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 September 30, 2020

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	OVID	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of November 5, 2020, the registrant had 63,435,222 shares of common stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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:

- statements regarding the impact of the COVID-19 pandemic and its effects on our operations, access to capital, research and development and clinical trials and potential disruption in the operations and business of third-party manufacturers, contract research organizations, or CROs, other service providers, and collaborators with whom we conduct business;
- 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. A summary of selected risks associated with our business are set forth below.

Summary of Selected Risks Associated with Our Business

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

- We have incurred significant operating losses since inception and expect to continue to incur substantial operating losses for the foreseeable future.
- We have never generated any revenue from drug sales. Our operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We will require additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our drug development efforts or other operations.
- Our future success is dependent on the successful clinical development, regulatory approval and commercialization of our current and future drug candidates. If we, or our licensees, are not able to obtain required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be adversely affected.
- Because the results of preclinical studies or earlier clinical trials are not necessarily predictive of future results, our drug candidates may not have favorable results in planned or future preclinical studies or clinical trials, or may not receive regulatory approval.
- Interim topline and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes in the final data.

- 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.
- Angelman syndrome has no treatments approved by the U.S. Food and Drug Administration, and the primary clinical endpoint, CGI-I-AS, has not previously been used as a sole primary endpoint in a pivotal clinical trial.
- If we are not successful in discovering, developing and commercializing additional drug candidates, our ability to expand our business and achieve our strategic objectives would be impaired.
- Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.
- Even if our current or future drug candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- 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.
- We are heavily dependent on our relationship with Takeda Pharmaceutical Company Limited ("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 dependent on our relationship with Angelini Pharma Rare Diseases AG ("Angelini") for the development and commercialization of OV101 in the European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey. Any disruption in our relationship with Angelini could lead to delays in the development and achievement of regulatory approval in these countries, which would materially harm our business.
- We may be required to make significant payments in connection with our licenses of OV101 from H. Lundbeck A/S and OV935 from Takeda.
- Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- Coverage and adequate reimbursement may not be available for our current or any future drug candidates, which could make it difficult for us to sell profitably, if approved.
- If we are unable to obtain and maintain patent protection for our current or any future drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our current and any future drug candidates.
- We intend to rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- COVID-19 could adversely impact our business, including our clinical trials and access to capital.
- We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.
- We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

Item 1. Financial Statements.

OVID THERAPEUTICS INC.
Condensed Consolidated Balance Sheets

	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 86,866,275	$ 41,897,144
Short-term investments	-	34,841,969
Related party receivable	648,995	1,131,146
Prepaid expenses and other current assets	2,831,564	1,942,933
Total current assets	90,346,834	79,813,192
Long-term prepaid expenses	599,046	359,539
Security deposit	154,376	135,390
Property and equipment, net	137,799	68,363
Other assets	360,961	467,247
Total assets	$ 91,599,016	$ 80,843,731
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,161,801	$ 3,256,098
Accrued expenses	11,420,475	7,266,706
Deferred revenue, current	3,150,454	-
Related party payable	226,536	10,804
Total current liabilities	17,959,266	10,533,608
Deferred revenue, net of current portion	9,935,512	-
Related party payable - noncurrent	61,200	286,562
Total liabilities	27,955,978	10,820,170
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; Series A convertible preferred stock, 10,000 shares designated, 5,506 and 7,762 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	$ 6	$ 8
Common stock, $0.001 par value; 125,000,000 shares authorized; 63,435,222 and 54,710,322 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	63,435	54,711
Additional paid-in-capital	335,742,193	283,122,894
Accumulated other comprehensive gain	-	2,469
Accumulated deficit	(272,162,596)	(213,156,521)
Total stockholders' equity	63,643,038	70,023,561
Total liabilities and stockholders' equity	$ 91,599,016	$ 80,843,731

See accompanying notes to these unaudited condensed consolidated financial statements

