizing the Northwestern Patent Rights for all uses. The Company has agreed that it will not use the Northwestern Patent Rights to develop any products for the treatment of cancer, but Northwestern may not grant rights in the technology to others for use in cancer. The Company also has an option, exercisable during the term of the agreement to an exclusive license under certain intellectual property rights covering novel compounds with the same or similar mechanism of action as the primary compound that is the subject of the license agreement. Northwestern has retained the right, on behalf of itself and other non-profit institutions, to use the Northwestern Patent Rights and practice the inventions claimed therein for educational and research purposes and to publish information about the inventions covered by the Northwestern Patent Rights.

Upon entry into the Northwestern agreement, the Company paid an upfront non-creditable one-time license issuance fee of $75,000, and is required to pay an annual license maintenance fee of $20,000, which will be creditable against any royalties payable to Northwestern following first commercial sale of licensed products under the agreement. The Company is responsible for all ongoing costs of filing, prosecuting and maintaining the Northwestern Patents, but also has the right to control such activities using its own patent counsel. In consideration for the rights granted to the Company under the Northwestern agreement, the Company is required to pay to Northwestern up to an aggregate of $5.3 million upon the achievement of certain development and regulatory milestones for the first product covered by the Northwestern Patents, and, upon commercialization of any such products, will be required to pay to Northwestern a tiered royalty on net sales of such products by the Company, its affiliates or sublicensees, at percentages in the low to mid-single-digits, subject to standard reductions and offsets. The Company's royalty obligations continue on a product-by-product and country-by-country basis until the later of the expiration of the last-to-expire valid claim in a licensed patent covering the applicable product in such country and 10 years following the first commercial sale of such product in such country. If the Company sublicenses a Northwestern Patent Right, it will be obligated to pay to Northwestern a specified percentage of sublicense revenue received by the Company, ranging from the high single digits to the low teens.

The Northwestern agreement requires that the Company use commercially reasonable efforts to develop and commercialize at least one product that is covered by the Northwestern Patent Rights.

Unless earlier terminated, the Northwestern agreement will remain in force until the expiration of the Company's payment obligations thereunder. The Company has the right to terminate the agreement for any reason upon prior written notice or for an uncured material breach by Northwestern. Northwestern may terminate the agreement for the Company's uncured material breach or insolvency.

As of June 30, 2021, none of these contingent payments were considered probable.

Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred. The Company is not currently involved in any legal matters arising in the normal course of business.

Under the terms of their respective employment agreements, certain of our executive officers are eligible to receive severance payments and benefits upon a termination without “cause” or due to “permanent disability,” or upon “resignation for good reason,” contingent upon the executive officer’s delivery to the Company of a satisfactory release of claims, and subject to the executive officer’s compliance with non-competition and non-solicitation restrictive covenants.

NOTE 10 – COLLABORATION AGREEMENTS

Angelini Collaboration

On July 9, 2020, the Company entered into the Angelini License Agreement with Angelini, pursuant to which the Company granted to Angelini exclusive rights to develop and commercialize OV101, a selective agonist of the $GABA_A$ receptor, for the treatment of Angelman syndrome in the European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey. On March 29, 2021, the Company received a notice of termination of the Angelini License Agreement. Subsequently, Angelini and the Company mutually agreed to waive the six month termination notice provisions and the Angelini License Agreement terminated effective March 31, 2021. The Company has been released from its performance obligations and will not be entitled to any future milestone payments under the Angelini License Agreement.

The Company evaluated the Angelini License Agreement to determine whether it is a collaborative arrangement for purposes of ASC 808. The Company concluded that because Angelini is not the ultimate decision maker or the legal owner of the license, Angelini is not considered an active participant and therefore the Angelini License Agreement is outside of the scope of ASC 808. The Company concluded that Angelini is a customer with regard to the combined license and research and development activities and as such the Angelini License Agreement should be evaluated under ASC 606.

The Company identified the following material promises under the Angelini License Agreement: (1) licensing of intellectual property with respect to OV101; (2) completion of certain ongoing trials; (3) transfer of a specified amount of compound and related information; (4) potential for funding 35% of the cost for Angelini future trials limited to $7.0 million; and (5) completion of the manufacturing process technology transfer.

The Company determined that the $7.0 million represented a potential payment to a customer and was deferred. The transfer of compound and related information is considered a contingent milestone payment that will be recognized upon acceptance by Angelini of the milestone. The Company further determined that the license and the completion of ongoing trials are distinct from each other, as each has value without the other. As such, for the purposes of ASC 606, the Company determined that these two material promises, represent distinct performance obligations.

The Company determined the transaction price is equal to the upfront fee of $20.0 million. The transaction price was allocated based on the standalone selling price of the license and the ongoing trials.

Pursuant to the Angelini License Agreement and during the year ended December 31, 2020, Angelini made an upfront payment to the Company of $20.0 million. Upon the transfer of the specified amount of compound and related information and acceptance by Angelini, Angelini paid the Company an additional $5.0 million. This performance obligation was determined to be variable consideration which was constrained and not considered part of the upfront transaction price allocation.

During the six months ended June 30, 2021 and effective upon termination of the Angelini License Agreement, the Company recognized $12.4 million of revenue consisting of $5.4 million of license revenue related to ongoing trials and the $7.0 million related to the potential 35% funding of the cost for Angelini future trials.

Takeda Collaboration

On January 6, 2017, the Company entered into a license and collaboration with Takeda, to jointly develop and commercialize the compound TAK-935, under which the Company licensed from Takeda certain exclusive rights to develop and commercialize soticlestat in certain territories.

In March 2021, the Company entered into the Takeda License and Termination Agreement with Takeda, pursuant to which Takeda secured rights to the Company’s 50% global share in soticlestat, which the Company had originally licensed from Takeda, and the Company granted to Takeda an exclusive worldwide license under the Company’s relevant intellectual property rights to develop and commercialize the investigational medicine soticlestat for the treatment of developmental and epileptic encephalopathies, including Dravet syndrome and Lennox-Gastaut syndrome.

Under the Takeda License and Termination Agreement, all rights in soticlestat are owned by Takeda or exclusively licensed to Takeda by the Company. Takeda assumed all responsibility for, and costs of, both development and commercialization of soticlestat, and the Company will no longer have any financial obligation to Takeda under the original collaboration agreement, including for milestone payments or any future development and commercialization costs. On March 29, 2021 upon the closing of the Takeda License and Termination Agreement, the Company received an upfront payment of $196.0 million and, if soticlestat is successfully developed, will be eligible to receive up to an additional $660.0 million upon achieving development, regulatory and sales milestones. In addition, the Company will be entitled to receive tiered royalties beginning in the low double-digits, and up to 20% on sales of soticlestat if it achieves regulatory approval. Royalties will be payable on a country-by-country and product-by-product basis for any all indications that soticlestat is approved in and sold during the period beginning on the date of the first commercial sale of such product in such country and ending on the later to occur of the expiration of patent rights covering the product in such country and a specified anniversary of such first commercial sale.

The Company identified the following material promises under the Takeda License and Termination Agreement: (1) no later than the second business day prior to the closing of the Takeda License and Termination Agreement (the "Closing Date"), the Company and Takeda were required to agree on an estimate of the development expenses that accrued, or would accrue, under the original collaboration agreement as of March 31, 2021; (2) on the Closing Date, the Company was required to (i) provide and transfer to Takeda the materials, information and data relating to the OV935 program, including clinical trial data and results, as further set forth in the Takeda License and Termination Agreement, (ii) assign to Takeda certain agreements applicable to the OV935 program, and (iii) assign to Takeda all of its right, title and interest in, to and under all intellectual property rights developed or created pursuant to the original collaboration agreement and owned jointly by the Company and Takeda as of the Closing Date; (3) within 45 days after March 31, 2021, the Company and Takeda are required to provide a written report to the finance officer designated by the other party setting forth a final total of the development expenses that accrued as of March 31, 2021 and, within 10 business days after receipt of such report, the finance officers shall agree on whether a net settlement payment is due from Takeda to the Company or from the Company to Takeda; and (4) within 75 days after the Closing Date, to the extent not provided on the Closing Date, Ovid shall provide to Takeda (i) any materials, information and data relating to the OV935 program, including clinical trial data and results, as further set forth in the Takeda License and Termination Agreement, (ii) other documents (including all expired agreements and related data developed thereunder) to the extent relating to the OV935 program that are necessary for the exploitation, development, commercialization and manufacture of OV935, as further set forth in the Takeda License and Termination Agreement and (iii) any tangible embodiments of the intellectual property rights controlled by Ovid that are reasonably necessary for, used in or held for use in Takeda's exploitation of the OV935 program.

The Company determined the transaction price is equal to the upfront fee of $196.0 million and is associated with all four performance obligations identified above. It is noted that the incremental effort associated with performance obligations three and four is negligible and not material in the context of the Takeda License and Termination Agreement since all of the information is related to the collaboration period for which the Company already has the information readily available. Therefore, since they are not material in the context of the Takeda License and Termination Agreement, the full upfront fee was allocated to the two performance obligations satisfied at closing.

During the six months ended June 30, 2021, the Company recognized a credit in research and development expenses of $2.6 million and $0.1 million in general and administrative expenses reimbursed to the Company from Takeda. During the six months ended June 30, 2020, the Company recognized a credit in research and development expenses of $1.1 million representing expenses to be reimbursed to the Company from Takeda.

NOTE 11 – RELATED PARTY TRANSACTIONS

In March 2021, the Company entered into the Takeda License and Termination Agreement with Takeda. For a description of the Takeda License and Termination Agreement, see Note 10.

In May 2020, entities affiliated with Biotechnology Value Fund, L.P. elected to convert an aggregate of 2,256 shares of Series A Preferred Stock owned by such holders into an aggregate of 2,256,000 shares of the Company's common stock.

In August 2020, the Company issued and sold an aggregate of 1,250,000 shares of common stock to entities affiliated with Biotechnology Value Fund, L.P., an existing stockholder for aggregate gross proceeds of $10.0 million.

NOTE 12 – NET (LOSS) INCOME PER SHARE

Basic net (loss) income per share is calculated based upon the weighted-average number of common shares outstanding during the period, excluding outstanding stock options that have been issued but are not yet vested. Diluted net (loss) income per share is calculated based upon the weighted-average number of common shares outstanding during the period plus the dilutive impact of weighted-average common equivalent shares outstanding during the period. The potentially dilutive shares of common stock resulting from the assumed exercise of outstanding stock options were determined under the treasury stock method.

The Basic and diluted net (loss) income per common share is presented in conformity with the two-class method required for participating securities and multiple classes of shares. The Company considers the preferred shares to be participating securities.

For any period in which the Company records net income, undistributed earnings allocated to the participating securities are subtracted from net income in determining net income attributable to common stockholders. The undistributed earnings have been allocated based on the participation rights of preferred shares and common shares as if the earnings for the year have been distributed. For periods in which the Company recognizes a net loss, undistributed losses are allocated only to common shares as the participating securities do not contractually participate in the Company's losses. Basic net (loss) income per share is computed by dividing the net (loss) income attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Participating securities are excluded from basic weighted-average common shares outstanding.

