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, 2017

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 No.)**
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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	☒ (Do not check if a small reporting company)	Small 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 10, 2017, the registrant had 24,601,936 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. 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," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" and elsewhere in this report, regarding, among other things:

- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- 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 maintain and establish 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.

You should not rely upon 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 are under no duty to update or revise any of the forward-looking statements, whether because of new information, future events or otherwise, after the date of this report.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

OVID THERAPEUTICS INC.
Condensed Balance Sheets (unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 106,115,648	$ 51,939,661
Prepaid and other current assets	1,195,669	221,507
Due from related parties	-	7,369
Deferred transaction costs	-	242,673
Total current assets	107,311,317	52,411,210
Security deposit	430,275	407,785
Property, plant and equipment, net	49,798	43,591
Other assets	215,748	165,301
Total assets	$ 108,007,138	$ 53,027,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,571,534	$ 857,169
Accrued expenses	3,493,493	2,876,243
Total current liabilities	7,065,027	3,733,412
Stockholders' Equity:		
Common stock, $0.001 par value; 125,000,000 and 58,000,000 shares authorized at June 30, 2017 and December 31, 2016, respectively, 24,601,936 and 9,838,590 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	24,602	9,839
Preferred Series A - zero and 5,121,453 shares authorized at June 30, 2017 and December 31, 2016, respectively zero and 2,382,069 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	2,382
Preferred Series B - zero and 12,038,506 shares authorized at June 30, 2017 and December 31, 2016, respectively zero and 5,599,282 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	5,599
Additional paid-in-capital	181,314,312	85,186,269
Accumulated deficit	(80,396,803)	(35,909,614)
Total stockholders' equity	100,942,111	49,294,475
Total liabilities and stockholders' equity	$ 108,007,138	$ 53,027,887

See accompanying notes to these unaudited condensed financial statements

OVID THERAPEUTICS INC.
Condensed Statements of Operations and Comprehensive Loss (unaudited)

	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016
Operating expenses:				
Research and development	$ 6,074,927	$ 1,770,202	$ 37,359,355	$ 2,896,804
General and administrative	4,213,173	3,646,731	7,191,039	6,234,624
Total operating expenses	10,288,100	5,416,933	44,550,394	9,131,428
Loss from operations	(10,288,100)	(5,416,933)	(44,550,394)	(9,131,428)
Interest income	39,721	31,307	63,205	63,636
Net loss and comprehensive loss	$ (10,248,379)	$ (5,385,626)	$ (44,487,189)	$ (9,067,792)
Net loss attributable to common stockholders	$ (10,248,379)	$ (5,385,626)	$ (44,487,189)	$ (9,067,792)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.55)	$ (3.18)	$ (0.92)
Weighted-average common shares outstanding basic and diluted	18,112,554	9,838,590	13,998,428	9,838,590

See accompanying notes to these unaudited condensed financial statements

OVID THERAPEUTICS INC.
Condensed Statement of Changes in Stockholders' Equity (unaudited)

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Series B-1 Preferred Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2016	9,838,590	$ 9,839	2,382,069	$ 2,382	5,599,282	$ 5,599	-	$ -	$ 85,186,269	$ (35,909,614)	$ 49,294,475
Issuance of Series B-1 Preferred Stock	-	-	-	-	-	-	1,781,996	1,782	25,859,446	-	25,861,228
Proceeds from Initial Public Offering, net of underwriting costs and commissions	5,000,000	5,000	-	-	-	-	-	-	69,745,000	-	69,750,000
Deferred offering costs reclassified to additional paid-in capital	-	-	-	-	-	-	-	-	(3,087,481)	-	(3,087,481)
Conversion of preferred stock into common stock	9,763,346	9,763	(2,382,069)	(2,382)	(5,599,282)	(5,599)	(1,781,996)	(1,782)	(464)	-	(464)
Stock-based compensation expense	-	-	-	-	-	-	-	-	3,611,542	-	3,611,542
Net loss	-	-	-	-	-	-	-	-	-	(44,487,189)	(44,487,189)
Balance, June 30, 2017	24,601,936	$ 24,602	-	$ -	-	$ -	-	$ -	$ 181,314,312	$ (80,396,803)	$ 100,942,111

See accompanying notes to these unaudited condensed financial statements

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

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Cash flows from operating activities:		
Net loss	$ (44,487,189)	$ (9,067,792)
Adjustments to reconcile net loss to cash used in operating activities:		
Noncash research and development expense	25,861,228	-
Stock-based compensation expenses	3,611,542	1,497,726
Depreciation and amortization	37,555	14,569
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(834,314)	(673,195)
Deferred transaction costs	(496,657)	(21,103)
Security deposit	(22,490)	(7,500)
Accounts payable	2,564,072	298,898
Accrued expenses	616,785	422,973
Due from/ to related parties	7,369	57,816
Deferred rent	-	23,675
Net cash used in operating activities	(13,142,099)	(7,453,933)
Cash flows from investing activities:		
Purchase of property and equipment	(21,998)	(21,950)
Software development and other assets	(61,766)	(13,500)
Net cash used in investing activities	(83,764)	(35,450)
Cash flows from financing activities:		
Proceeds from initial public offering, net of offering expenses	67,401,850	-
Net cash provided by financing activities	67,401,850	-
Net increase (decrease) in cash and cash equivalents	54,175,987	(7,489,383)
Cash and cash equivalents, at beginning of period	51,939,661	69,944,292
Cash and cash equivalents, at end of period	$ 106,115,648	$ 62,454,909

See accompanying notes to these unaudited condensed 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, raising capital, and has financed its operations through issuance of convertible preferred stock ("Preferred Stock"), common stock and other equity instruments. The Company has not generated any revenue. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, 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.

On May 10, 2017, the Company completed its initial public offering ("IPO") of 5,000,000 shares of the Company's common stock at a public offering price of $15.00 per share. The gross proceeds from the IPO were $75.0 million and the net proceeds were $66.7 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. At the time of the IPO the Series A Preferred Stock, the Series B Preferred Stock, and the Series B-1 Preferred Stock were converted into common stock (see Note 6).

The Company has incurred operating losses since inception and had an accumulated deficit of $80.4 million as of June 30, 2017. The Company expects to continue to incur net losses for at least the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt or equity financing to fund its operations. Management believes that the Company's existing cash and cash equivalents as of June 30, 2017, will be sufficient to fund its current operating plans through at least the next 12 months. Management expects that future sources of funding may include new or expanded partnering arrangements and sales of equity or debt securities. 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 business strategies. 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.

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 Prospectus that forms a part of the Company's Registration Statement on Form S-1 (File No. 333-217245), which was filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424 on May 5, 2017 (the "Prospectus"). There have been no material changes to the significant accounting policies during the period ended June 30, 2017, except for those listed below.

(A) Unaudited Interim Condensed Financial Statements

The interim condensed balance sheet at June 30, 2017, and the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2017 and 2016, changes in stockholder's equity for the six months ended June 30, 2017, and cash flows for the six months ended June 30, 2017 and 2016 are unaudited. The accompanying unaudited condensed 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 can be condensed or omitted. These condensed 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, 2017 and 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other future annual or interim period. The balance sheet as of December 31, 2016 included herein was derived from the audited financial statements as of that date. These interim condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2016.