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

	For the Three Months Ended September 30, 2020	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2020	For the Nine Months Ended September 30, 2019
Revenue:				
License revenue	$ 6,914,034	$ —	$ 6,914,034	$ —
Operating expenses:				
Research and development	$ 15,875,295	$ 11,597,633	$ 46,533,610	$ 30,052,432
General and administrative	7,442,401	5,168,103	20,220,160	14,089,106
Total operating expenses	23,317,696	16,765,736	66,753,770	44,141,538
Loss from operations	(16,403,662)	(16,765,736)	(59,839,736)	(44,141,538)
Other (expense) income, net	(21,127)	131,164	833,661	649,504
Net loss	$ (16,424,789)	$ (16,634,572)	$ (59,006,075)	$ (43,492,034)
Net loss attributable to common stockholders	$ (16,424,789)	$ (16,634,572)	$ (59,006,075)	$ (43,492,034)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.43)	$ (1.04)	$ (1.21)
Weighted-average common shares outstanding basic and diluted	59,406,215	38,504,825	56,586,640	35,872,441

See accompanying notes to these unaudited condensed consolidated financial statements

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

	For the Three Months Ended September 30, 2020	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2020	For the Nine Months Ended September 30, 2019
Net loss	$ (16,424,789)	$ (16,634,572)	$ (59,006,075)	$ (43,492,034)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	-	-	(2,469)	1,829
Comprehensive loss	$ (16,424,789)	$ (16,634,572)	$ (59,008,544)	$ (43,490,205)

See accompanying notes to these unaudited condensed consolidated financial statements

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

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
Balance, December 31, 2019	7,762	$ 8	54,710,322	$ 54,711	$ 283,122,894	$ 2,469	$ (213,156,521)	$ 70,023,561
ATM offering costs	-	-	-	-	2,053	-	-	2,053
Stock-based compensation expense	-	-	-	-	1,302,931	-	-	1,302,931
Issuance of common stock from employee stock purchase plan	-	-	43,743	43	83,067	-	-	83,110
Other comprehensive income	-	-	-	-	-	63,235	-	63,235
Net loss	-	-	-	-	-	-	(20,030,090)	(20,030,090)
Balance, March 31, 2020	7,762	8	54,754,065	54,754	284,510,945	65,704	(233,186,611)	51,444,800
ATM offering costs	-	-	-	-	(61,260)	-	-	(61,260)
Conversion of series A convertible preferred stock to common stock	(2,256)	(2)	2,256,000	2,256	(2,254)	-	-	-
Stock-based compensation expense	-	-	-	-	1,555,332	-	-	1,555,332
Issuance of common stock from exercise of stock options	-	-	72,035	72	160,870	-	-	160,942
Other comprehensive loss	-	-	-	-	-	(65,704)	-	(65,704)
Net loss	-	-	-	-	-	-	(22,551,196)	(22,551,196)
Balance, June 30, 2020	5,506	6	57,082,100	57,082	286,163,633	-	(255,737,807)	30,482,914
Stock-based compensation expense	-	-	-	-	2,616,241	-	-	2,616,241
Proceeds from August 2020 Offering, net of underwriting costs and commissions	-	-	6,250,000	6,250	46,725,185	-	-	46,731,435
Issuance of common stock from employee stock purchase plan	-	-	61,721	62	120,294			120,356
Issuance of common stock from exercise of stock options	-	-	41,401	41	116,840	-	-	116,881
Net loss	-	-	-	-	-	-	(16,424,789)	(16,424,789)
Balance, September 30, 2020	5,506	$ 6	63,435,222	$ 63,435	$ 335,742,193	$ -	$ (272,162,596)	$ 63,643,038

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
Balance, December 31, 2018	-	$ -	24,654,114	$ 24,654	$ 191,477,598	$ (1,829)	$ (152,695,278)	$ 38,805,145
Proceeds from February 2019 Offering, net of underwriting costs and commissions	2,500	3	13,993,778	13,994	30,508,031	-	-	30,522,028
Stock-based compensation expense	-	-	-	-	1,642,540	-	-	1,642,540
Issuance of common stock from employee stock purchase plan	-	-	45,126	45	73,059	-	-	73,104
Other comprehensive income	-	-	-	-	-	3,179	-	3,179
Net loss	-	-	-	-	-	-	(13,800,195)	(13,800,195)
Balance, March 31, 2019	2,500	3	38,693,018	38,693	223,701,228	1,350	(166,495,473)	57,245,801
Underwriting costs related to February 2019 Offering	-	-	-	-	(1,193)	-	-	(1,193)
Stock-based compensation expense	-	-	-	-	1,251,908	-	-	1,251,908
Other comprehensive loss	-	-	-	-	-	(1,350)	-	(1,350)
Net loss	-	-	-	-	-	-	(13,057,267)	(13,057,267)
Balance, June 30, 2019	2,500	3	38,693,018	38,693	224,951,943	-	(179,552,740)	45,437,899
Stock-based compensation expense	-	-	-	-	1,184,481	-	-	1,184,481
Issuance of common stock from employee stock purchase plan	-	-	35,416	36	58,755	-	-	58,791
Conversion of common stock to Series A convertible preferred stock	1,262	1	(1,262,000)	(1,262)	1,261	-	-	-
Net loss	-	-	-	-	-	-	(16,634,572)	(16,634,572)
Balance, September 30, 2019	3,762	$ 4	37,466,434	$ 37,467	$ 226,196,440	$ -	$ (196,187,312)	$ 30,046,599