The following table summarizes the calculation of basic and diluted net (loss) income per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net (loss) income	$ (15,788,427)	$ (22,551,196)	$ 160,218,880	$ (42,581,286)
Net income attributable to participating securities	-	-	(4,824,587)	-
Net (loss) income attributable to common stockholders	$ (15,788,427)	$ (22,551,196)	$ 155,394,293	$ (42,581,286)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net (loss) income attributable to common stockholders	$ (15,788,427)	$ (22,551,196)	$ 155,394,293	$ (42,581,286)
Weighted-average common shares outstanding, basic	67,818,366	55,607,110	66,953,431	55,161,360
Dilutive effect of outstanding stock options	-	-	612,330	-
Weighted-average common shares outstanding, diluted	67,818,366	55,607,110	67,565,761	55,161,360
Net (loss) income per share, basic	$ (0.23)	$ (0.41)	$ 2.32	$ (0.77)
Net (loss) income per share, diluted	$ (0.23)	$ (0.41)	$ 2.30	$ (0.77)

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as they would be anti-dilutive:

	June 30,	
	2021	2020
Stock options to purchase common stock	10,352,559	8,225,320
Series A convertible preferred stock	-	5,506

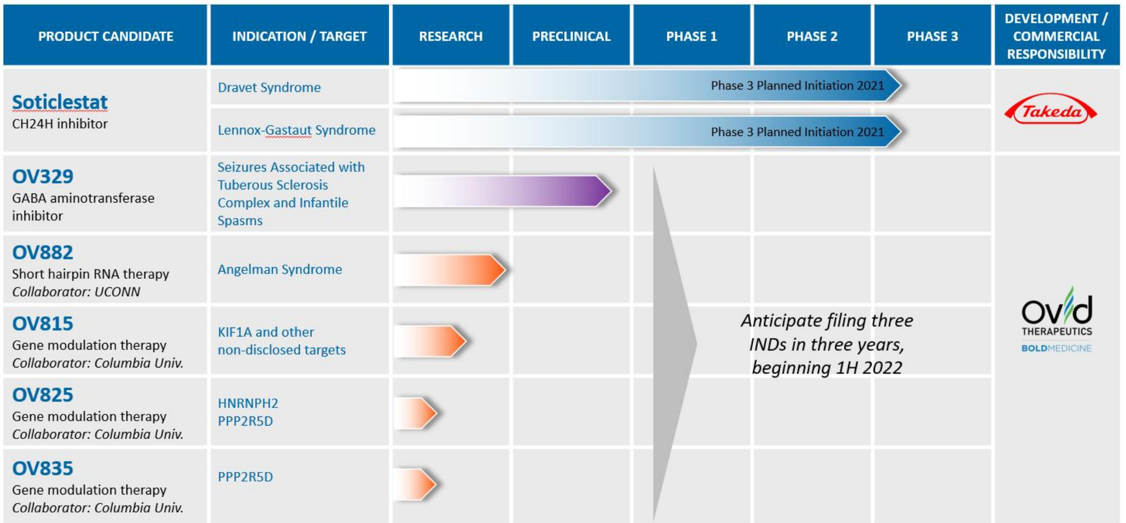
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited condensed consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission ("SEC") on March 15, 2021. In addition to historical financial information, the following discussion contains forward-looking statements based upon our current plans, expectations and beliefs that involve risks, uncertainties and assumptions. Our actual results may differ materially from those described in or implied by these forward-looking statements because of many factors, including those set forth under the section titled "Risk Factors" in Part II, Item 1A. Such factors may be amplified by the ongoing COVID-19 pandemic and its potential impact on our business and the global economy.

Overview

We are a biopharmaceutical company focused on developing impactful medicines for patients and families living with rare neurological disorders. We believe these disorders represent an attractive area for drug development as the understanding of the underlying biology has grown meaningfully over the last few years and today represent a substantial opportunity medically and commercially. Based on the rapid increase in scientific understanding of the role of genetics and key biological pathways relevant to diseases of the brain, we aim to identify, discover and develop novel compounds for the treatment of rare neurological disorders. We have built a deep knowledge of such diseases, how to treat them and how to develop the clinically meaningful endpoints required for development of a compound in these disorders. As a result of this knowledge, we have developed a pipeline of first-in-class compounds and programs and have demonstrated our model by progressing multiple compounds through to late-stage development. We continue to execute on our strategy to build this pipeline by discovering in-licensing and collaborating with leading biopharmaceutical companies and academic institutions.

Our latest pipeline includes two late-stage programs and several earlier-stage programs.



Since our inception in April 2014, we have devoted substantially all of our efforts to organizing and planning our business, building our management and technical team, acquiring operating assets and raising capital.

During the six months ended June 30, 2021, we generated $208.4 million of license and other revenue through our Collaboration and License Agreement ("the Angelini License Agreement") with Angelini Pharma Rare Diseases AG ("Angelini") and our Royalty, License and Termination agreement (the "Takeda License and Termination Agreement") with Takeda Pharmaceutical Company Limited ("Takeda") and have otherwise funded our business primarily through the sale of our capital stock. Through June 30, 2021, we have raised net proceeds of $275.4 million from the sale of our convertible preferred stock and our common stock. As of June 30, 2021, we had $212.2 million in cash and cash equivalents. We recorded net income of $160.2 million for the six months ended June 30, 2021 and net losses $42.6 million for the six months ended June 30, 2020. As of June 30, 2021, we had an accumulated deficit of $134.0 million.

Although we recorded net income of $160.2 million during the six months ended June 30, 2021, we expect to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned preclinical studies and clinical trials and expenditures on our other research and development and commercial development activities. We expect our expenses will increase substantially over time as we:

- continue the ongoing and planned preclinical and clinical development of our drug candidates;
- build a portfolio of drug candidates through the development, acquisition or in-license of drugs, drug candidates or technologies;
- pursue collaborations and other arrangements with other leading biopharmaceutical companies and academic institutions;

- initiate preclinical studies and clinical trials for any additional drug candidates that we may pursue in the future;
- seek marketing approvals for our current and future drug candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any drug candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- implement operational, financial and management systems; and
- attract, hire and retain additional administrative, clinical, regulatory, manufacturing, commercial and scientific personnel.

Recent Developments

Discontinuation of Development of OV101

In April 2021, we announced that we will discontinue development of OV101 (gaboxadol), a delta (δ)-selective GABAA receptor agonist, in Angelman syndrome, and that we do not plan to initiate further clinical studies of OV101 in Fragile X syndrome. As a result, we intend to reprioritize our resources to focus on the development of our earlier-stage pipeline, including OV882, a short hairpin RNA therapy targeting UBE3A gene expression in neurons, as a potential treatment for Angelman syndrome.

COVID-19 Update

We have implemented business continuity plans designed to address and mitigate the impact of the ongoing COVID-19 pandemic on our employees and our business. We continue to operate normally with all of our employees continuing to work productively at home and abiding by new or re-imposed travel restrictions issued by federal, state and local governments. Our current plans to return to the office remain fluid as the COVID-19 pandemic persists and federal, state and local guidelines, rules and regulations continue to evolve.

Financial Operations Overview

Revenue

Since inception, we recognized $25.0 million of revenue under the Angelini License Agreement and $196.0 million in connection with the Takeda License and Termination Agreement. We have not generated any revenue from commercial drug sales and do not expect to generate any revenue from commercial drug sales unless or until we obtain regulatory approval of and commercialize one or more of our current or future drug candidates. In the future, we may generate revenue from a combination of research and development payments, license fees and other upfront or milestone payments.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our product discovery efforts and the development of our product candidates, which include, among other things:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- fees paid to consultants for services directly related to our drug development and regulatory effort;
- expenses incurred under agreements with contract research organizations, as well as contract manufacturing organizations and consultants that conduct preclinical studies and clinical trials;
- costs associated with preclinical activities and development activities;
- costs associated with technology and intellectual property licenses;
- milestone payments and other costs under licensing agreements; and
- depreciation expense for assets used in research and development activities.

Costs incurred in connection with research and development activities are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or other information provided to us by our vendors.

Research and development activities are and will continue to be central to our business model. We expect our research and development expenses to increase over the next several years as we advance our current and future drug candidates through preclinical studies and clinical trials. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. It is difficult to determine with certainty the duration and costs of any preclinical study or clinical trial that we may conduct. The duration, costs and timing of clinical trial programs and development of our current and future drug candidates will depend on a variety of factors that include, but are not limited to, the following:

- number of clinical trials required for approval and any requirement for extension trials;
- per patient trial costs;

- number of patients who participate in the clinical trials;
- number of sites included in the clinical trials;
- countries in which the clinical trial is conducted;
- length of time required to enroll eligible patients;
- number of doses that patients receive;
- drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- duration of patient follow-up; and
- efficacy and safety profile of the drug candidate.

In addition, the probability of success for any of our current or future drug candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each drug candidate, as well as an assessment of each drug candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and stock-based compensation expense, related to our executive, finance, business development and support functions. Other general and administrative expenses include costs associated with operating as a public company described below, travel expenses, conferences, professional fees for auditing, tax and legal services and facility-related costs.

Other (Expenses) Income, Net

Other (expense) income primarily consists of interest income earned on our cash and cash equivalents maintained in money market funds and prior short-term investments that were maintained in U.S. treasury notes.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table summarizes the results of our operations for the periods indicated:

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Change
		(in thousands)	
Revenue:			
License and other revenue	$ -	$ -	$ -
License revenue - related party	-	-	-
Total revenue	-	-	-
Operating expenses:			
Research and development	$ 7,684	$ 16,033	$ (8,349)
General and administrative	6,629	7,109	(480)
Total operating expenses	14,313	23,142	(8,829)
(Loss) from operations	(14,313)	(23,142)	8,829
Other (expense) income, net	(3)	590	(593)
(Loss) before provision for income taxes	(14,315)	(22,552)	8,237
Provision for income taxes	1,473	-	1,473
Net loss	$ (15,788)	$ (22,552)	$ 6,764

Revenue

No revenue was generated during the three months ended June 30, 2021 and 2020.

Research and Development Expenses

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Change
		(in thousands)	
Preclinical and development expenses	$ 3,006	$ 11,497	$ (8,491)
Payroll and payroll-related expenses	3,829	3,664	165
Other expenses	849	872	(23)
Total research and development	$ 7,684	$ 16,033	$ (8,349)

During the three months ended June 30, 2021, total research and development expenses were $7.7 million compared to $16.0 million for the three months ended June 30, 2020. The decrease of $8.3 million was primarily due to decreased preclinical and development expenses related to the decision to discontinue the clinical study of OV101 in Angelman syndrome and Fragile X syndrome and the termination of the Takeda collaboration agreement for OV935.

General and Administrative Expenses

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Change
		(in thousands)	
Payroll and payroll-related expenses	$ 3,640	$ 2,937	$ 703
Legal and professional fees	2,063	3,169	(1,106)
General office expenses	926	1,003	(77)
Total general and administrative	$ 6,629	$ 7,109	$ (480)

General and administrative expenses were $6.6 million for the three months ended June 30, 2021 compared to $7.1 million for the three months ended June 30, 2020. The decrease of $0.5 million was primarily due to a decrease in legal and professional fees of $1.1 million offset by an increase in payroll and payroll-related expenses of $0.7 million.

Provision for income taxes

The provision for income taxes was $1.5 million for the three months ended June 30, 2021. There was no provision for income taxes for the three months ended June 30, 2020. The increase was due to the revenue generated as a result of the $196.0 million of revenue recorded in connection with the Takeda License and Termination Agreement.

Other (Expense) Income, net

We incurred nominal other expenses for the three months ended June 30, 2021. Other income was $0.6 million for the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes the results of our operations for the periods indicated:

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Change
		(in thousands)	
Revenue:			
License and other revenue	$ 12,383	$ -	$ 12,383
License revenue - related party	196,000	-	196,000
Total revenue	208,383	-	208,383
Operating Expenses:			
Research and development	$ 23,933	$ 30,658	$ (6,725)
General and administrative	22,206	12,778	9,428
Total operating expenses	46,138	43,436	2,702
Income (loss) from operations	162,244	(43,436)	205,680
Other (expense) income, net	(52)	855	(907)
Income (loss) before provision for income taxes	162,192	(42,581)	204,773
Provision for income taxes	1,973	-	1,973
Net income (loss)	$ 160,219	$ (42,581)	$ 206,747

Revenue

Total revenue was $208.4 million for the six months ended June 30, 2021. We did not generate any revenue during the six months ended June 30, 2020. The increase in total revenue was due to $12.4 million of revenue recorded in connection with the Angelini License Agreement and $196.0 million of revenue recorded in connection with the Takeda License and Termination Agreement.

Research and Development Expenses

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Change
		(in thousands)	
Preclinical and development expense	$ 14,141	$ 21,249	$ (7,108)
Payroll and payroll-related expenses	7,746	7,586	160
Other expenses	2,045	1,823	222
Total research and development	$ 23,933	$ 30,658	$ (6,725)

Research and development expenses were $23.9 million for the six months ended June 30, 2021 compared to $30.7 million for the six months ended June 30, 2020. The decrease of $6.7 million was primarily due to decreased preclinical and development expenses related to the decision to discontinue the clinical study of OV101 in Angelman syndrome and Fragile X syndrome and the termination of the Takeda collaboration agreement for OV935.