(B) Reverse Stock Split

In connection with the IPO, the Board of Directors and the stockholders of the Company approved a one-for-2.15 reverse stock split of the Company's issued and outstanding common stock and preferred stock. The reverse stock split became effective on May 1, 2017. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

(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 expenses during the reporting period. Actual results could differ materially from those estimates.

(D) Collaboration Arrangement

License and Collaboration Agreement with Takeda Pharmaceutical Company Limited

The Company accounts for the license and collaboration agreement with Takeda Pharmaceutical Company Limited ("Takeda") in accordance with Accounting Standard Codification ("ASC") 808 – "Collaborative Arrangements." As Ovid and Takeda are sharing 50/50 in the drug development and throughout the life of this compound, the Company records 50% of the net expenses of the development costs in research and development. When Ovid incurs the majority of the costs and Takeda transfers a payment to Ovid to equalize the costs, Ovid records the participation by Takeda as a reduction of its research and development expenses, as the parties under the collaboration are sharing in the costs and the payment represents reimbursement of costs by Takeda. When Takeda incurs the majority of the costs and Ovid transfers a payment to Takeda (to equalize the costs), Ovid records the participation in Takeda's expenses as research and development costs in its statement of operations, as Ovid and Takeda are sharing in the research and development activities and this participation represents Ovid's share of the research and development costs in the specific period.

(E) Recent Accounting Pronouncements

Recent accounting standards which have been adopted

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU 2016-09 simplifies various aspects of the accounting for share-based payments. The simplifications include: (a) recording all tax effects associated with stock-based compensation through the income statement, as opposed to recording certain amounts in other paid-in capital, which eliminates the complications of tracking a "windfall pool," but will increase the volatility of income tax expense; (b) allowing entities to withhold shares to satisfy the employer's statutory tax withholding requirement up to the highest marginal tax rate applicable to employees rather than the employer's minimum statutory rate, without requiring liability classification for the award; (c) modifying the requirement to estimate the number of awards that will ultimately vest by providing an accounting policy election to either estimate the number of forfeitures or recognize forfeitures as they occur; and (d) changing certain presentation requirements in the statement of cash flows, including removing the requirement to present excess tax benefits as an inflow from financing activities and an outflow from operating activities, and requiring the cash paid to taxing authorities arising from withheld shares to be classified as a financing activity. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period.

The Company early adopted ASU 2016-09 as of September 30, 2016 on a retroactive basis to the beginning of the period. In connection with the early adoption, the Company elected an accounting policy to record forfeitures as they occur. There was no financial statement impact upon adoption for the above accounting policy election. In addition, there was no financial statement impact of adopting ASU 2016-09 provisions regarding recognition of tax effects associated with stock-based compensation as the Company is in a net operating loss ("NOL") position with a full valuation allowance. Also, for the period from inception through December 31, 2016, the Company did not record an income statement benefit for excess tax benefits as there were no exercises of options during the period.

New accounting standards which have not yet been adopted

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting. This new standard clarifies when to account for a change to the terms or conditions of share-based payment award as a modification. Under the new guidance, modification accounting is required unless the fair value, the vesting conditions, or the classification of the award remain the same as the original award. ASU 2017-09 is effective for public companies for fiscal years beginning on or after December 15, 2017. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. This new standard clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires, among others, that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. ASU 2017-01 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. ASU 2016-15 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on the Company's statements of cash flows upon adoption.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)." ASU 2016-02 was issued to increase transparency and comparability among entities by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about lease arrangements. ASU 2016-02 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact of adopting ASU 2016-02 on the Company's results of operations and financial position.

NOTE 3 – PRECLINICAL AND CLINICAL AGREEMENTS

On May 5, 2016, the Company entered into a Start Up Agreement ("SUA") with a clinical research organization for the study entitled "Safety and Efficacy of Gaboxadol in Angelman Syndrome: A Phase 2 Study of OV101 in adolescents and adults." Under the terms of the SUA, as amended, the direct fees and pass-through expenses are not to exceed $854,463 and $584,267, respectively, (a) without prior written authorization from the Company or (b) in the event of early termination which triggers necessary wind down activities. The term of the SUA, as amended, expired on August 31, 2016.

On August 26, 2016, the Company entered into a Master Services Agreement ("MSA") with a clinical research organization replacing the above mentioned SUA. In connection with the execution of the MSA, the Company provided an upfront retainer of $355,435. This retainer has been reflected within security deposits on the balance sheet. During the six months ended June 30, 2017, the Company has expensed approximately $2,144,541 related to both the MSA and the SUA.

In the normal course of business, the Company enters into various firm purchase commitments related to certain preclinical studies and clinical trials. As of June 30, 2017, the noncancellable commitments totaled approximately $420,000 of which $82,558 has been paid as of June 30, 2017, and the balance is expected to be paid within the next fiscal year.

NOTE 4 – PROPERTY AND EQUIPMENT AND INTANGIBLE ASSETS

Property and equipment is summarized as follows:

	June 30, 2017	December 31, 2016
Furniture and equipment	$ 85,781	$ 63,783
Less accumulated depreciation	(35,983)	(20,192)
Total property, plant and equipment, net	$ 49,798	$ 43,591

Depreciation expense was $11,984 and $7,053 for the six months ended June 30, 2017 and 2016, respectively. Depreciation expense was $6,655 and $3,993 for the three months ended June 30, 2017 and 2016, respectively.

Intangible assets, net of accumulated amortization, were $131,100 and $110,073 as of June 30, 2017 and December 31, 2016, respectively, and are included in other assets. Amortization expense was $25,571 and $7,513 for the six months ended June 30, 2017 and 2016, respectively. Amortization expense was $12,437 and $4,680 for the three months ended June 30, 2017 and 2016, respectively.

NOTE 5 – ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30, 2017	December 31, 2016
Collaboration agreement accrual	$ 1,242,042	$ -
Payroll and bonus accrual	866,887	1,324,649
Professional fees accrual	697,329	874,525
Clinical trials accrual	562,915	409,804
Other	124,320	267,265
Total	$ 3,493,493	$ 2,876,243

NOTE 6 – STOCKHOLDERS' EQUITY AND PREFERRED STOCK

The Company's capital structure consists of common stock and preferred stock with certain rights and privileges summarized below.

The Company was initially authorized to issue 1,000 shares of common stock at $0.001 par value per share. The eighth amendment to the Company's certificate of incorporation was made on January 6, 2017 to increase the authorized shares of common stock available for issuance to 62,000,000 at $0.001 par value, and shares of Preferred Stock to 20,991,252.

On May 10, 2017, the Company filed an amended and restated certificate of incorporation with the Secretary of the State of Delaware, which was approved by the Company's Board of Directors and stockholders on April 12, 2017 and April 24, 2017, respectively, and which went effective immediately after the closing of the Company's IPO on May 10, 2017. Pursuant to the amended and restated certificate of incorporation, the Company is authorized to issue 125,000,000 shares of common stock and 10,000,000 shares of preferred stock. Upon completion of its IPO, on May 10, 2017, the Company issued 5,000,000 shares of its common stock, and 2,382,069 shares of Series A Preferred Stock, 5,599,282 shares of Series B Preferred Stock and 1,781,996 shares Series B-1 Preferred Stock were converted into 9,763,346 shares of common stock.