See accompanying notes to these unaudited condensed consolidated financial statements

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

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (59,006,075)	$ (43,492,034)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation expense	5,474,504	4,078,929
Depreciation and amortization expense	223,807	201,201
Change in accrued interest and accretion of discount on short-term investments	(199,408)	12,863
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(888,631)	924,800
Security deposit	(18,986)	8,605
Related party receivable	482,151	600,104
Long-term prepaid expenses	(239,507)	1,790,941
Accounts payable	(202,120)	1,455,155
Accrued expenses	4,223,397	(407,167)
Deferred revenue	13,085,966	-
Related party payable	(9,630)	624,335
Net cash used in operating activities	(37,074,532)	(34,202,268)
Cash flows from investing activities:		
Purchases of short-term investments	(9,961,092)	-
Proceeds from maturities of short-term investments	45,000,000	5,000,000
Purchase of property and equipment	(85,357)	(25,911)
Software development and other assets	(214,842)	(6,265)
Net cash provided by investing activities	34,738,709	4,967,824
Cash flows from financing activities:		
Proceeds from August 2020 Offering, net of offering expenses	46,952,500	-
Proceeds from February 2019 Offering, net of offering expenses	-	30,520,835
ATM offering costs	(128,835)	-
Proceeds from employee stock purchase plan	203,466	131,895
Proceeds from exercise of options	277,823	-
Net cash provided by financing activities	47,304,954	30,652,730
Net increase in cash and cash equivalents	44,969,131	1,418,286
Cash and cash equivalents, at beginning of period	41,897,144	36,489,618
Cash and cash equivalents, at end of period	$ 86,866,275	$ 37,907,904
Non-cash investing and financing activities:		
Software development and other costs in accrued expenses and accounts payable	$ 25,598	$ 125,852
Purchase of property and equipment in accounts payable	$ 26,082	$ 4,946
Offering costs in accrued expenses and accounts payable	$ 221,065	$ —

See accompanying notes to these unaudited condensed consolidated financial statements

NOTE 1 – NATURE OF OPERATIONS

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

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

Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its capital stock and interest income. As of September 30, 2020, the Company had approximately $86.9 million in cash and cash equivalents. Since inception, the Company has generated $6.9 million in revenue as part of the Company's license and collaboration agreement (the "Angelini License Agreement") with Angelini Pharma Rare Diseases AG ("Angelini"). The Company has incurred recurring losses, has experienced negative operating cash flows and requires significant cash resources to execute its business plans. The Company has an accumulated deficit of $272.2 million as of September 30, 2020, working capital of $72.4 million and had cash outflows from operating activities of $37.1 million for the nine months ended September 30, 2020.

The Company has incurred operating losses since inception and 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 through either equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or a combination of any such transactions. Management has identified certain conditions or events, which, considered in the aggregate, could raise substantial doubt about the Company's ability to continue as a going concern including the risk that the Company will be unable to raise adequate additional capital to fund the Company's operations through at least the next 12 months from the date of filing of the Company's Quarterly Report on Form 10-Q. The Company's management believes it can pursue implementing various cost-cutting measures in order to manage liquidity. The Company's management believes that these actions alleviate the substantial doubt referred to above. These mitigating actions may not be successful in alleviating the substantial doubt about the Company's ability to continue as a going concern. Further, the failure to raise capital as and when needed could have a negative impact on the Company's financial condition and ability to pursue its business strategy. If the Company is unable to raise capital, it may be required to delay, reduce the scope of or eliminate research and development programs, or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain drug candidates that the Company might otherwise seek to develop or commercialize independently.