General and Administrative Expenses

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020	Change
		(in thousands)	
Payroll and payroll-related expenses	$ 7,425	$ 5,717	$ 1,708
Legal and professional fees	12,816	5,101	7,715
General office expenses	1,965	1,960	5
Total general and administrative	$ 22,206	$ 12,778	$ 9,428

General and administrative expenses were $22.2 million for the six months ended June 30, 2021 compared to $12.8 million for the six months ended June 30, 2020. The increase of $9.4 million was primarily due to an increase in legal and professional fees of $7.7 million, which includes $8.2 million of one-time fees related to the Takeda License and Termination Agreement, an increase in payroll and payroll-related expenses of $1.7 million.

Provision for income taxes

The provision for income taxes was $2.0 million for the six months ended June 30, 2021. There was no provision for income taxes for the six months ended June 30, 2020. The increase was due to the revenue generated as a result of the $196.0 million of revenue recorded in connection with the Takeda License and Termination Agreement.

Other (Expense) Income, net

We incurred nominal other expenses for the six months ended June 30, 2021. Other income was $0.9 million for the six months ended June 30, 2020.

Liquidity and Capital Resources

Overview

As of June 30, 2021, we had total cash and cash equivalents of $212.2 million as compared to $72.0 million of cash and cash equivalents as of December 31, 2020. The $140.2 million increase in total cash and cash equivalents was due primarily to the one-time upfront payment of $196.0 million received as part of the Takeda License and Termination Agreement, partially offset by operating expenses of $46.1 million for the six months ended June 30, 2021.

In November 2020, we filed a shelf registration statement on Form S-3 (Registration No. 333-250054) that allows us to sell up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities and/or warrants (the “S-3 Registration Statement”), which includes a prospectus covering the issuance and sale of up to $75.0 million of common stock pursuant to an at-the-market (“ATM”) offering program. As of June 30, 2021, we had $250.0 million available under our S-3 Registration Statement, including $75.0 million available pursuant to our ATM program.

Similar to other development stage biotechnology companies, we have generated limited revenue, which has been through the Angelini License Agreement. With the exception of the three months ended March 31, 2021, when we received the one-time upfront payment of $196.0 million as part of the Takeda License and Termination Agreement, we have incurred losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the next several years. We recorded net income of approximately $160.2 million and net losses of $42.6 million for the six months ended June 30, 2021 and 2020, respectively. We expect to incur net losses in subsequent periods. As of June 30, 2021, we had an accumulated deficit of $134.0 million and working capital of $204.6 million.

We believe that our existing cash and cash equivalents as of June 30, 2021 will be sufficient to fund our current operating plans through at least the next 12 months from the date of the filing of this Quarterly Report on Form 10-Q.

We plan to finance our cash needs through either equity offerings, debt financings, collaborations, strategic alliances, or licensing agreements or a combination of any such transactions. To the extent that we raise additional capital through future equity offerings or debt financings, ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. There can be no assurance that such financings will be obtained on terms acceptable to us, if at all. The ongoing COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. If we raise additional funds through collaborations, strategic alliances or licensing agreements with third parties for one or more of our current or future drug candidates, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 141,482	$ (35,605)
Investing activities	(1,595)	34,777
Financing activities	246	185
Net increase (decrease) in cash and cash equivalents	$ 140,133	$ (643)

Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities was $141.5 million for the six months ended June 30, 2021, which consisted of net income of $160.2 million offset by a net of $18.7 million of non-cash charges and indirect cash changes, primarily related to $2.6 million of stock-based compensation expense and $12.4 million of deferred revenue. Net cash used in operating activities was $35.6 million for the six months ended June 30, 2020, which consisted of a net loss of $42.6 million offset by a net of $7.0 million of non-cash charges and indirect cash changes, primarily related to $2.9 million of stock-based compensation expense.

Net Cash (Used In) Provided by Investing Activities

Net cash used in investing activities was $1.6 million for the six months ended June 30, 2021, compared to $34.8 million of net cash provided by investing activities for the six months ended June 30, 2020. Net cash used in investing activities during the six months ended June 30, 2021 consisted of purchases of equity investments compared to the cash provided by maturities of short-term investments during the six months ended June 30, 2020.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $0.2 million for the six months ended June 30, 2021 primarily due to purchases of shares under the 2017 employee stock purchase plan and the exercise of options. Net cash provided by financing activities of $0.2 million for the six months ended June 30, 2020 was primarily due to proceeds from exercise of options and purchases of shares under the 2017 employee stock purchase plan, offset by expenses related to our ATM program.

Contractual Obligations and Commitments

As of June 30, 2021, we had no material contractual obligations or commitments. We had no long-term debt or capital leases and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase order basis. We excluded any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under license agreements we have entered into with various entities pursuant to which we have in-licensed certain intellectual property as contractual obligations or commitments, including our agreement with Northwestern. Pursuant to this license agreement, we have agreed to make milestone payments up to an aggregate of $5.3 million upon the achievement of certain development, regulatory and sales milestones. We excluded these contingent payments given that the timing, probability, and amount, if any, of such payments cannot be reasonably estimated at this time.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2022. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- reduced disclosure about our executive compensation arrangements;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of reduced reporting requirements in this Quarterly Report on Form 10-Q and may continue to do so until such time that we are no longer an emerging growth company. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (b) December 31, 2022, the last day of the fiscal year following the fifth anniversary of the completion of the our IPO, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In addition, we are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the revenue and expenses incurred during the reported periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on 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 apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

During the six months ended June 30, 2021, there were no material changes to our critical accounting policies as reported for the year ended December 31, 2020 as part of our Annual Report on Form 10-K, which was filed with the SEC on March 15, 2021. In addition, see Note 2 of our Condensed Financial Statements under the heading "Recent Accounting Pronouncements" for new accounting pronouncements or changes to the accounting pronouncements during the six months ended June 30, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. As of June 30, 2021, we had cash and cash equivalents of $212.2 million that were held in an interest-bearing money market account. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and short-term investments and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short-term investments. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are comprised of U.S. Treasury and U.S. Treasury-backed repurchase agreements as well as treasury notes and high quality short-term corporate bonds.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our 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 cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent quarter ended June 30, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur. In addition, such risks may be amplified by the COVID-19 pandemic and its potential impact on Ovid's business and the global economy.

Risks Related to Our Financial Position and Need for Additional Capital

Historically, we have incurred significant operating losses and expect to continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

We have historically incurred significant operating losses. Due to a one-time, upfront payment of $196.0 million pursuant to the royalty, license and termination agreement (the "Takeda License and Termination Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"), our net income was $160.2 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $134.0 million. We expect to incur increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our drug candidates, as well as hiring employees and building our infrastructure.

We have no drugs approved for commercialization and have never generated any revenue from drug sales. All of our drug candidates are still in the preclinical testing stage. It could be several years, if ever, before we have a commercialized drug. We expect to continue to incur significant expenses and operating losses over the next several years, and the net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance the preclinical and clinical development of our drug candidates;
- continue to build a portfolio of drug candidates through the acquisition or in-license of drugs, drug candidates or technologies;
- initiate preclinical studies and clinical trials for any additional drug candidates that we may pursue in the future;
- experience further delays in our preclinical studies due to the ongoing COVID-19 pandemic;
- seek marketing approvals for our current and future drug candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any drug candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- implement operational, financial and management systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current and future drug candidates.

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 would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Our operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our operations have consumed substantial amounts of cash since our inception in April 2014, primarily due to organizing and staffing our company, business planning, raising capital, acquiring assets and undertaking the development of our drug candidates. We have not yet demonstrated the ability to obtain marketing approvals, manufacture a commercial-scale drug or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had more experience developing drug candidates.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

We will require additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our drug development efforts or other operations.

Our operations have consumed substantial amounts of cash since our inception. We expect our expenses to increase as we advance our current and future drug candidates through preclinical studies and clinical trials, commercialize our drug candidates, and pursue the acquisition or in-licensing of any additional drug candidates. Our expenses could increase beyond expectations if the FDA or other regulatory authorities require us to perform preclinical studies or clinical trials in addition to those that we currently anticipate. In addition, even if we obtain marketing approval for our drug candidates, they may not achieve commercial success. Our revenue, if any, will be derived from sales of drugs that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for any drug candidates that we develop or otherwise acquire, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution.

As of June 30, 2021, our cash and cash equivalents were $212.2 million, and we had an accumulated deficit of $134.0 million. We believe that our existing cash and cash equivalents will fund our current operating plans through at least 12 months from the filing of this Quarterly Report on Form 10-Q. However, our operating plans may change because of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We will require more capital in order to advance the preclinical and clinical development, obtain regulatory approval and, following regulatory approval, commercialize our current or future drug candidates. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future drug candidates. The COVID-19 pandemic has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital. If we do not raise additional capital in sufficient amounts, or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which will harm our business, operating results and prospects.

Raising additional capital or acquiring or licensing assets by issuing equity or debt securities may cause dilution to our stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

Until such time as we can generate substantial revenue from drug sales, if ever, we expect to finance our cash needs through a combination of equity and debt financings, strategic alliances, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we issue additional equity securities, our stockholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition, we may issue equity or debt securities as consideration for obtaining rights to additional compounds.

Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, issuing additional equity, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, 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 capital when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise develop and market ourselves.

Our ability to use our net operating loss ("NOL") carryforwards and certain other tax attributes to offset future taxable income may be subject to limitation.

Our NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our federal NOLs generated in tax years beginning on or before December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Under the Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the utilization of such federal NOLs incurred in the taxable year beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the Tax Act and CARES Act.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage over a rolling three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

For the six months ended June 30, 2021, we recorded a U.S. federal and state income tax provision of $1.8 million and $0.2 million, respectively, in each case on a pre-tax income of $162.2 million. As of June 30, 2021, we had available approximately $18.4 million, $58.3 million, and $58.3 million of unused NOL carryforwards for U.S. federal, New York State, and New York City income tax purposes, respectively, that may be applied against future taxable income. Even if we achieve profitability in future periods, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations. Additionally, the net operating losses incurred in future years will be reduced by the recognized built-in loss of approximately $5 million.

Risks Related to the Development and Commercialization of Our Drug Candidates

We are very early in our development efforts and all our drug candidates are in preclinical development. If we are unable to successfully develop, receive regulatory approval for and commercialize our drug candidates for these or any other indications, or successfully develop any other drug candidates, or experience significant delays in doing so, our business will be harmed.

We are very early in our development efforts and all of the drug candidates for which we control developmental and commercial responsibility are still in preclinical development. We anticipate filing three investigational new drug ("IND") applications in three years, beginning in the first half of 2022. Following IND acceptance, each of our drug candidates will need to be progressed through clinical development in order to achieve regulatory approval, and we will also need to address issues relating to manufacture and supply, which may involve building our own capacity and expertise. In order to commercialize any product that achieves regulatory approval, we will need to build a commercial organization or successfully outsource commercialization, all of which will require substantial investment and significant marketing efforts before we have the ability to generate any revenue from drug sales. We do not have any drugs that are approved for commercial sale, and we may never be able to develop or commercialize marketable drugs.

Our ability to generate revenue from drug sales and achieve profitability depends on our ability, alone or with any current or future collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our current and future drug candidates. We do not anticipate generating revenue from drug sales for the next several years, if ever. Our ability to generate revenue from drug sales depends heavily on our, or any current or future collaborators', success in the following areas, including but not limited to:

- timely and successfully completing preclinical and clinical development of our current and future drug candidates;
- obtaining regulatory approvals for our current and future drug candidates for which we successfully complete clinical trials;
- launching and commercializing any drug candidates for which we obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualifying for coverage and adequate reimbursement by government and third-party payors for any drug candidates for which we obtain regulatory approval, both in the United States and internationally;
- developing, validating and maintaining a commercially viable, sustainable, scalable, reproducible and transferable manufacturing process for our current and future drug candidates that is compliant with current good manufacturing practices ("cGMP");
- establishing and maintaining supply and manufacturing relationships with third parties that can provide an adequate amount and quality of drugs and services to support clinical development, as well as the market demand for our current and future drug candidates, if approved;
- obtaining market acceptance, if and when approved, of our current or any future drug candidates as a viable treatment option by physicians, patients, third-party payors and others in the medical community;
- effectively addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;

- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations pursuant to such arrangements;
- obtaining and maintaining orphan drug exclusivity for any of our current and future drug candidates for which we obtain regulatory approval;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- avoiding and defending against third-party interference or infringement claims; and
- securing appropriate pricing in the United States, the European Union and other countries.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the drug candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any drug candidate we develop, we may not be able to continue our operations.