NOTE 7 – STOCK-BASED COMPENSATION

On August 29, 2014, the Company's Board of Directors adopted and approved the 2014 Equity Incentive Plan (the "2014 Plan"), which authorized the Company to grant shares of common stock in the form of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock and restricted stock units. The types of stock-based awards, including share purchase rights amount, terms, and exercisability provisions of grants are determined by the Company's Board of Directors. The purpose of the 2014 Plan is to provide the Company with the flexibility to issue stock-based awards as part of an overall compensation package to attract and retain qualified personnel.

The Company's Board of Directors adopted and the Company's stockholders approved the 2017 equity incentive plan ("2017 Plan"), which became effective immediately prior to the execution of the underwriting agreement related to the IPO on May 4, 2017. The initial reserve of shares of common stock that may be issued under the 2017 Plan is 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 2014 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 IPO on May 4, 2017. The initial reserve of shares of common stock that may be issued under the 2017 ESPP is 279,069 shares. No offering periods under the 2017 ESPP had been initiated as of June 30, 2017.

Unless specified otherwise in an individual option agreement, stock options granted under the 2014 Plan and 2017 Plan generally have a ten-year term and a four-year vesting period. The vesting requirement is conditioned upon 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 twelve months.

Performance-based option awards generally have similar vesting terms, with vesting commencing on the date the performance condition is achieved and expire in accordance to the specific terms of the agreement. At June 30, 2017, there were 46,511 performance-based options outstanding and unvested.

The fair value of options granted during the six months ended June 30, 2017 and 2016 was estimated using the Black-Scholes option valuation model. The inputs for the Black-Scholes valuation model require management's significant assumptions and are detailed in the table below. Prior to the IPO, the common stock price was determined by the Board of Directors. In the absence of market data for the Company's common stock, the Board of Directors considered various factors in estimating the fair value of the common stock at the time of each option grant which included but was not limited to the common stock valuation performed by a third party independent valuation firm, the Company's performance and future economic outlook, the potential financing available to the Company, and the valuation of common stock of similar companies in the industry. 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 Nos. 107 and 110 as the Company's shares just recently became publicly traded. 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 cancelled. Unvested nonemployee options are marked-to-market at each reporting period.

The Company granted 27,906 and 34,882 stock options to nonemployee consultants for services rendered during the six months ended June 30, 2017 and 2016, respectively. There were 51,600 and 85,754 unvested nonemployee options outstanding as of June 30, 2017, and 2016, respectively. Total expense recognized related to the nonemployee stock options for the three months ended June 30, 2017 and 2016 was $72,247 and $37,871, respectively. Total expense recognized related to the nonemployee stock options for the six months ended June 30, 2017 and 2016 was $306,205 and $69,075, respectively. Total unrecognized compensation expenses related to the nonemployee stock options was $432,899 as of June 30, 2017. During the six months ended June 30, 2017, the Company recognized $162,700 in expenses for non-employee performance-based option awards.

The Company granted 1,302,084 and 577,434 stock options to employees during the six months ended June 30, 2017 and 2016 respectively. There were 2,775,620 and 2,083,245 unvested employee options outstanding as of June 30, 2017, and 2016, respectively. Total expense recognized related to the employee stock options for the three months ended June 30, 2017 and 2016 was $2,120,641 and $744,991 respectively. Total expense recognized related to the employee stock options for the six months ended June 30, 2017 and 2016 was $3,305,337 and $1,428,651 respectively. Total unrecognized compensation expense related to employee stock options was $14,106,293 as of June 30, 2017. During the three months ended June 30, 2017, the Company recognized $830,997 in expenses for employee performance-based option awards.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 589,255	$ 355,635	$ 1,259,430	$ 605,086
General and administrative	1,603,633	421,096	2,352,112	892,640
Total	$ 2,192,888	$ 776,731	$ 3,611,542	$ 1,497,726

The fair value of employee options granted during the three and six months ended June 30, 2017 and 2016, respectively, was estimated by utilizing the following assumptions:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
Volatility	79.61%	83.39%	80.53%	83.63%
Expected term in years	6.08	6.06	6.08	6.06
Dividend rate	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	1.93%	1.50%	2.08%	1.50%
Fair value of option on grant date	$ 7.74	$ 5.01	$ 6.34	$ 5.18

The fair value of nonemployee options granted and remeasured during the three and six months ended June 30, 2017 and 2016, respectively, was estimated by utilizing the following assumptions:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
Volatility	78.01%	83.39%	79.57%	83.43%
Expected term in years	4.02	5.16	4.52	5.19
Dividend rate	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	1.72%	1.10%	1.86%	1.20%
Fair value of option on grant date	$ 8.41	$ 4.75	$ 7.53	$ 5.14

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 at December 31, 2016	2,987,729	$ 7.46	8.82	$ 837,036
Granted	1,329,990	9.07	9.61	
Exercised	-	-		
Forfeited	(139,534)	6.26		
Options Outstanding June 30, 2017	4,178,185	$ 8.02	8.77	$ 10,568,518
Vested and expected to vest at June 30, 2017	4,178,185	$ 8.02	8.77	$ 10,568,518
Exercisable at June 30, 2017	1,350,965	$ 7.69	8.42	$ 3,785,547

At June 30, 2017 there was approximately $14,539,192 of unamortized share–based compensation expense, which is expected to be recognized over a remaining average vesting period of 2.88 years.

NOTE 8 – INCOME TAXES

The Company did not record a federal or state income tax provision for the periods presented as it has incurred net losses since inception. In addition, the net deferred tax assets generated form the net operating losses have been fully reserved as the Company believes it is not more likely than not that the benefit will be realized.

On February 15, 2017, the Company was approved for a $200,251 refundable credit towards future New York City tax expense. The credit is for qualified emerging technology companies (“QETCS”) focused on biotechnology located in New York City.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

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, each of our named executive officers is 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 named executive officer's delivery to us of a satisfactory release of claims, and subject to the named executive officer's compliance with non-competition and non-solicitation restrictive covenants for two years following the termination date.

NOTE 10 – COLLABORATION AGREEMENT

Takeda Collaboration

On January 6, 2017, the Company entered into a license and collaboration agreement with Takeda, pursuant to which Takeda granted the Company an exclusive license to commercialize the compound TAK-935, which the Company now refers to as OV935, in certain territories, and a co-exclusive worldwide license, together with Takeda, to develop OV935. In consideration of certain license rights granted to the Company pursuant to the Takeda collaboration, the Company issued 1,781,996 shares of its Series B-1 Preferred Stock (Note 6), pursuant to a Series B-1 preferred stock purchase agreement entered into on January 6, 2017, at an ascribed price per share of $14.513 on January 6, 2017 for an aggregate fair value of $25,861,228, which was recorded as research and development expense at the date of the transaction. Under the Takeda collaboration, the Company is obligated to pay Takeda future payments if and when certain milestones are achieved. Upon the first patient enrollment in the first Phase 3 trial for the first of the initial indications the Company and Takeda are focusing on in the Takeda collaboration, the Company is obligated to issue to Takeda the number of unregistered shares of the Company's common stock equal to the lesser of (a) 8% of the Company outstanding capital stock on the issuance date or (b) $50.0 million divided by the applicable share price, unless certain events occur. The remaining potential global commercial and regulatory milestone payments equal approximately $35.0 million and can be satisfied in cash or unregistered shares of the Company's common stock at its election, unless certain events occur. During the three and six months ended June 30, 2017, the Company recognized $1,242,042 and $2,776,148 respectively, in research and development expenses representing research and development expenses reimbursed to Takeda in respect of this collaboration agreement. The 1,781,996 shares of Series B-1 Preferred Stock held by Takeda was automatically converted into 1,781,996 shares of the Company's common stock upon the completion of its IPO. As of June 30, 2017, $1.5 million was included within accounts payable.