Our future success is dependent on the successful clinical development, regulatory approval and commercialization of our current and future drug candidates. If we, or our licensees, are not able to obtain the required regulatory approvals, we, or our licensees, will not be able to commercialize our drug candidates, and our ability to generate revenue will be adversely affected.

We do not have any drugs that have received regulatory approval. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize our current and future drug candidates in a timely manner. Activities associated with the development and commercialization of our current and future drug candidates are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain regulatory approval in the United States or other jurisdictions would prevent us from commercializing and marketing our current and future drug candidates. An inability to effectively develop and commercialize our current and future drug candidates, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, could have an adverse effect on our business, financial condition, results of operations and growth prospects.

Further, activities associated with the development and commercialization of our current and future drug candidates are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain regulatory approval in the United States or other jurisdictions would prevent us from commercializing and marketing our current and future drug candidates.

Even if we obtain approval from the FDA and comparable foreign regulatory authorities for our current and future drug candidates, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of that drug candidate or any other drug candidate that we may in-license, develop or acquire in the future. In certain circumstances, our third-party licensees are responsible for obtaining regulatory approvals in the countries covered by the license, and we are dependent on their efforts in order to achieve the necessary approvals in order to commercialize our products. If any future licensees fail to perform their obligations to develop and obtain regulatory approvals for the licensed products, we may not be able to commercialize our products in the affected countries, or our ability to do so may be substantially delayed.

Furthermore, even if we obtain regulatory approval for our current and future drug candidates, we will still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize our current and future drug candidates, we may not be able to generate sufficient revenue to continue our business.

Because the results of preclinical studies or earlier clinical trials are not necessarily predictive of future results, our drug candidates may not have favorable results in planned or future preclinical studies or clinical trials, or may not receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that subsequent clinical trials will generate similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. Frequently, drug candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. For instance, our NEPTUNE trial of OV101, one of our former drug candidates, did not meet its primary endpoints despite earlier encouraging results of STARS, the first clinical trial evaluating efficacy of OV101 in patients with Angelman syndrome. The results from preclinical studies of our current and future drug candidates may not be predictive of the effects of these compounds in later stage clinical trials. If we do not observe favorable results in clinical trials of one of our drug candidates, we may decide to delay or abandon clinical development of that drug candidate. Any such delay or abandonment could harm our business, financial condition, results of operations and prospects.

It is difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval for our gene therapy candidates.

Our future success depends in part on the successful development of our OV882 and OV815 gene therapy product candidates. We may experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to internal and external commercial manufacturing sites, which may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

The regulatory approval process for novel gene therapy products such as ours can be more expensive and take longer than for other product types, which are better known or more extensively studied to date. Regulatory approaches and requirements for gene therapy products continue to evolve, and any changes could create significant delay and unpredictability for product development and approval as compared to technologies with which regulatory authorities have more substantial experience.

Also, before a clinical trial can begin to enroll at a site, each clinical site's Institutional Review Board ("IRB") and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess appropriateness to conduct the clinical trial at that site. In addition, adverse events in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory authorities outside the U.S. to change the requirements for human research on or for approval of any of our product candidates.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain marketing approvals for our product candidates.

Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Trials using early versions of retroviral vectors, which integrate into, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events. The risk of serious adverse events remains a concern for gene therapy and we cannot assure that it will not occur in any of our future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material.

Adverse events in trials or studies conducted by us or other parties, even if not ultimately attributable to our product candidates, and resulting publicity, could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

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

From time to time, we have and may in the future publish or report preliminary or interim data from our clinical trials. Preliminary or interim data from our clinical trials and those of our partners may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Preliminary or topline results 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 or reported. As a result, preliminary or interim data should be considered carefully and with caution until final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Preclinical studies and clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes. Further, we may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy in our preclinical studies and clinical trials to the satisfaction of applicable regulatory authorities.

All of our current drug candidates are in preclinical development and their risk of failure is high. We must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that each of our drug candidates are safe and effective for its intended indications before we are prepared to submit a new drug application ("NDA") or Biologics License Application ("BLA") for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA or BLA for any of our product candidates or whether any such application will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous review and regulatory requirements by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. For instance, the FDA may not agree with our proposed endpoints for any future clinical trial of our product candidates, which may delay the commencement of such clinical trial.

We estimate that the successful completion of clinical trials of our product candidates will take at least several years to complete, if not longer. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Furthermore, failure can occur at any stage and we could encounter problems that cause us to abandon or repeat clinical trials. Events that may prevent successful or timely completion of clinical development include:

- our inability to generate sufficient preclinical, toxicology or other data to support the initiation of clinical trials;
- our inability to develop and validate disease-relevant clinical endpoints;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations ("CROs") and clinical trial sites;
- delays in opening investigational sites;
- delays or difficulty in recruiting and enrollment of suitable patients to participate in our clinical trials, whether as a result of the COVID-19 pandemic or otherwise;

- imposition of a clinical hold by regulatory authorities because of a serious adverse event, concerns with a class of drug candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters and public health epidemics.

Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be limited, which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned preclinical studies and clinical trials.

Further, clinical endpoints for certain diseases we are targeting, such as Angelman syndrome, have not been established, and accordingly we may have to develop new modalities or modify existing endpoints to measure efficacy, which may increase the time it takes for us to commence or complete clinical trials. In addition, we believe investigators in this area may be inexperienced in conducting trials in this area due to the current lack of drugs to treat these disorders, which may result in increased time and expense to train investigators and open clinical sites.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our drug candidates, we may need to conduct additional testing to bridge our modified drug candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our drug candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our drug candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our drug candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy (“REMS”);
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an IRB may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA’s current Good Clinical Practice (“GCP”) regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be negatively impacted, and our ability to generate revenues from our drug candidates may be delayed.

If we are not successful in discovering, developing and commercializing additional drug candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop and potentially commercialize a portfolio of drug candidates to treat rare neurological disorders. We intend to do so by in-licensing and entering into collaborations with leading biopharmaceutical companies or academic institutions for new drug candidates. Identifying new drug candidates requires substantial technical, financial and human resources, whether or not any drug candidates are ultimately identified. The COVID-19 pandemic could also impact our ability to do in-person due diligence, negotiations and other interactions to identify new opportunities. Even if we identify drug candidates that initially show promise, we may fail to in-license or acquire these assets and may also fail to successfully develop and commercialize such drug candidates for many reasons, including the following:

- the research methodology used may not be successful in identifying potential drug candidates;
- competitors may develop alternatives that render any drug candidate we develop obsolete;
- any drug candidate we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a drug 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 drug candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a drug candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors, even if approved.

We have limited financial and management resources and, as a result, we may forego or delay the pursuit of opportunities with other drug candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

If we are unsuccessful in identifying and developing additional drug candidates or are unable to do so, our key growth strategy and business will be harmed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. The number of patients suffering from some of the rare neurological disorders we are pursuing is small and has not been established with precision. If the actual number of patients with these disorders is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our drug candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial, any such enrollment issues could cause delays or prevent development and approval of our drug candidates. Because we are focused on addressing rare neurological disorders, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our drug candidates, or could render further development impossible.

Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our drug candidates in larger, longer and more extensive clinical programs, or as use of these drug candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 trials or, in some cases, after they are made available to patients on a commercial scale after approval. For example, adverse events were reported in certain clinical trials for OV101 and OV935, two of our former drug candidates. If clinical experience indicates that any of our drug candidates causes adverse events or serious or life-threatening adverse events, the development of that drug candidate may fail or be delayed, or, if the drug candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our drug candidates, the commercial prospects of our drug candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if any of our drug candidates receive marketing approval, the FDA could require us to include a black box warning in our label or adopt REMS to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our drug candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such drug candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a drug candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;
- we may need to conduct a recall; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our drug candidates and could significantly harm our business, prospects, financial condition and results of operations.

If the market opportunities for our drug candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer. Because the patient populations in the market for our drug candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.

We focus our research and drug development on treatments for rare neurological disorders. Given the small number of patients who have the disorders that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our drug candidates. Our projections of both the number of people who have these disorders, as well as the subset of people with these disorders who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our drug candidates may be limited or may not be amenable to treatment with our drug candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug 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.

More established companies may have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts, relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products, and marketing approved drugs. These companies also have significantly greater research and marketing capabilities than we do. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed.

As a result of these factors, our competitors may obtain regulatory approval of their drugs before we are able to, which may limit our ability to develop or commercialize our drug candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted and cheaper than ours, and may also be more successful than us in manufacturing and marketing their drugs. These appreciable advantages could render our drug candidates obsolete or non-competitive before we can recover the expenses of such drug candidates' development and commercialization.

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, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if our current or future drug candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our current or future drug candidates receive marketing approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant drug revenue and may not become profitable. The degree of market acceptance of our current or future drug candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments and therapies;
- the safety profile of our drug candidate compared to alternative treatments and therapies;
- effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such drug for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the drug together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our drug candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our drug candidates. Because we expect sales of our drug candidates, if approved, to generate substantially all of our drug revenues for the foreseeable future, the failure of our drugs to find market acceptance would harm our business and could require us to seek additional financing.

Even if we obtain and maintain approval for our current or future drug candidates from the FDA, we may never obtain approval for our current or future drug candidates outside of the United States, which would limit our market opportunities and could harm our business.

Approval of a drug candidate in the United States by the FDA does not ensure approval of such drug candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our current and future drug candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a drug candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, which may require additional preclinical studies or clinical trials. In many countries outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any drug candidates, if approved, is also subject to approval. Obtaining approval for our current and future drug candidates in the European Union from the European Commission following the opinion of the European Medicines Agency, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. The FDA [WO1] and comparable foreign regulatory authorities have the ability to limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. 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 current and future drug candidates in certain countries. In certain cases, we are dependent on third parties to obtain such foreign regulatory approvals, and any delay or failure of performance of such third parties could delay or prevent our ability to commercialize our products in the affected countries. Due to the ongoing COVID-19 pandemic, it is possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our drug candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our current and future drug candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

If we seek approval to commercialize our current or future drug candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If we seek approval of our current or future drug candidates outside of the United States, we expect that we will be subject to additional risks in commercialization including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- the potential requirement of additional clinical studies in international jurisdictions;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters and public health pandemics, such as COVID-19.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in and outside of Europe with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their own products in foreign countries to be very challenging.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any drug candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current and any future drug candidates in clinical trials and may face an even greater risk if we commercialize any drug candidate that we may develop. If we cannot successfully defend ourselves against claims that any such drug candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any drug candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any drug candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Licensing and Collaboration Arrangements

Under the Takeda License and Termination Agreement, we are entitled to receive royalty and milestone payments in connection with the development and commercialization of soticlestat. If Takeda fails to progress or discontinues the development of soticlestat, we may not receive some or all of such payments, which would materially harm our business.

In March 2021, we entered into the Takeda License and Termination Agreement, pursuant to which Takeda secured rights to our 50% global share in soticlestat, which we had originally licensed from Takeda, and we granted to Takeda an exclusive worldwide license under our relevant intellectual property rights to develop and commercialize the investigational medicine soticlestat for the treatment of developmental and epileptic encephalopathies, including Dravet syndrome and Lennox-Gastaut syndrome. All rights in soticlestat are now owned by Takeda or exclusively licensed to Takeda by us. Following the closing date of the Takeda License and Termination Agreement, Takeda assumed all responsibility for, and costs of, both development and commercialization of soticlestat, and we will no longer have any financial obligation to Takeda under the original collaboration agreement, including for milestone payments or any future development and commercialization costs. Upon closing of the Takeda License and Termination Agreement, we received a one-time, upfront payment of $196.0 million and, if soticlestat is successfully developed, we will be eligible to receive up to an additional $660.0 million upon achieving specified development, regulatory and sales milestones. In addition, if soticlestat achieves regulatory approval, we will be entitled to receive tiered royalties at percentages ranging from the low double-digits, and up to 20% on sales of soticlestat. Royalties will be payable on a country-by-country and product-by-product basis during the period beginning on the date of the first commercial sale of such product in such country and ending on the later to occur of the expiration of patent rights covering the product in such country and a specified anniversary of such first commercial sale.

Under the terms of the Takeda License and Termination Agreement, Takeda now has sole discretion over the conduct of the development and commercialization of soticlestat. If for any reason, Takeda fails to progress, or elects to terminate the development of soticlestat as contemplated by the Takeda License and Termination Agreement, or if the development or commercialization of soticlestat is delayed or deprioritized by Takeda, we may not receive some or all of the royalty and milestone payments under such agreement. We are dependent upon Takeda's progression of such development and the resulting payments to fund the regulatory development of our current and future drug candidates. If we are unable to find alternative sources of revenue, our inability to receive royalty or milestone payments under the Takeda License and Termination Agreement would negatively impact our business and results of operations.

Risks associated with the in-licensing or acquisition of drug candidates could cause substantial delays in the preclinical and clinical development of our drug candidates.

We have previously acquired and we may acquire or in-license drug candidates for preclinical or clinical development in the future as we continue to build our pipeline. Such arrangements with third parties may impose, diligence, development and commercialization obligations, milestone payments, royalty payments, indemnification and other obligations on us. Our obligations to pay milestone, royalty and other payments to our licensors may be substantial, and the amount and timing of such payments may impact our ability to progress the development and commercialization of our drug candidates. Our rights to use any licensed intellectual property may be subject to the continuation of and our compliance with the terms of any such agreements. Additionally, disputes may arise regarding our rights to intellectual property licensed to us or acquired by us from a third party, including but not limited to:

- the scope of intellectual property rights included in, and rights granted under, any license or other agreement;
- the sublicensing of patent and other rights under such agreements;
- our compliance with our diligence obligations under any license agreement;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators;
- the scope and duration of our payment obligations, and our ability to make such payments when they are owed;
- our need to acquire additional intellectual property rights from third parties that may impact payments due under such agreements;
- the rights of our licensors to terminate any such agreement;
- our rights and obligations upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

Disputes over intellectual property and other rights that we have licensed or acquired, or may license or acquire in the future, from third parties could prevent or impair our ability to maintain any such arrangements on acceptable terms, result in delays in the commencement or completion of our preclinical studies and clinical trials and impact our ability to successfully develop and commercialize the affected drug candidates. If we fail to comply with our obligations under any future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

We may be required to relinquish important rights to and control over the development and commercialization of our drug candidates to any future collaborators.

Our current and future collaborations could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage of ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our drug candidates;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new version of a drug candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our drug candidates, limiting our potential revenues from these products;
- we rely on our current collaborators to manufacture drug substance and drug product and may do so with respect to future collaborators, which could result in disputes or delays;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our drug candidates.

We may explore additional strategic collaborations that may never materialize or may fail.

Our business strategy is based on acquiring or in-licensing compounds directed at rare neurological disorders. As a result, we intend to periodically explore a variety of possible additional strategic collaborations in an effort to gain access to additional drug candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

Risks Related to Regulatory Compliance

Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We may be subject to broadly applicable healthcare laws and regulations that may impact the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any product candidates for which we obtain marketing approval. The healthcare laws that may affect us include: the federal fraud and abuse laws, including the federal Anti-Kickback Statute, and false claims and civil monetary penalties laws, including the False Claims Act and Civil Monetary Penalties Law; federal data privacy and security laws, including the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act; and the federal Physician Payments Sunshine Act related to ownership and investment interests and payments and/or other transfers of value made to or held by physicians (including doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and, beginning in 2022, information regarding payments and transfers of value provided to and other healthcare professionals, such as physician assistants and nurse practitioners among others, during the previous year. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Coverage and adequate reimbursement may not be available for our current or any future drug candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any drug candidates that we commercialize, if approved, will depend in part on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third-party payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future drug candidates that we develop. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively PPACA) was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There have been executive, judicial, Congressional and executive branch challenges to certain aspects of the PPACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. . It is possible that the PPACA will be subject to judicial or

Congressional challenges in the future. It is unclear how any challenges and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. Any reduction in reimbursement from government payors may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

It is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic.

We may not be able to obtain or maintain orphan drug designations or exclusivity for our drug candidates, which could limit the potential profitability of our drug candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for an indication for which it receives the designation, then the drug is entitled to a period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication for the exclusivity period except in limited situations. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Obtaining orphan drug designations is important to our business strategy; however, obtaining an orphan drug designation can be difficult and we may not be successful in doing so. Even if we were to obtain orphan drug designation for a drug candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any drug candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable drug candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

Even if we obtain regulatory approval for our current or future drug candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for our current or future drug candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our current or future drug candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our current or future drug candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of drug candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our current or future drug candidates and harm our business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process, or suspend or restrict regulatory approval of our drug 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, which would harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our current or any future drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and drug candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and any future drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future development programs and drug candidates. The patent prosecution 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.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current or any future drug candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our current or any future drug candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any drug candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a drug candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and drug candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current or any future drug candidates, it could dissuade companies from collaborating with us to develop drug candidates, and threaten our ability to commercialize, future drugs. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United

States law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent 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. On December 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith 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 harm our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (the “USPTO”) or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future drug candidates, we may be open to competition from generic versions of such drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our drug candidates but that are not covered by the claims of any patents, should they issue, that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or control may not provide us with any competitive advantages, or may be held invalid or unenforceable because of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

The proprietary map of disease-relevant biological pathways underlying orphan disorders of the brain that we developed would not be appropriate for patent protection and, as a result, we rely on trade secrets to protect this aspect of our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our current and any future drug candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future drug candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future drug candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our drug candidate(s) and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or drug candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our current or any future drug candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. See the section herein titled "Legal Proceedings" for additional information.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future drug candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 this type of litigation. There could also 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 an adverse effect on the price of our common stock.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future drug candidates.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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 actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These drugs may compete with our drugs in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture or commercialize our current or any future drug candidates, or if we collaborate with additional third parties for the development of our current or any future drug candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets would harm our business.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our current and any future drug candidates.

We do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage and distribution, or testing. We have been in the past, and will continue to be, dependent on third parties to manufacture the clinical supplies of our drug candidates.

Further, we also will rely on third-party manufacturers to supply us with sufficient quantities of our drug candidates to be used, if approved, for commercialization. Any significant delay in the supply of a drug candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves including:

- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future drug candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

We intend to rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct any preclinical studies or clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies or clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with good laboratory practices ("GLPs") and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization guidelines for any of our drug candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we will rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs 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 harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any drug candidate that we develop. As a result, our financial results and the commercial prospects for any drug candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future drug candidates.

If our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

COVID-19 could adversely impact our business, including our preclinical studies, clinical trials and access to capital.

The ongoing COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. In response to these public health directives and orders, we have implemented work-from-home policies for all employees. Our current plans to return to the office remain fluid as federal, state and local guidelines, rules and regulations continue to evolve. The effects of the executive orders, the shelter-in-place orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders related to COVID-19 may adversely impact our business operations and the business operations of our CROs conducting our preclinical studies and clinical trials and our third-party manufacturing facilities in the United States and other countries. In particular, some of our third-party manufacturers which we use for the supply of materials for drug candidates or other materials necessary to manufacture product to conduct preclinical studies and clinical trials are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these tests and trials. Currently, we expect no material impact on the clinical supply of any of our drug candidates.

In addition, our previous clinical trials were, and our future clinical trials may be, affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be willing or able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our previous and planned clinical trials.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business, our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries, and business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this ‘‘Risk Factors’’ section.

We are highly dependent on the services of our senior management team, including our Chairman and Chief Executive Officer, Dr. Jeremy Levin, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team, including our Chairman and Chief Executive Officer, Dr. Levin. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. This risk may be further amplified given the particularly competitive hiring market in New York City, the location of our corporate headquarters.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop drug candidates and our business will be limited and we may experience constraints on our development objectives.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our drug candidates, harming future regulatory approvals, sales of our drug candidates and our results of operations. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

We may need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of June 30, 2021, we had 60 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, our ability to commercialize drug candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, consultants, distributors, and collaborators may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of pharmaceuticals, 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. It is not always possible to identify and deter misconduct by our 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. Further, because of the work from home policies we implemented due to COVID-19, information that is normally protected, including company confidential information, may be less secure. If actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. In addition, due to the COVID-19 pandemic, we have enabled all of our employees to work remotely, which may make us more vulnerable to cyberattacks. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors’ and/or business partners’ information technology systems or other similar data security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, in May 2016, the EU formally adopted the General Data Protection Regulation, or GDPR, which applies to all EU member states as of May 25, 2018 and replaces the former EU Data Protection Directive. The regulation introduces new data protection requirements in the EU and imposes substantial fines for breaches of the data protection rules. The GDPR must be implemented into national laws by the EU member states imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the GDPR and related national laws of EU member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. The GDPR will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with EU data protection rules.

Additionally, California enacted the California Consumer Privacy Act (the “CCPA”) legislation that has been dubbed the first “GDPR-like” law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability.

Risks Related to Being a Public Company

We are an “emerging growth company” and a “smaller reporting company” and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are an emerging growth company (“EGC”), as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) December 31, 2022, the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (“SEC”). For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (“Section 404”);
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure obligations regarding executive compensation arrangements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us so long as we qualify as an EGC. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not an EGC.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We will continue to incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these and other compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required, under Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The Nasdaq Stock Market LLC, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Risks Related to the Ownership of Our Common Stock and Other General Matters

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our common stock.

The market price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. As a result of this volatility, you may lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you paid for the shares. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our current and any future drug candidates or those of our competitors;
- the success of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our current and any future drug candidates or clinical development programs;

- the results of our efforts to discover, develop, acquire or in-license additional drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

***There is no public market for our Series A convertible preferred stock*.**

There is no established public trading market for our Series A convertible preferred stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A convertible preferred stock on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the Series A convertible preferred stock will be limited.

We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. In November 2020, we filed a shelf registration statement on Form S-3 (Registration No. 333-250054) that allows us to sell up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities and/or warrants (the "S-3 Registration Statement"), which includes a prospectus covering the issuance and sale of up to $75.0 million of common stock pursuant to an at-the-market ("ATM") offering program. As of June 30, 2021, we had $250.0 million available under our S-3 Registration Statement, including $75.0 million available pursuant to our ATM program. Financing activities may have an adverse impact on our stockholders' rights as well as on our operations, and such additional funding may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it may result in dilution to our existing stockholders and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as redeeming our shares, making investments, issuing additional equity, limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us. Any of these events could significantly harm our business, financial condition and prospects.

You will be diluted by any conversions of outstanding Series A convertible preferred stock and exercises of outstanding options.

As of June 30, 2021, we had outstanding options to purchase an aggregate of 10,964,889 shares of our common stock at a weighted average exercise price of $5.17 per share and 1,250,000 shares of common stock issuable upon conversion of outstanding Series A convertible preferred stock for no additional consideration. Such Series A convertible preferred stock is convertible any time at the option of the holder thereof subject to the beneficial ownership limitations described in Note 6 to the financial statements contained in this Quarterly Report on Form 10-Q. The exercise of such options and conversion of the Series A convertible preferred stock for shares of our common stock will result in further dilution of your investment and could negatively affect the market price of our common stock. In addition, you may experience further dilution if we issue common stock, or securities convertible into common stock, in the future. As a result of this dilution, you may receive significantly less than the full purchase price you paid for the shares in the event of liquidation.

Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon our shares of our common stock outstanding as of August 6, 2021, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 51% of our outstanding common stock.

Takeda, a greater than 5% holder, has agreed to, among other things, (i) a standstill provision, (ii) restrictions on its ability to sell or otherwise transfer it shares of our stock, (iii) vote its shares on certain matters in accordance with the holders of a majority of shares of our common stock and

(iv) restrictions on the percentage of our outstanding common stock it may own, in accordance with the terms of the Takeda License and Termination Agreement.