The Takeda collaboration will expire upon the cessation of commercialization of the products by both the Company and Takeda. Either party may terminate the Takeda collaboration because of the other party's uncured material breach or insolvency, for safety reasons, or, after completion of the first proof of mechanism clinical trial, for convenience. Takeda may terminate the Takeda collaboration for the Company's (or the Company's sublicensee's) challenge to the patents licensed under the Takeda collaboration. If the collaboration is terminated by Takeda for material breach by the Company, bankruptcy or patent challenge or by the Company for convenience or safety reasons, the Company's rights to the products will cease, the Company will transition all activities related to the products to Takeda, and the Company will grant Takeda an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by the Company to commercialize OV935 and products containing OV935 for the treatment of certain rare neurological disorders. If the collaboration is terminated by the Company for Takeda's material breach or bankruptcy or by Takeda for convenience or safety reasons, Takeda's rights to the products will cease, Takeda will transition all activities related to the products to us, and Takeda will grant us an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to commercialize OV935 and products containing OV935 for the treatment of certain rare neurological disorders.

NOTE 11 – RELATED PARTY TRANSACTIONS

As of December 31, 2016, amounts due from related parties represented travel related expenses.

NOTE 12 – NET LOSS PER SHARE

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the Preferred Stock and options have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares outstanding used to calculate both basic and diluted loss per common share are the same.

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

	For the Six Months Ended June 30,	
	2017	2016
Stock options to purchase common stock	4,178,185	2,565,796
Preferred stock convertible into common stock	-	7,981,351
Total	4,178,185	10,547,147

NOTE 13 – SUBSEQUENT EVENTS

Equity Awards

On August 8, 2017, the Company granted a performance-based option award for 50,000 shares to an employee with an exercise price of $7.17 per share.

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 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 Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-217245), which was filed with the SEC pursuant to Rule 424 on May 5, 2017. 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.

Overview

We are a biopharmaceutical company focused exclusively 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; yet has remained underappreciated by the industry. Our experienced team began with a vision to integrate the biology and symptomology of rare neurological conditions to employ innovative research and clinical strategies for the development of our drug candidates. Using recent scientific advances in genetics and the biological pathways of the brain, we have created a proprietary map of disease-relevant pathways to identify and acquire novel compounds for the treatment of rare neurological disorders. We are executing on our strategy by in-licensing and collaborating with leading biopharmaceutical companies and academic institutions. We are developing a robust pipeline of clinical assets with an initial focus on neurodevelopmental disorders and rare developmental and/or epileptic encephalopathies. Our most advanced candidate, OV101, has commenced a Phase 2 trial, which is primarily a safety trial that is designed to provide proof-of-concept on efficacy parameters, in adults with Angelman syndrome. OV101 has also commenced a Phase 1 trial in adolescents with Angelman syndrome or Fragile X syndrome. Along with our collaborator, Takeda Pharmaceutical Company Limited ("Takeda"), in June 2017 we initiated patient recruitment in our Phase 1b/2a trial of OV935 in adults with rare epileptic encephalopathies.

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.

On May 1, 2017, we effected a 1-for-2.15 reverse stock split of our outstanding common stock and convertible preferred stock. Stockholders entitled to fractional shares because of the reverse stock split will receive a cash payment in lieu of receiving fractional shares. All of our historical share and per share information shown in the accompanying unaudited condensed financial statements and related notes have been retroactively adjusted to give effect to this reverse stock split.

On May 10, 2017, we completed our initial public offering (the "IPO"), of 5,000,000 shares of our common stock at a public offering price of $15.00 per share. The gross proceeds from the IPO were $75.0 million and the net proceeds were $66.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

Since our inception, we have not generated any revenue and have funded our business primarily through the sale of our capital stock. Through June 30, 2017, we have raised net proceeds of $142.3 million from the sale of convertible preferred stock and our IPO. As of June 30, 2017, we had $106.1 million in cash and cash equivalents. We recorded net losses of $44.5 million, which includes a non-cash charge of $25.9 million related to our Takeda collaboration and $9.1 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had an accumulated deficit of approximately $80.4 million.

We expect to continue 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 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 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;
- 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.

License and Collaboration Agreement with Takeda Pharmaceutical Company Limited

In January 2017, we entered into a license and collaboration agreement, or the Takeda collaboration, with Takeda Pharmaceutical Company Limited, or Takeda. All activities of the collaboration regarding OV935 will be guided by the Takeda/Ovid "One Team" concept, an integrated and interdisciplinary team from both companies devoted to the successful advancement of OV935 across rare epilepsy syndromes. Under the agreement, we will take the lead in clinical development activities and commercialization of the compound OV935 and products containing this compound for the treatment of certain rare neurological disorders in the United States, Canada, the European Union and Israel. Takeda will take the lead in commercialization of OV935 in Japan and has the option to lead in Asia and other selected geographies. We and Takeda will initially share equally all development and commercialization costs and expenses prior to launch of a product and all revenues and commercialization costs and expenses after launch.

Please see Note 10 of our unaudited financial statements included in this Quarterly Report on Form 10-Q and the sections titled "Business—License and Collaboration Agreements—License and Collaboration Agreement with Takeda" and "Certain Relationships and Related Party Transactions—Series B-1 Convertible Preferred Stock Purchase Agreement with Takeda" in our Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-217245), which was filed with the SEC pursuant to Rule 424 on May 5, 2017, for additional information.

Financial Operations Overview

Revenue

We have not generated any revenue from commercial drug sales and do not expect to generate any revenue 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 also seek to 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:

- fees related to the acquisition of the rights to OV101 and OV935;
- 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 for the foreseeable future 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 that 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 travel expenses, conferences, professional fees for auditing, tax and legal services and facility-related costs.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with being a publicly traded company. These increases will include legal and accounting fees, costs associated with maintaining compliance with The NASDAQ Global Select Market LLC and the Securities and Exchange Commission ("SEC"), directors' and officers' liability insurance premiums and fees associated with investor relations. In addition, if our current or future drug candidates are approved for sale, we expect that we would incur expenses associated with building our commercial and distribution infrastructure.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents maintained in money market funds.