If our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power, Takeda standstill provisions, voting obligations and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree with.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. We do currently have research coverage offered by several industry or financial analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Additionally, the Takeda standstill provisions and transfer restrictions in the Takeda License and Termination Agreement may delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile. For example, on August 25, 2020, we announced the topline results of our ELEKTRA clinical trial, and our stock experienced a material decline. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

Our business plan is to continue to evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary drugs, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we engage in future acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or drugs that may be important to the development of our business.

Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Some of the holders of our securities have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares would result in the shares becoming freely tradable without restriction under the Securities Act except for shares held by our affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on May 10, 2017).
3.2	Corrected Amended and Restated Certificate of Designation of Series A Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on September 24, 2019).
3.3	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on May 10, 2017).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-217245), filed with the Commission on April 25, 2017).
4.2	Form of Series A Preferred Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on February 21, 2019).
4.3	Second Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated January 6, 2017 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-217245), filed with the Commission on April 10, 2017).
10.1+	Amended and Restated Executive Employment Agreement between the Company and Jeffrey Rona, effective June 2, 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 and 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	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates a management contract or compensatory plan.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

OVID THERAPEUTICS INC.

Date: August 13, 2021	By: /s/ Jeremy M. Levin Jeremy M. Levin Chief Executive Officer (Principal Executive Officer)
Date: August 13, 2021	By: /s/ Jeffrey Rona Jeffrey Rona Chief Business and Finance Officer (Principal Financial and Accounting Officer)

Exhibit 10.1

AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

Jeff Rona ("***Executive***") is currently employed by **OVID THERAPEUTICS INC.** (the "***Company***") as its Chief Business Officer pursuant to the terms of an Executive Employment Agreement with the Company effective September 30, 2020 (the "***Prior Agreement***"). Executive and the Company hereby agree to this amended agreement. The terms and conditions set forth in this **AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT** (this "***Agreement***") shall become effective as of June 2, 2021 (the "***Effective Date***") and shall supersede and replace the terms and conditions set forth in the Prior Agreement. Certain bolded terms used in this Agreement are defined in Section 6.

WHEREAS, the Company is a biopharmaceutical company;

WHEREAS, the Company desires to employ Executive in the position set forth below, and wishes to provide Executive with certain compensation and benefits in return for such services, as set forth in this Agreement; and

WHEREAS, Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits, as set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Company and Executive agree as follows:

1. TERMS OF EMPLOYMENT

1.

1.1. Position, Duties and Location. Executive shall now serve as Chief Business and Financial Officer reporting to the Company's CEO. Executive shall perform those duties and responsibilities as are customary for such position and as may be directed by the Company and the Board from time to time. During Executive's employment with the Company, Executive shall devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies. Executive's primary office location will be the Company's offices in Colorado. Notwithstanding the foregoing, the Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time, and to require reasonable business travel. During Executive's employment with the Company, Executive shall not engage in any activity that conflicts with or is detrimental to the Company's best interests, as determined by the CEO.

Executive may participate in side activities such as board or committee member, advisor or consultant (the "***Activities***"), provided that Executive obtains their manager's prior written consent, and that none of the following activities involve activities in the area of neurology, detract from Ovid's reputation, impact Executive's full time duties to the Company, or could reasonably result in the disclosure or use of the Company's proprietary or confidential information. The manager may rescind their consent to Executive's participation in the Activities, or participation in other business or public activities, if the manager, in their sole discretion, determines that such activities compromise or threaten to compromise the Company's business interests or conflict with Executive's duties to the Company.

0.2. Employment Term. Executive will be employed by the Company on an "at-will" basis. This means that either the Company or Executive may terminate Executive's employment at any time, for any reason, with or without Cause, and with or without advance notice (provided that (a) Resignation for Good Reason (as defined below) requires certain advanced notice by Executive of Executive's termination of employment as set forth below and (b) as a professional courtesy, Executive agrees to provide the Company with at least sixty (60) days advance written notice of a voluntary resignation by Executive that is not a Resignation for Good Reason). Subject to the terms herein, it also means that Executive's job title, duties, responsibilities, reporting level, compensation and benefits, as well as the Company's personnel policies and procedures, may be changed with or without notice at any time in the Company's sole discretion. This at-will employment relationship shall not be modified by any conflicting actions or representations of any Company employee or other party before or during the term of Executive's employment.

0.3. Compensation.

a) Annual Base Salary. Executive's annual base salary shall be paid at the rate of $455,000 per year ("***Annual Base Salary***"), payable in equal installments, less applicable payroll deductions and withholdings, on the Company's ordinary payroll cycle. Executive's Annual Base Salary shall be subject to annual review by the Board and may be adjusted from time to time. As an exempt salaried employee, Executive will be required to work the Company's normal business hours, and such additional time as appropriate for Executive's work assignments and position, and Executive will not be entitled to overtime compensation.

b) Benefits. Executive will be eligible to participate in all of the Company's employee benefits and benefit plans that the Company generally makes available to its full-time employees and executives in accordance with the terms and conditions of the benefit plans and applicable policies as in effect from time to time.

c) Bonus. Executive shall be eligible to earn an annual performance bonus of up to forty percent (40%) of Executive's Annual Base Salary (the "***Target Performance Bonus***"). The Target Performance Bonus shall be based upon the Company's assessment of Executive's attainment of written Company and individual objectives as set by the Company in its sole discretion. The Company may increase the Target Performance Bonus in its sole discretion. Bonus payments, if any, shall be subject to applicable payroll deductions and withholdings. Following the close of each calendar year, the Company shall determine whether Executive has earned a Target Performance Bonus, and the amount of any such bonus, based on the achievement of such objectives. Executive must be an employee of the Company in good standing on the Target Performance Bonus payment date to be eligible to receive a Target Performance Bonus, and no partial or prorated bonuses shall be provided. The Target Performance Bonus, if earned, shall be paid on or before March 15th of the calendar year after the applicable bonus year. Executive's bonus eligibility is subject to change in the discretion of the Company. If Executive's start date with the Company falls within the fourth quarter, the Executive will not be eligible for a target bonus for that calendar year.

d) Equity Compensation. Subject to the approval of the Board, Executive will be issued, on the Effective Date, an option to purchase one hundred thousand (100,000) shares of the Company's common stock (the "***Option***"). The Option will be evidenced by a stock option agreement and be subject to the terms and conditions of the Company's 2017 Equity Incentive Plan (the "***Equity Plan***"). The exercise price per share of the Option will be equal to the per share fair market value of the Company's common stock on the date the Option is granted, as defined under the Equity Plan. The vesting schedule of the Option will be as follows: twenty-five percent (25%) of the shares of the Company's common stock subject to the Option will vest on the one year anniversary of the Effective Date, and one thirty-sixth (1/36th) of the remaining shares of the Company's common stock subject to the Option will vest each month thereafter on the same day of the month as the Effective date (and if there is no corresponding day, on the last day of the month), so long as Executive remains an employee, consultant, director or officer of the Company, and subject to the terms and conditions of the stock option agreement and the Equity Plan. Subject to the approval of the Board, the stock option agreement shall provide that upon a Change in Control Termination, the vesting and exercisability of the Option shall be accelerated in full. At the discretion of the Board, Executive will be eligible to receive additional options to purchase shares of the Company's common stock.

e) Any raise or bonus connected with performance in you first calendar year of service will be prorated from your start date. Ongoing Stock Option Grants are awarded at the Company's discretion; eligible Ovidians typically are awarded these grants in the first quarter. New Ovidians who start in the fourth quarter are not eligible for a raise or bonus for that calendar year and are not eligible for the Ongoing Grant awarded in first quarter of the following year.

0.4. Reimbursement of Expenses. Subject to Section 4.8(c), the Company shall reimburse Executive for Executive's necessary and reasonable business expenses incurred in connection with Executive's duties in accordance with the Company's generally applicable expense reimbursement policies as in effect from time to time.

0.5. Indemnification Agreement. Executive and Company shall enter into an Indemnity Agreement (the "Indemnification Agreement"), which shall be effective as of the Start Date and is incorporated herein by reference.

0.6. Compliance with Confidentiality Agreement and Company Policies. Executive shall execute and abide by all terms and provisions of the Confidentiality Agreement to be signed on or prior to the Start Date (or any successor agreement thereto), attached hereto as **Exhibit A**. Executive shall also abide by all terms and provisions of the Company's Code of Business Conduct and Ethics, attached hereto as **Exhibit D**. In addition, Executive is required to abide by the Company's policies and procedures, including but not limited to the Company's Employee Handbook, as adopted or modified from time to time within the Company's discretion; *provided*, *however*, that in the event the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. COVERED TERMINATION SEVERANCE BENEFITS

2.

0.7. Severance Benefits. Upon a Covered Termination, then subject to Section 4 below and Executive's continued compliance with the terms of this Agreement, the Company shall provide Executive with the severance benefits set forth in this Section 2 (the "***Severance Benefits***").

0.8. Salary Payment. The Company shall pay Executive, as cash severance, (i) Executive's Monthly Base Salary, multiplied by (ii) the number of months in the Covered Termination Severance Period, less applicable payroll deductions and withholdings (the "***Severance***"). The Severance shall be paid (except as set forth in Section 4) in equal installments on the Company's ordinary payroll cycle commencing on the first regularly-scheduled payroll date occurring on or after the Release Deadline Date (as set forth in Section 4.1).

0.9. Health Continuation Payments.

a) The Company will pay Executive on the first day of each month a fully taxable cash payment equal to the applicable premium for Executive, her spouse and any dependents for the group health plan maintained by the Company for the month in which the Covered Termination occurs, subject to applicable tax withholdings but grossed up for all taxes owed by the Executive on such payment, for the duration of the Covered Termination Benefits Period. Such coverage shall be counted as coverage pursuant to COBRA. The Company shall have no obligation in respect of any premium payments following the effective date of the Executive's coverage by a health insurance plan of a subsequent employer. Executive shall be required to notify the Company immediately if Executive becomes covered by a health insurance plan of a subsequent employer.

b) For purposes of this Section 2.3, (i) references to COBRA shall be deemed to include analogous provisions of state law, and (ii) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by Executive under a Code Section 125 health care reimbursement plan, which amounts, if any, are the sole responsibility of Executive.

3. CHANGE IN CONTROL SEVERANCE BENEFITS

3.

0.10. Change in Control Severance Benefits. Upon a Change in Control Termination, then subject to Section 4 below and Executive's continued compliance with the terms of this Agreement, the Company shall provide Executive with the severance benefits set forth in this Section 3 (the "***Change in Control Severance Benefits***").

0.11. Salary Payment. The Company shall pay Executive, as cash severance, (i) Executive's Monthly Base Salary, multiplied by (ii) the number of months in the Change in Control Severance Period, less applicable payroll deductions and withholdings (the "***Change in Control Severance***"). The Change in Control Severance shall be paid (except as set forth in Section 4) in equal installments on the Company's ordinary payroll cycle commencing on the first regularly-scheduled payroll date occurring on or after the Release Deadline Date.

0.12. Health Continuation Payments.

a) The Company will pay Executive on the first day of each month a fully taxable cash payment equal to the applicable premium for Executive, her spouse and any dependents for the group health plan maintained by the Company for the month in which the Change in Control Termination occurs, subject to applicable tax withholdings but grossed up for all taxes owed by the Executive on such payment, for the duration of the Change in Control Benefits Period. Such coverage shall be counted as coverage pursuant to COBRA. The Company shall have no obligation in respect of any premium payments following the effective date of the Executive's coverage by a health insurance plan of a subsequent employer. Executive shall be required to notify the Company immediately if Executive becomes covered by a health insurance plan of a subsequent employer.

b) For purposes of this Section 3.3, (i) references to COBRA shall be deemed to include analogous provisions of state law, and (ii) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by Executive under a Code Section 125 health care reimbursement plan, which amounts, if any, are the sole responsibility of Executive.

0.13. Change in Control Termination Vesting Acceleration Benefits. Upon a Change in Control Termination, (i) the vesting and exercisability of all outstanding options to purchase the Company's common stock (or stock appreciation rights or other rights with respect to the stock of the Company issued pursuant to any equity incentive plan of the Company) that are held by Executive on the Termination Date shall be accelerated in full, (ii) each such option shall be exercisable and to the extent not exercised, expire on the latest date permitted under the Equity Plan and (iii) any reacquisition or repurchase rights held by the Company with respect to common stock issued or issuable (or with respect to other rights with respect to the stock of the Company issued or issuable) pursuant to any other stock award granted to Executive pursuant to any equity incentive plan of the Company shall lapse.

4. LIMITATIONS AND CONDITIONS ON BENEFITS

4.

0.14. Release Prior to Payment of Severance Benefits and Change in Control Severance Benefits. The receipt of any Severance Benefits or Change in Control Severance Benefits pursuant to this Agreement is subject to Executive signing and not revoking a separation agreement and general release of claims (the "***Release***"), in substantially the form attached hereto and incorporated herein as **Exhibit B** or **Exhibit C**, as appropriate, and subject to any further modifications as determined in the Company's discretion, which Release must become effective and irrevocable no later than the sixtieth (60th) day following Executive's Termination Date (the "***Release Deadline Date***"). If the Release does not become effective and irrevocable by the Release Deadline Date, Executive will forfeit any right to any Severance Benefits or Change in Control Severance Benefits under this Agreement. In no event will Severance Benefits or Change in Control Severance Benefits be paid or provided until after the Release Deadline Date. On the first regularly-scheduled payroll date occurring on or after the Release Deadline Date, the Company will pay Executive the Severance or Change in Control Severance amount that Executive would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the Severance or Change in Control Severance amount being paid as originally scheduled. The Company may modify the Release in its discretion to comply with changes in applicable law at any time prior to Executive's execution of such Release.

0.15. Return of Company Property. Not later than the Termination Date, or earlier if requested by the Company, Executive shall return to the Company all documents (and all copies thereof) and other property belonging to the Company that Executive has in his or her possession or control. The documents and property to be returned include, but are not limited to, all files, correspondence, email, memoranda, notes, notebooks, records, plans, forecasts, reports, studies, analyses, compilations of data, proposals, agreements, financial information, research and development information, marketing information, operational and personnel information, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones and servers), credit cards, entry cards, identification badges and keys, and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part). Executive agrees to make a diligent search to locate any such documents, property and information. If Executive has used any personally owned computer, server or e-mail system to receive, store, review, prepare or transmit any Company confidential or proprietary data, materials or information, then within ten (10) business days after the Termination Date, or earlier if requested by the Company, Executive shall provide the Company with a computer-useable copy of all such information and then permanently delete and expunge such confidential or proprietary information from those systems. Executive agrees to provide the Company with a certification that the necessary copying and/or deletion is done.

0.16. Cooperation and Continued Compliance with Restrictive Covenants.

a) After the Termination Date, Executive shall cooperate fully with the Company, at reasonable times as agreed between Executive and the Company, in connection with its actual or contemplated defense, prosecution or investigation of any existing or future litigation, arbitrations, mediations, claims, demands, audits, government or regulatory inquiries, or other matters arising from events, acts or failures to act that occurred during the time period in which Executive was employed by the Company (including any period of employment with an entity acquired by the Company). Such cooperation includes, without limitation, being available upon reasonable notice, without subpoena, to provide accurate and complete advice, assistance and information to the Company, including offering and explaining evidence, providing truthful and accurate sworn statements, and participating in discovery and trial preparation and testimony. Executive also agrees to promptly send the Company copies of all correspondence (for example, but not limited to, subpoenas) received by Executive in connection with any such legal proceedings, unless Executive is expressly prohibited by law from so doing. Nothing in this Agreement prohibits Executive from responding accurately and fully to any request for information if required by legal process or in connection with a government investigation. In addition, nothing in this Agreement is intended to prohibit or restrain Executive in any manner from making disclosures that are protected under the whistleblower provisions of federal law or regulation or under other applicable law or regulation. The Company will reimburse Executive for reasonable out-of-pocket expenses incurred in connection with any such cooperation (excluding foregone wages, salary or other compensation) within thirty (30) days of Executive's timely presentation of appropriate documentation thereof, in accordance with the Company's standard reimbursement policies and procedures. The Company will reasonably accommodate Executive's scheduling needs with respect to any such cooperation after the Termination Date.

b) After the Termination Date, Executive shall continue to abide by Executive's continuing obligations under the Confidentiality Agreement.

c) From the Start Date and through and including the Change in Control Severance Period or Covered Termination Severance Period as defined below, or, if Executive is Terminated with Cause, for one year after Executive's Termination Date, whichever is applicable, Executive shall not, without the Company's prior written consent, whether directly or indirectly be employed, under contract with, provide services to or on behalf of, or be involved with any business or organization (whether "for profit" or "not-for-profit"), or applicable Division thereof (as defined below), which researches, develops, creates, manufactures, designs and/or sells compounds and/or related pharmaceuticals, medicines and/or therapies to treat rare or orphan neurological conditions or diseases, and/or otherwise competes with products and/or services then under research or development by or offered or sold by the Company in the same therapeutic category. Nothing in Section 4.3(c) shall prohibit Executive from investing as a less than one percent (1%) shareholder in securities of any company listed on a national securities exchange or quoted on an automated quotation system.

d) From the Start Date until twelve (12) months after Termination Date, Executive shall not hire or retain, or attempt to hire or retain, any of the Company's then-existing board members, employees, advisors, consultants, collaborators, investigators or agents and shall not induce any such to give up employment with or to cease providing services to the Company, and shall not otherwise interfere with, or attempt to interfere with, the relationship of any such person with the Company; or attempt in any manner to solicit, persuade or induce any Client of the Company to terminate, reduce or refrain from renewing or extending its contractual or other relationship with the Company in regard to the purchase of products or services marketed or sold by the Company, or to become a Client of or enter into any contractual or other relationship with Executive or any other individual, person or entity in regard to the purchase of products or services similar or identical to those marketed or sold by the Company.

e) Executive acknowledges and agrees that Executive's obligations under this Section 4.3 are an essential part of the consideration Executive is providing hereunder in exchange for which and in reliance upon which the Company has agreed to provide the payments and benefits under this Agreement. Executive further acknowledges and agrees that Executive's violation of this Section 4.3 inevitably would involve use or disclosure of the Company's proprietary and confidential information. If it is determined by a court of competent jurisdiction in any state that any restriction in this Section 4.3 is excessive in duration or scope or is unreasonable or unenforceable under the laws of that state, it is the intention of the parties that such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the law of that state.

0.17. Parachute Payments.

a) Parachute Payment Limitation. If any payment or benefit (including payments and benefits pursuant to this Agreement) Executive would receive in connection with a Change in Control from the Company or otherwise ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this paragraph, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Payment are paid to Executive, which of the following two alternative forms of payment shall be paid to Executive: (A) payment in full of the entire amount of the Payment (a "***Full Payment***"), or (B) payment of only a part of the Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). A Full Payment shall be made in the event that the amount received by the Executive on a net after-tax basis is greater than what would be received by the Executive on a net after-tax basis if the Reduced Payment were made, otherwise a Reduced Payment shall be made. If a Reduced Payment is made, (i) the Payment shall be paid only to the extent permitted under the Reduced Payment alternative, and Executive shall have no rights to any additional payments and/or benefits constituting the Payment, and (ii) reduction in payments and/or benefits shall occur in the following order: (A) reduction of cash payments; (B) cancellation of accelerated vesting of equity awards other than stock options; (C) cancellation of accelerated vesting of stock options; and (D) reduction of other benefits paid to Executive. In the event that acceleration of compensation from Executive's equity awards is to be reduced, such acceleration of vesting shall be canceled in the reverse order of the date of grant.

b) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 4.4. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

c) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. If the independent registered public accounting firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with an opinion reasonably acceptable to Executive that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

0.18. Certain Reductions and Offsets. To the extent that any federal, state or local laws, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other so-called "plant closing" laws, require the Company to give advance notice or make a payment of any kind to Executive because of Executive's involuntary termination due to a layoff, reduction in force, plant or facility closing, sale of business, change in control or any other similar event or reason, the benefits payable under this Agreement shall be correspondingly reduced. The benefits provided under this Agreement are intended to satisfy any and all statutory obligations that may arise out of Executive's involuntary termination of employment for the foregoing reasons, and the parties shall construe and enforce the terms of this Agreement accordingly.

0.19. Mitigation. Except as otherwise specifically provided herein, Executive shall not be required to mitigate damages or the amount of any payment provided under this Agreement by seeking other employment or otherwise, nor shall the amount of any payment or benefit provided for under this Agreement be reduced by any compensation earned by Executive as a result of employment by another employer or by any retirement benefits received by Executive after the date of a Covered Termination or Change in Control Termination (except as expressly provided in Sections 2.3 and 3.3 above).

0.20. Indebtedness of Executive. If Executive is indebted to the Company on the effective date of a Covered Termination or Change in Control Termination Date, the Company reserves the right to offset any Severance Benefits or Change in Control Severance Benefits under this Agreement by the amount of such indebtedness, subject to the requirements of Section 409A of the Code and applicable law.

0.21. Application of Section 409A.

a) Separation from Service. Notwithstanding any provision to the contrary in this Agreement, no amount deemed deferred compensation subject to Section 409A of the Code shall be payable pursuant to Section 2 or Section 3 unless Executive's termination of employment constitutes a "separation from service" with the Company within the meaning of Section 409A of the Code and the Department of Treasury Regulations and other guidance promulgated thereunder and, except as provided under Section 4.8(b) hereof, any such amount shall not be paid, or in the case of installments, commence payment, until the first regularly-scheduled payroll date occurring on or after the sixtieth (60th) day following Executive's separation from service. Any installment payments that would have been made to Executive during the sixty (60) day period immediately following Executive's separation from service but for the preceding sentence shall be paid to Executive on the first regularly-scheduled payroll date occurring on or after the sixtieth (60th) day after Executive's separation from service and the remaining payments shall be made as provided in this Agreement.

b) Specified Executive. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed at the time of his or her separation from service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six (6)-month period measured from the date of Executive's "separation from service" with the Company (as such term is defined in the Treasury Regulations issued under Section 409A of the Code) or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 4.8(b) shall be paid in a lump sum to Executive, and any remaining payments due under this Agreement shall be paid as otherwise provided herein.

c) Expense Reimbursements. To the extent that any reimbursement payable pursuant to this Agreement is subject to the provisions of Section 409A of the Code, any such reimbursement payable to Executive pursuant to this Agreement shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred; the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year; and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

d) Installments. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment.

0.22. Tax Withholding. All payments under this Agreement shall be subject to applicable withholding for federal, state and local income and employment taxes.

0.23. No Duplication of Severance Benefits. The Severance Benefits and Change in Control Severance Benefits provided in Section 2 and Section 3 are mutually exclusive of each other, and in no event shall Executive receive any Severance Benefits or Change in Control Severance Benefits pursuant to both Section 2 and Section 3.

5. TERMINATION WITH CAUSE OR BY VOLUNTARY RESIGNATION; OTHER RIGHTS AND BENEFITS

5.

0.24. Termination for Cause; Resignation Without Good Reason; Death or Disability. If, at any time, the Company terminates Executive's employment with the Company for Cause, or upon a voluntary resignation by Executive that is not a Resignation for Good Reason, or Executive's employment terminates for any reason not entitling Executive to the Severance Benefits or Change in Control Severance Benefits, or if Executive's employment terminates as a result of Executive's death or disability (other than a Permanent Disability in the case of a Covered Termination), then the Company shall have no further obligation to Executive hereunder except for the payment or provision, as applicable, of (i) the portion of the Annual Base Salary accrued through Executive's last day of employment, (ii) all unreimbursed expenses (if any), subject to Sections 1.4 and 4.8(c), and (iii) any unused vacation (if applicable) accrued through Executive's last day of employment. Under these circumstances, Executive will not be entitled to any other form of compensation, including any Severance Benefits or Change in Control Severance Benefits, other than Executive's rights to the vested portion of Executive's Option and any other rights to which Executive is entitled under the Company's benefit programs.