Results of Operations

Comparison of the three months ended June 30, 2017 and 2016

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Change $
	(in thousands)		
Research and development	$ 6,075	$ 1,770	$ 4,305
General and administrative	4,213	3,647	566
Total operating expenses	10,288	5,417	4,871
Loss from operations	(10,288)	(5,417)	(4,871)
Interest income	40	31	9
Loss	(10,248)	(5,386)	(4,862)
Net loss and comprehensive loss	$ (10,248)	$ (5,386)	$ (4,862)

Research and Development Expenses

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Change $
		(in thousands)	
Preclinical and development expense	$ 3,868	$ 459	$ 3,409
Payroll and payroll-related expenses	1,920	1,028	892
Other expenses	287	283	4
Total research and development	$ 6,075	$ 1,770	$ 4,305

Research and development expenses were $6.1 million for the three months ended June 30, 2017 compared to $1.8 million for the three months ended June 30, 2016. The increase of $4.3 million was primarily due to an increase in preclinical and development expenses for the clinical studies of OV101 and our Takeda collaboration expenses related to OV935. During the three months ended June 30, 2017, total research and development expenses consisted of $3.9 million in preclinical and development expenses, of which $1.2 million represents amounts reimbursable to Takeda in respect of the Takeda collaboration, $1.9 million in payroll and payroll-related expenses, of which $0.6 million related to stock-based compensation, due to increased headcount in the research and development department, and $0.3 million in other expenses. During the three months ended June 30, 2016, total research and development expenses consisted of $0.5 million in preclinical and development expenses, $1.0 million in compensation expenses, of which $0.4 million related to stock-based compensation, and $0.3 million in other expenses.

General and Administrative Expenses

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Change $
		(in thousands)	
Payroll and payroll-related expenses	$ 2,852	$ 2,086	$ 766
Legal and professional fees	860	1,279	(419)
General office expenses	501	281	220
Total general and administrative	$ 4,213	$ 3,647	$ 566

General and administrative expenses were $4.2 million for three months ended June 30, 2017 compared to $3.6 million for the three months ended June 30, 2016. The increase of $0.6 million was primarily due to the increase in payroll and payroll-related expenses of $0.8 million because of increased headcount.

Interest Income (Expense), Net

Interest income increased to $40 thousand for the three months ended June 30, 2017 from $31 thousand for the three months ended June 30, 2016. The increase is attributable to increased interest on our cash, and cash equivalents because of the proceeds received from our IPO.

Comparison of the six months ended June 30, 2017 and 2016

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

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016	Change $
		(in thousands)	
Research and development	$ 37,359	$ 2,897	$ 34,462
General and administrative	7,191	6,235	956
Total operating expenses	44,550	9,132	35,418
Loss from operations	(44,550)	(9,132)	(35,418)
Interest income	63	64	(1)
Loss	(44,487)	(9,068)	(35,419)
Net loss and comprehensive loss	$ (44,487)	$ (9,068)	$ (35,419)

Research and Development Expenses

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016	Change $
		(in thousands)	
Preclinical and development expense	$ 33,317	$ 750	$ 32,567
Payroll and payroll-related expenses	3,555	1,795	1,760
Other expenses	487	351	136
Total research and development	$ 37,359	$ 2,897	$ 34,462

Research and development expenses were $37.4 million for the six months ended June 30, 2017 compared to $2.9 million for the six months ended June 30, 2016. The increase of $34.5 million was primarily due to an increase in preclinical and development expenses for the clinical studies of OV101 and the issuance of Series B-1 Preferred Stock to Takeda as an upfront payment upon signing the collaboration agreement for OV935. During the six months ended June 30, 2017, total research and development expenses consisted of $33.3 million in preclinical and development expenses, of which $25.9 million related to the issuance of Series B-1 Preferred Stock associated with the collaboration rights to OV935 and $2.7 million represents amounts reimbursable to Takeda in respect of the Takeda collaboration, $3.6 million in payroll and payroll-related expenses, of which $1.0 million related to stock-based compensation, due to increased headcount in the research and development department, and $0.5 million in other expenses. During the six months ended June 30, 2016, total research and development expenses consisted of $0.8 million in preclinical and development expenses, $1.8 million in compensation expenses, of which $0.6 million related to stock-based compensation, and $0.4 million in other expenses.

General and Administrative Expenses

	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016	Change $
		(in thousands)	
Payroll and payroll-related expenses	$ 4,848	$ 3,475	$ 1,373
Legal and professional fees	1,707	2,244	(537)
General office expenses	636	516	120
Total general and administrative	$ 7,191	$ 6,235	$ 956

General and administrative expenses were $7.2 million for the six months ended June 30, 2017 compared to $6.2 million for the six months ended June 30, 2016. The increase of $1.0 million was primarily due to the increase in payroll and payroll-related expenses of $1.4 million because of increased headcount.

Interest Income

Interest income remained the same at $63 thousand for the six months ended June 30, 2017.

Liquidity and Capital Resources

Overview

As of June 30, 2017, we had total cash and cash equivalents of $106.1 million as compared to $51.9 million as of December 31, 2016. The $54.2 million increase in total cash was due primarily to the receipt of $66.7 million of net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, offset by operating expenses.

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 incurred net losses of approximately $44.5 million, which includes a non-cash charge of $25.9 million related to our Takeda collaboration, and $9.1 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had an accumulated deficit of approximately $80.4 million, working capital of $100.2 million and cash and cash equivalents of $106.1 million.

We believe that our existing cash and cash equivalents as of June 30, 2017 will be sufficient to fund our current operating plans through at least the next 12 months.

Until such time, if ever, as we can generate revenue from drug sales, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaborations, license and development agreements. To the extent that we raise additional capital through future equity offerings or debt financings, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt 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. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue our research and development programs or future commercialization efforts. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements 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, 2017	Six Months Ended June 30, 2016
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (13,142)	$ (7,454)
Investing activities	(84)	(35)
Financing activities	67,402	-
Net increase (decrease) in cash and cash equivalents	$ 54,176	$ (7,489)

Net Cash Used in Operating Activities

Net cash used in operating activities was $13.1 million for the six months ended June 30, 2017 and consisted of net losses of $44.4 million offset by $29.5 million of net non-cash charges, of which $25.9 million related to the issuance of Series B-1 Preferred Stock associated with the collaboration rights to OV935 compared to $6.8 million for the six months ended June 30, 2016 and consisted of net losses of $9.1 million offset by $1.5 million of net non-cash charges. The increase of $6.3 million in net cash used in operating activities was primarily due to an increase in our costs related to our research and development programs and an increase in our payroll and payroll-related expenses as the result of increased headcount as we continue to build our management team and expand our operations.

Net Cash Used in Investing Activities

Net cash used in investing activities was $84 thousand for the six months ended June 30, 2017 compared to $35 thousand for thesix months ended June 30, 2016. The increase in cash used was primarily due to an increase in external software development costs.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $67.4 million for the six months ended June 30, 2017 was primarily due to the receipt of $66.7 million of net proceeds from our IPO, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Contractual Obligations and Commitments

As of June 30, 2017, there were no other material changes in our contractual obligations from those disclosed in our Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-217245), which was filed with the SEC pursuant to Rule 424 on May 5, 2017.

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.

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, or GAAP. 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, 2017, except as described in Note 2 to the unaudited interim condensed financial statements, there were no material changes to our critical accounting policies as reported for the year ended December 31, 2016 as part of our Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-217245), which was filed with the SEC pursuant to Rule 424 on May 5, 2017.