0.25. Other Rights and Benefits. Nothing in this Agreement shall prevent or limit Executive's continuing or future participation in any benefit, bonus, incentive or other plans, programs, policies or practices provided by the Company and for which Executive may otherwise qualify, nor shall anything herein limit or otherwise affect such rights as Executive may have under other agreements with the Company except as provided in Section 4 and Section 5.1 above. Except as otherwise expressly provided herein, amounts that are vested benefits or that Executive is otherwise entitled to receive under any plan, policy, practice or program of the Company at or subsequent to the date of a Change in Control shall be payable in accordance with such plan, policy, practice or program.

6. DEFINITIONS

For purposes of this Agreement, the following definitions shall apply:

6.

0.26. "***Board***" means the Board of Directors of the Company, or the compensation committee thereof, as determinations or responsibilities may be delegated by the Board to the compensation committee.

0.27. "***Cause***" shall mean a determination by the Company based upon reasonably available information of Executive's: (i) unauthorized use or disclosure of the Company's confidential information or trade secrets; (ii) material breach of any agreement to which the Executive and the Company are a party; (iii) material failure to comply with the Company's written policies or rules; (iv) conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State; (v) negligence or willful misconduct relating to Executive's performance of her duties on behalf of the Company; (vi) continuing failure to perform material and lawful assigned duties after receiving thirty (30) days' written notification of the failure from the Company if such breach is not cured (if curable) during that thirty (30) day period; (vii) failure to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested Executive's cooperation without prejudice or personal liability to Executive; (viii) violation of employee or ethical guidelines including, without limitation, violations of business practices and ethics commonly in place in similar companies in the United States; or (ix) violation of the Company code of conduct and/or any contractual code of conduct to which the Company is obligated.

0.28. "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

a) Any natural person, entity or group within the meaning of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as amended ("***Exchange Act Person***"), becomes the owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (i) on account of the acquisition of securities of the Company by any institutional investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions that are primarily a private financing transaction for the Company or (ii) solely because the level of ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

b) There is consummated a merger, consolidation or similar transaction involving, directly or indirectly, the Company if, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (i) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (ii) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction; or

c) There is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportion as their ownership of the Company immediately prior to such sale, lease, license or other disposition.

The term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company. Notwithstanding the foregoing or any other provision of this Agreement, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any affiliate and the participant shall supersede the foregoing definition with respect to stock awards subject to such agreement (it being understood, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply).

0.29. "***Change in Control Benefits Period***" means the period of twelve (12) months commencing on the Termination Date.

0.30. "***Change in Control Severance Period***" means the period of twelve (12) months commencing on the Termination Date.

0.31. "***Change in Control Termination***" means an "***Involuntary Termination Without Cause***" or "***Resignation for Good Reason***," either of which occurs within three (3) months prior to or upon or within twelve (12) months following the closing of a Change in Control or Dissolution Event, provided that any such termination is a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h). Death and disability shall not be deemed Change in Control Terminations.

0.32. "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

0.33. "***Code***" means the Internal Revenue Code of 1986, as amended.

0.34. "***Company***" means Ovid Therapeutics Inc. or, following a Change in Control, the surviving entity resulting from such transaction, or any subsequent surviving entity resulting from any subsequent Change in Control.

0.35. "***Confidentiality Agreement***" means Senior Executive Confidential Information and Invention Assignment Agreement with the Company, (or any successor agreement thereto).

0.36. "***Covered Termination***" means an "***Involuntary Termination Without Cause***" or "***Resignation for Good Reason***," provided that any such termination is a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h). Death and disability, other than a Permanent Disability, shall not be deemed Covered Terminations. If an Involuntary Termination Without Cause or

Resignation for Good Reason qualifies as a Change in Control Termination, it shall not constitute a Covered Termination.

0.37. "***Covered Termination Benefits Period***" means the period of twelve (12) months commencing on the Termination Date.

0.38. "***Covered Termination Severance Period***" means the period of twelve (12) months commencing on the Termination Date.

0.39. "***Dissolution Event***" means the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur.

0.40. "***Involuntary Termination Without Cause***" means Executive's dismissal or discharge by the Company for reasons other than Cause and other than as a result of death or disability; *provided*, *however*, that for purposes of a Covered Termination, Involuntary Termination Without Cause shall include Executive's dismissal or discharge by the Company for reasons of Permanent Disability.

0.41. "***Monthly Base Salary***" means $1/12^{th}$ of Executive's Annual Base Salary (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect on the date of a Covered Termination or Change in Control Termination.

0.42. "***Permanent Disability***" means total and permanent disability as defined in Code Section 22(e)(3).

0.43. "***Resignation for Good Reason***" means Executive's resignation from all employee positions Executive then holds with the Company within ninety (90) days following any of the following events taken without Executive's consent, provided Executive has given the Company written notice of such event within thirty (30) days after the first occurrence of such event and the Company has not cured such event within thirty (30) days thereafter:

a) A material decrease in Executive's Annual Base Salary, other than in connection with a decrease in compensation for all comparable executives of the Company;

b) A relocation of Executive's principal place of work outside of a fifty (50) mile radius of its current location; or

c) The Company's material breach of this Agreement.

0.44. "***Termination Date***" means the effective date of a Change in Control Termination, a Covered Termination, a termination for Cause or any other circumstance under which the employment relationship between Executive and the Company terminates, as applicable.

0.45. "***Division***" shall mean only that part, unit or therapeutic category of a larger entity that is competitive with the Company, but not an entire company itself, if other divisions, units or therapeutic categories of such larger company are not competitive with the Company.

0.46. "***Client***" shall mean (A) anyone who is a client of the Company as of, or at any time during the one-year period immediately preceding, the termination of Executive's employment, but only if Executive had a direct relationship with, supervisory responsibility for or otherwise were involved with such client during Executive's employment with the Company; and (B) any prospective client to whom the Company made a new business presentation (or similar offering of services) at any time during the one-year period immediately preceding, or six-month period immediately following, Executive's employment termination (but only if initial discussions between the Company and such prospective client relating to the rendering of services occurred prior to the termination date, and only if Executive participated in or supervised such presentation and/or its preparation or the discussions leading up to it).

0.47. "***Solicit***" shall mean: (A) active solicitation of any Client or Company employee, board member, advisor, consultant, collaborator, investigator or agents; (B) the provision of information regarding any Client or Company employee, board member, advisor, consultant, collaborator, investigator or agents to any third party where such information could be useful to such third party in attempting to obtain business from such Client or attempting to hire any such Company employee; (C) participation in any meetings, discussions, or other communications with any third party regarding any Client or Company employee, board member, advisor, consultant, collaborator, investigator or agents where the purpose or effect of such meeting, discussion or communication is to obtain business from such Client or employ such Company employee; and (D) any other passive use of information about any Client or Company employee, board member, advisor, consultant, collaborator, investigator or agents which has the purpose or effect of assisting a third party or causing harm to the business of the Company.

7. GENERAL PROVISIONS

7.

0.48. Employment Status. This Agreement does not constitute a contract of employment or impose upon Executive any obligation to remain as an employee, or impose on the Company any obligation (i) to retain Executive as an employee, (ii) to change the status of Executive as an at-will employee or (iii) to change the Company's policies regarding termination of employment.

0.49. Notices. Any notices provided hereunder must be in writing, and such notices or any other written communication shall be deemed effective upon the earlier of personal delivery (including personal delivery by facsimile or email transmission (to a facsimile number or email address designated in advance by the receiving party)) or the third day after mailing by first class mail, to the Company at its primary office location and to Executive at Executive's address as listed in the Company's payroll records. Any payments made by the Company to Executive under the terms of this Agreement shall be delivered to Executive either in person or at the address as listed in the Company's payroll records.

0.50. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is determined to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law.

0.51. Waiver. If either party should waive any breach of any provisions of this Agreement, he, she or it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

0.52. Complete Agreement. This Agreement, together with **Exhibits A** thru **D**, the Confidentiality Agreement and the Indemnification Agreement, forms the complete and exclusive statement of Executive's employment agreement with the Company, and supersedes and replaces any other agreements or promises made to Executive by anyone, whether oral or written (including but not limited to the Prior Agreement).

0.53. Amendment or Termination of Agreement; Continuation of Agreement. Except for those changes expressly reserved to the Company's or the Board's discretion in this Agreement, this Agreement may be changed or terminated only upon the mutual written consent of the Company and Executive. The written consent of the Company to a change or termination of this Agreement must be signed by an executive officer of the Company (other than Executive) after such change or termination has been approved by the Board. Unless so terminated, this Agreement shall continue in effect for as long as Executive continues to be employed by the Company or by any surviving entity following any Change in Control. For the avoidance of any doubt, if, following a Change in Control, Executive continues to be employed by the surviving entity without a Change in Control Termination and the surviving entity then undergoes a Change in Control, following which Executive is terminated by the subsequent surviving entity in a Change in Control Termination, Executive shall receive the benefits described in Section 3 hereof.

0.54. Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement. Facsimile and electronic image copies of signatures shall be equivalent to original signatures.

0.55. Headings. The headings of the Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

0.56. Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive, and the Company, and any surviving entity resulting from a Change in Control and upon any other person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company, and their respective successors, assigns, heirs, executors and administrators, without regard to whether or not such person actively assumes any rights or duties hereunder; *provided*, *however*, that Executive may not assign any duties hereunder and may not assign any rights hereunder without the written consent of the Company, which consent shall not be withheld unreasonably.

0.57. Choice of Law. This Agreement shall be construed and enforced in accordance with the laws of the State of New York without regard to conflicts of law principles.

0.58. Arbitration. To ensure the rapid and economical resolution of any disputes that may arise under or relate to this Agreement or Executive's employment relationship, Executive and the Company agree that, unless otherwise prohibited by applicable law, any and all disputes, claims, or causes of action, in law or equity, arising from or relating to the performance, enforcement, execution, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment (collectively, "***Claims***"), shall be resolved by final, binding, and (to the extent permitted by law) confidential arbitration before a single arbitrator in New York, New York. Executive and the Company agree that they shall resolve all such Claims in accordance with the provisions of Section 12 of the Confidential Information and Invention Assignment Agreement attached hereto as Exhibit A.

0.59. Construction of Agreement. In the event of a conflict between the text of this Agreement and any summary, description or other information regarding this Agreement, the text of this Agreement shall control.

0.60. Circular 230 Disclaimer. **THE FOLLOWING DISCLAIMER IS PROVIDED IN ACCORDANCE WITH THE INTERNAL REVENUE SERVICE'S CIRCULAR 230 (21 C.F.R. PART 10). ANY TAX ADVICE CONTAINED IN THIS AGREEMENT IS INTENDED TO BE PRELIMINARY, FOR DISCUSSION PURPOSES ONLY**

AND NOT FINAL. ANY SUCH ADVICE IS NOT INTENDED TO BE USED FOR MARKETING, PROMOTING OR RECOMMENDING ANY TRANSACTION OR FOR THE USE OF ANY PERSON IN CONNECTION WITH THE PREPARATION OF ANY TAX RETURN. ACCORDINGLY, THIS ADVICE IS NOT INTENDED OR WRITTEN TO BE USED, AND IT CANNOT BE USED, BY ANY PERSON FOR THE PURPOSE OF AVOIDING TAX PENALTIES THAT MAY BE IMPOSED ON SUCH PERSON.

REVIEWED, UNDERSTOOD AND ACCEPTED:

OVID THERAPEUTICS INC.		**EXECUTIVE**	
By:	______________________	By:	______________________
Name:	Suzanne K. Wakamoto	Name:	Jeff Rona
Title:	SVP, Human Resources		

Exhibit 31.1

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

I, Jeremy M. Levin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ovid Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2021

By: /s/ Jeremy M. Levin
Jeremy M. Levin
Chief Executive Officer
(Principal Executive Officer)

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

I, Jeffrey Rona, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ovid Therapeutics Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 13, 2021

By: /s/ Jeffrey Rona
Jeffrey Rona
Chief Business and Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jeremy M. Levin, Chief Executive Officer of Ovid Therapeutics Inc. (the “Company”), and Jeffrey Rona, Chief Business and Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2021, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 13, 2021

/s/ Jeremy M. Levin	/s/ Jeffrey Rona
Jeremy M. Levin	Jeffrey Rona
Chief Executive Officer (Principal Executive Officer)	Chief Business and Financial Officer (Principal Financial and Accounting Officer)