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, 2017, we had cash equivalents of $106.0 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 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. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents in institutional market funds that are comprised of U.S. Treasury and U.S. Treasury-backed repurchase agreements.

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, 2017, 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, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2017. Thus, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On July 25, 2017, a notice of opposition was filed at the Trademark Trial and Appeal Board of the U.S. Patent and Trademark Office (the "Appeal Board") in which Ovid Technologies, Inc. objected to our pending trademark applications for the marks OVID THERAPEUTICS and OVID THERAPEUTICS BOLDMEDICINE (and Design) for pharmaceutical product development and related services based on Ovid Technologies' registrations for the marks OVID and OVIDMD for computer software, computer information services, medical information services, and other services. On July 25, 2017, a petition for cancellation was filed at the Appeal Board in which Ovid Technologies, Inc. seeks cancellation of our trademark registrations for the mark OVID for pharmaceutical product research, development, evaluation, and related services based on Ovid Technologies' registrations for the OVID and OVIDMD marks. The only issue decided in these proceedings is the right to register a trademark and the only remedy is to allow, deny or cancel registration. No form of monetary or injunctive relief is available in these 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.

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since inception in April 2014, we have incurred significant operating losses. Our net loss for the three and six months ended June 30, 2017 was $9.1 million and $44.6 million, respectively. As of June 30, 2017, we had an accumulated deficit of $80.5 million. We expect to continue to incur significant expenses and 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 to building out our management team and infrastructure. It could be several years, if ever, before we have a commercialized drug. 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 the ongoing and planned 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;
- 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.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical products and development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase and profitability could be further delayed if we decide to or are required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities such as the European Medicines Agency, or EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current and future drug candidates. 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.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable 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.

We have a limited operating history and have never generated any revenue from drug sales. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company founded in April 2014. Our operations have consumed substantial amounts of cash since our inception, primarily due to organizing and staffing our company, business planning, raising capital, acquiring assets and undertaking the development of OV101 and OV935. We have not yet demonstrated the ability to complete clinical trials of any of our drug candidates, 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.

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:

- 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, or 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;
- our ability to obtain and maintain 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.

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 in connection with our ongoing and planned activities, particularly as we continue to develop and commercialize our drug candidates, in addition to costs associated with the acquisition or in-licensing of any additional drug candidates we may pursue. Our expenses could increase beyond expectations if the FDA or other regulatory authorities require us to perform clinical and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for our drug candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of June 30, 2017, our cash and cash equivalents was $106.1 million. We believe that the net proceeds from our IPO, together with our existing cash and cash equivalents, will fund our current operating plans through at least the next 12 months. 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.

In any event, we will require more capital to pursue additional preclinical and clinical activities, regulatory approval and the commercialization of our current or future drug candidates. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. 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.

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. For example, in our arrangement with Takeda, upon the achievement of a certain development milestone, we will be obligated to issue to Takeda additional securities equal to up to 8% of our outstanding capital stock in certain situations which will dilute our stockholders. In addition, further dilution may occur if we elect to issue shares of common stock to Takeda as payment for the remaining potential global commercial and regulatory milestone payments, which aggregate to approximately $35.0 million.

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, 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.

We may be required to make significant payments in connection with our licenses of OV101 from Lundbeck and OV935 from Takeda.

We acquired rights to OV101, pursuant to a license agreement with H. Lundbeck A/S, or Lundbeck, in March 2015, or the Lundbeck agreement. Under the Lundbeck agreement, we are subject to significant obligations, including payment obligations upon achievement of specified milestones and royalties on drug sales, as well as other material obligations. We are obligated to pay Lundbeck milestone payments up to an aggregate of $181.0 million upon the achievement of certain development, regulatory and sales milestone events. In addition, we are obligated to pay Lundbeck tiered royalties based on net sales of OV101. If these payments become due under the terms of the Lundbeck agreement, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

We also acquired rights to OV935 pursuant to a license and collaboration agreement with Takeda, or the Takeda collaboration, in January 2017. Under the Takeda collaboration, we are obligated to pay Takeda future payments upon achievement of specified milestones. Upon the first patient enrollment in the first Phase 3 trial for the first of the initial indications we and Takeda are focusing on pursuant to the Takeda collaboration, we are obligated to issue to Takeda the number of unregistered shares of our common stock equal to the lesser of (i) 8% of our outstanding capital stock on the issuance date or (ii) $50.0 million divided by the applicable share price, unless certain events occur. In the event such payment would cause Takeda to own over 19.99% of our outstanding capital stock or other events occur, such payment must be paid in cash. The remaining potential global commercial and regulatory milestone payments equal approximately $35.0 million and can be satisfied in cash or unregistered shares of our common stock at our election, unless certain events occur in which Takeda can require us to pay such payments in cash. If these payments become due under the terms of the Takeda collaboration and we can only pay, or choose to pay, these payments in cash, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future and/or subsequent shifts in our stock ownership (some of which shifts 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 will 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. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows.

Risks Related to the Development and Commercialization of Our Drug Candidates

Our future success is dependent on the successful clinical development, regulatory approval and commercialization of our current and future drug candidates. If we are not able to obtain required regulatory approvals, we 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 will 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.

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 later clinical trials will generate the same 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, although OV101 was observed to have a favorable safety and oral bioavailability profile in previously conducted clinical trials in primary insomnia, OV101 has not been previously tested in human patients with Angelman syndrome and Fragile X syndrome and OV935 has not been tested in patients with rare developmental and/or epileptic encephalopathies and the FDA has not yet made any determination regarding safety and efficacy of either OV101 or OV935 in these indications. The results from preclinical studies of OV101 and OV935 in animal models and the results from the OV101 clinical trials in primary insomnia may not be predictive of the effects of these compounds in human patients with the targeted disease. Our approach of targeting the extrasynaptic GABAA receptor with OV101 and cholesterol 24-hydroxylase with OV935 are both novel and unproven and as such, the cost and time needed to develop OV101 and OV935 is difficult to predict and our efforts may not be successful. If we do not observe favorable results in clinical trials of our drug candidates, we may decide to delay or abandon clinical development of such drug candidate. Any such delay or abandonment could harm our business, financial condition, results of operations and prospects.

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.

Prior to March 2015, we had no involvement with or control over the preclinical and clinical research and development of OV101. We have relied on Lundbeck or its prior licensee to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of OV101 and having correctly collected and interpreted the data from these trials. If the research and development processes or the results of the development programs prior to our acquisition of OV101 prove to be unreliable, this could result in increased costs and delays in the development of OV101, which could adversely affect any future revenue from this drug candidate.

Similarly, we acquired rights to OV935 from Takeda in January 2017. Because we were not involved in the development of OV935 prior to January 2017, we may experience difficulties in the transition of certain development activities from Takeda and its affiliates to us, which may result in delays in clinical trials, as well as problems in our development efforts, particularly if we do not receive all of the necessary products, information, reports and data from Takeda and its affiliates in a timely manner. Further, we have had no involvement with or control over the preclinical and clinical development of OV935 to date. We have relied on Takeda having conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our agreement with Takeda and having correctly collected and interpreted the data from these trials. To the extent any of these has not occurred, expected development time and costs may be increased which could adversely affect any future revenue from this drug candidate.

We may also acquire or in-license additional drug candidates for preclinical or clinical development in the future as we continue to build our pipeline. The risks associated with acquiring or in-licensing current or future drug candidates could result in delays in the commencement or completion of our preclinical studies and clinical trials, if ever, and our ability to generate revenues from our drug candidates may be delayed.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate for its intended indications. Clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;

- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- 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; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Further, clinical endpoints for certain diseases we are targeting, such as Angelman syndrome and Fragile X 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, or 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 institutional review board, or 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, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug, or 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.

Angelman syndrome has no FDA-approved treatments, and the clinical endpoints to obtain approval are not well defined.

We intend to seek a broad indication for OV101 to treat Angelman syndrome. However, Angelman syndrome is characterized by a variety of signs and symptoms, such as delayed development, intellectual disability, severe speech impairment, problems with movement and balance, seizures, sleep disorders and anxiety. In order to obtain a broad indication for treatment of Angelman syndrome from the FDA, we would need to demonstrate efficacy on several of the key symptoms of Angelman syndrome. If we fail to do so, our clinical development may be delayed or our label may be limited. In addition, the FDA has not endorsed any primary efficacy endpoints with respect to development of drugs to treat Angelman syndrome. As a result, we must develop acceptable endpoints and seek the FDA's agreement before seeking approval of OV101. If we fail to reach such an agreement with the FDA as to how to measure efficacy in Angelman syndrome patients in our trials, our clinical development plan will be delayed.

Our primary endpoint in the Phase 2 trial of OV101 in adults with Angelman syndrome is safety. While we are also evaluating indications of efficacy as exploratory endpoints, this is primarily a safety trial that is designed to provide a proof-of-concept on the efficacy parameters. Hence, we do not know whether we will be able to obtain a statistically significant result in any of these exploratory endpoints.

Before we can begin trials for OV101 in adolescents with Angelman syndrome, we will need to complete a Phase 1 pharmacokinetic trial of OV101 initially in adolescents with Angelman syndrome, which may make enrollment and demonstrating efficacy more difficult and time consuming.

The FDA has requested that we obtain certain pharmacokinetic and tolerability data in adolescents prior to enrolling them in our clinical trials. Therefore, we are currently conducting a Phase 2 trial of OV101 initially in adults over the age of 18 with Angelman syndrome. However, genetic testing for Angelman syndrome is fairly new, and most patients who have been conclusively tested for Angelman syndrome are young. Because older patients often do not undergo genetic testing since there are currently no approved therapies for this disorder, we believe that many adult Angelman syndrome patients have not received a confirmed diagnosis of Angelman syndrome. As a result, we may experience difficulties enrolling patients in the trial or we may discover that enrollment takes longer than we anticipate. In addition, certain aspects of Angelman syndrome, such as sleep disturbances, may change with age. As a result, demonstrating a statistically significant and clinical meaningful effect in adults with respect to these symptoms may be more difficult, may take longer or may require more patients than demonstrating an effect in adolescents or pediatric patients.

If we decide to seek approval to treat Angelman syndrome in patients younger than 18, we must include these patients in our clinical trials. However, the FDA may not allow us to enroll children or adolescents in our clinical trials if the pharmacokinetic and tolerability data in these populations are not consistent with the data in adults. If we are unable to enroll children and adolescents in our clinical trials, any approval we receive would be limited to adults, which would significantly reduce the commercial potential of OV101.

We must develop a new formulation of OV101 for use in young children initially, and eventually for infants and toddlers, and we may be unable to successfully develop an appropriate formulation.

Our existing formulation of OV101 is an oral capsule. For use in young pediatric patients, we will need to develop an oral liquid formulation of OV101 or a solid formulation that can be sprinkled on applesauce or similar semi-solid foods. While we have begun developing these formulations, we do not know if our efforts will be successful or if the FDA will agree that the new formulation is comparable to our current formulation. We may experience manufacturing problems such as with solubility or stability or we may discover that the new formulation is less effective than an oral capsule. In addition, we will need to conduct bridging studies to demonstrate that the new formulation is equivalent to our oral capsule, which could result in delays in development and additional costs.

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.

In September 2016, the FDA granted orphan drug designation for OV101 for the treatment of Angelman syndrome. We intend to pursue orphan drug designation for OV101 in additional indications, as well as for OV935 and potential other future drug candidates. 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.

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 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. Our approach to business development, including our efforts to map the biological pathways related to orphan disorders of the brain and our relationships among the pharmaceutical industry, may not result in viable drug candidates for clinical development. 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.

We have limited financial and management resources and, as a result, we may forego or delay 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.

We are heavily dependent on our relationship with Takeda for the development and commercialization of OV935. Any disruption in our relationship with Takeda could lead to delays in, or the termination of, the development of OV935, which would materially harm our business.

We are jointly developing OV935 with Takeda pursuant to the Takeda collaboration, which also granted us intellectual property rights to OV935. The development and commercialization of OV935 is highly dependent upon our relationship with Takeda, including Takeda's responsibility for interactions with regulatory authorities until the first product obtains marketing approval. If for any reason the Takeda collaboration is terminated, or we otherwise lose the intellectual property rights to OV935, our business would be adversely affected. The Takeda collaboration imposes on us rights and obligations, including but not limited to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance and intellectual property

protection. After a negotiated time period, each party has the right to terminate the license for convenience uponsix to twelve months' notice to the other party, which would result in us being unable to co-develop and sell OV935. Further, if we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Takeda, and Takeda may have the right to terminate the license. Takeda could also breach its obligations under the agreement, or may not commit a sufficient amount of resources to satisfy its obligations, which would result in the development of OV935 being materially delayed or terminated.

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.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

Our drug candidates will require clinical testing before we are prepared to submit a new drug application, or NDA, for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our drug candidates or whether any such NDA 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 regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any future clinical trial of our drug candidates, which may delay the commencement of our clinical trials. In addition, we may not succeed in developing and validating disease-relevant clinical endpoints based on insights regarding biological pathways for the disorders we are studying. The clinical trial process is also time-consuming. We estimate that the successful completion of clinical trials of our drug candidates will take at least several years to complete, if not longer. Furthermore, failure can occur at any stage and we could encounter problems that cause us to abandon or repeat clinical trials.

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 Angelman syndrome, Fragile X syndrome and rare developmental and/or epileptic encephalopathies, such as Dravet syndrome, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex, 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. 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. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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, in one of the trials conducted by Lundbeck, there were reports of hallucinations in drug abusers at 30mg and 45mg doses of OV101, which are higher than the 10mg and 15mg doses that were effective for sedation. In addition, some patients treated with OV101 in the Lundbeck Phase 3 trials experienced headaches, nausea and dizziness. Patients in our ongoing or planned clinical trials may experience similar or other side effects after treatment with OV101. If additional clinical experience indicates that any of our current drug candidates, including OV101 and OV935, and any future drug candidates has side effects or causes serious or life-threatening side effects, the development of the 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.

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.

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 of 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;
- 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 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 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.

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.

If we are unable to establish sales and marketing capabilities, or enter into agreements with third parties to market and sell our current or any future drug candidates, we may be unable to generate any revenue from drug sales.

To successfully commercialize any drug candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any drug candidate we may develop will be expensive and time-consuming and could delay any drug launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into additional collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our drug candidates, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our current and future drug candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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, including 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 EMA, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a drug candidate is approved, the FDA or the European Commission, as the case may be, may 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.

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, in particular in the European Union and Israel, 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;
- 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 including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union, Israel and 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 Regulatory Compliance

Our relationships with customers, physicians, and third-party payors will 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.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other health care laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The Patient Protection and Affordable Care Act, as amended, or the PPACA, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The PPACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers, and their respective business associates;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and 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 of drugs from 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 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 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 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 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.

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 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. The PPACA, among other things: (i) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new

Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Additionally, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biologic drugs that are demonstrated to be "biosimilar or interchangeable" with an FDA-approved biologic drug. This new pathway could allow competitors to reference data from biologic drugs already approved after 12 years from the time of approval. This could expose us to potential competition by lower-cost biosimilars even if we commercialize a biologic drug candidate faster than our competitors. Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May, 2017. More recently, the Senate Republicans introduced and then updated a bill to replace the PPACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the PPACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. Each of these measures was rejected by the full Senate. Congress will likely consider other legislation to replace elements of the PPACA. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our drug candidates, if approved, and, accordingly, our financial operations.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that these and 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. Any reduction in reimbursement from Medicare or other government programs 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.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

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.

Pursuant to the Lundbeck Agreement, we obtained an exclusive, worldwide license to develop, manufacture and commercialize OV101 for the treatment of human disease. However, the Lundbeck Agreement permits Lundbeck and certain other entities to manufacture and research OV101 and, in certain situations, to perform additional non-commercial activities involving OV101, all of which could result in new patentable inventions concerning the manufacture or use of OV101. While the Lundbeck Agreement prohibits Lundbeck from filing certain patent applications regarding OV101 and obligates Lundbeck to include certain newly filed patents in the license granted to us, if new patents issue that cover valuable methods for making or using OV101, we would be prohibited from employing such methods to manufacture or use OV101 unless we obtain a license to such patents.

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 September 16, 2011, the Leahy-Smith America Invents Act, or 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, or 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.

We may be unable to prevent third parties from selling, making, promoting, manufacturing, or distributing alternative polymorphic forms of OV101.

We currently have issued patents directed to polymorphic forms of OV101. These patents would not prevent a third-party from creating, making and marketing alternative polymorphic forms that fall outside the scope of these patent claims. There can be no assurance that any such alternative polymorphic forms will not be therapeutically equivalent and/or commercially feasible. In the event an alternative polymorphic form of OV101 is developed and approved for use in indications that we may seek approval for, the marketability and commercial success of OV101, if approved, could be materially harmed.

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 such as OV101, 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.

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, whichcould 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 have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage and distribution, or testing. We will be dependent on third parties to manufacture the clinical supplies of our drug candidates. The drug substance for OV101 was manufactured by Lundbeck. We believe that the drug substance transferred from Lundbeck under the Lundbeck agreement will be sufficient for us to complete our ongoing and future clinical trials. We will also continue to rely on Takeda to provide the drug product supply for our planned clinical trials in OV935.

Further, we also will rely on third-party manufacturers to supply us with sufficient quantities of our drug candidates, including OV101 and OV935, 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 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 nonclinical 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 the good laboratory practices, or GLPs, and good clinical practices, or 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 Conference on 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 nonclinical 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.

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.

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.

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

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.

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

As of June 30, 2017, we had 37 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 of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government

investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a negative impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Risks Related to the Ownership of Our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, and you could lose all or part of your investment

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. 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 pay 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.

Concentration of ownership of our common stock among our existing 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 1, 2017, our executive officers, directors and principal stockholders, in the aggregate, beneficially own shares representing approximately 56.5% of our outstanding common stock.

Takeda, a greater than 5% holder, may receive additional securities upon the achievement of certain development, commercial and regulatory milestones pursuant to the Takeda collaboration. Specifically, we will be obligated to issue additional securities to Takeda equal to the lesser of 8% of our outstanding capital stock or $50.0 million unless certain events occur, and may issue, at our discretion, additional securities to Takeda upon the achievement of other milestones. Further, pursuant to the Series B-1 preferred stock purchase agreement entered into with Takeda in January 2017, or the Takeda stock purchase agreement, Takeda 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.

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. If no, or only a few, analysts publish research or reports about our business, the trading price of our stock would likely decrease. 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.

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.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. All of the stockholders who held shares of our capital stock prior to our IPO are subject to lock-up agreements with the underwriters of our IPO that restrict such stockholders' ability to transfer shares of our common stock that they held prior to the consummation of our IPO. Moreover, holders of an aggregate of approximately 19,601,936 shares of our common stock will have rights, subject to some 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. We recently registered all shares of common stock that we may issue under our equity compensation plans. They can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or 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) 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, or 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, or 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; 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 intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an EGC. For example, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an EGC, which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an EGC, we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. 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 incur increased costs because of operating as a public company, and our management will be required to 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 will need to devote a substantial amount of time to these and other compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 stock purchase 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.

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

On May 10, 2017, we completed our IPO and sold 5,000,000 shares of common stock at the initial public offering price of $15.00 per share, for an aggregate offering of $75.0 million, before underwriting discounts, commissions and offering expenses. We received $66.7 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates.

The offer and sale of the shares in our IPO were registered pursuant to our Registration Statement on Form S-1 (File No. 333-217245), which was declared effective by the SEC on May 4, 2017. Citigroup Global Markets Inc. and Cowen and Company, LLC acted as joint book-running managers for the offering, and William Blair & Company, L.L.C. and JMP Securities LLC acted as co-managers for the offering.

There has been no material change in the planned use of proceeds from our IPO as described in our Prospectus that forms a part of the Company's Registration Statement on Form S-1 (File No. 333-217245), which was filed with the SEC pursuant to Rule 424 on May 5, 2017. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy. We have not used any of the proceeds from the IPO.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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 10, 2017

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

Date: August 10, 2017

By: /s/ Timothy Daly
Timothy Daly
Vice President, Finance and Corporate Controller
(Principal Financial and Accounting Officer)

Exhibit Index

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	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	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 Jeremy M. Levin, effective May 4, 2017 (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-217245), filed with the Commission on April 18, 2017).
10.2	Amended and Restated Executive Employment Agreement between the Company and Amit Rakhit, effective May 4, 2017 (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-217245), filed with the Commission on April 18, 2017).
10.3	Amended and Restated Executive Employment Agreement between the Company and Dirk Haasner, effective May 4, 2017 (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-217245), filed with the Commission on April 18, 2017).
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	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.

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 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)) 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) 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

   (c) 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 10, 2017

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

Exhibit 31.2

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

I, Timothy Daly, certify that:

1. I have reviewed this 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)) 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) 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

   (c) 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 10, 2017

By: /s/ Timothy Daly
Timothy Daly
Vice President, Finance and Corporate Controller
(Principal Financial and 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 Timothy Daly, Vice President, Finance and Corporate Controller 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, 2017, 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 10, 2017

/s/ Jeremy M. Levin
Jeremy M. Levin
Chief Executive Officer

/s/ Timothy Daly
Timothy Daly
Vice President, Finance and Corporate Controller