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

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

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 11, 2020. There have been no material changes to the significant accounting policies during the period ended September 30, 2020, except for items mentioned below.

(A) Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet at September 30, 2020, the condensed consolidated statements of operations, comprehensive loss, cash flows, and stockholders' equity for the three and nine months ended September 30, 2020 and 2019 are unaudited. The accompanying unaudited

condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and following the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP are condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of its financial information. The results of operations for the three and nine months ended September 30, 2020 and 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. The balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements as of and for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K.

(B) Basis of Presentation and Consolidation

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

(C) Use of Estimates

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

(D) Fair Value of Financial Instruments

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

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

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies.
- Level 3—Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

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

(E) Revenue Recognition

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

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

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost-plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure.

License Revenue:

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

During the three months ended September 30, 2020, the Company entered into a sublicense agreement with a certain sublicensee in territories outside of the United States. This sublicensing agreement grants certain intellectual property rights and set forth various respective obligations including completion of certain ongoing trials, transfer of a specified amount of compound and related information, transfer of specified components of the technology transfer and a commitment to fund 35% of the cost for certain future studies as needed (see note 10).

(F) Recent Accounting Pronouncements

Recent accounting standards which have been adopted

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

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

On November 5, 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808), - which amends ASC 808 to clarify when transactions between participants in a collaborative arrangement under ASC 808 are within the scope of the FASB's new revenue standard, ASU 2014-09 (codified in ASC 606). The amendments require the application of ASC 606 existing guidance to determine the units of account that are distinct in a collaborative arrangement for purposes of identifying transactions with customers. If a unit of account within the collaborative arrangement is distinct and is with a customer, an entity shall apply the guidance in Topic 606 to that unit of account. In a transaction between collaborative participants, an entity is precluded by ASU 2018-18 from presenting a transaction together with "revenue from contracts with customers" unless the unit of account is within the scope of ASC 606 and the entity applies the guidance in ASC 606 to such unit of account. The amended guidance is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The adoption of this standard effective January 1, 2020 impacted the Company's recognition of revenue related to the Angelini license agreement (see note 10).

NOTE 3 – CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

All short-term investments are classified as available-for-sale. The following tables summarize the fair value of cash, cash equivalents and short-term investments, as well as gross unrealized holding gains and losses as of September 30, 2020 and December 31, 2019:

	September 30, 2020			
	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
Cash	$ 3,310,485	$ -	$ -	$ 3,310,485
Money market funds (a)	83,555,790	-	-	83,555,790
Total cash and cash equivalents	$ 86,866,275	$ -	$ -	$ 86,866,275

(a) As of September 30, 2020, the Company's Level 1 assets consisted of money market funds totaling $83.6 million. The Company had no level 2 or level 3 assets or liabilities as of September 30, 2020.

	December 31, 2019			
	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
Cash	$ 501,537	$ -	$ -	$ 501,537
Money market funds (a)	41,395,607	-	-	41,395,607
Total cash and cash equivalents	$ 41,897,144	$ -	$ -	$ 41,897,144
U.S. treasury notes (a)	$ 34,839,500	$ 2,469	$ -	34,841,969
Total short-term investments	$ 34,839,500	$ 2,469	$ -	$ 34,841,969

(a) As of December 31, 2019, the Company's Level 1 assets consisted of money market funds and U.S. treasury notes totaling $76.2 million. The Company had no level 2 or level 3 assets or liabilities as of December 31, 2019.

As of September 30, 2020, the aggregate fair value of securities that were in an unrealized gain position for less than 12 months was zero. As of December 31, 2019, the aggregate fair value of securities that were in an unrealized gain position for less than 12 months was $34.8 million. The Company did not hold any securities in an unrealized gain or loss position for more than 12 months as of September 30, 2020.

There were no realized gains or losses on available-for-sale securities during the three and nine months ended September 30, 2020 and the year ended December 31, 2019.

NOTE 4 – PROPERTY AND EQUIPMENT AND INTANGIBLE ASSETS

Property and equipment is summarized as follows:

	September 30, 2020	December 31, 2019
Furniture and equipment	$ 305,156	$ 193,717
Less accumulated depreciation	(167,357)	(125,354)
Total property and equipment, net	$ 137,799	$ 68,363

Depreciation expense was $42,000 and $28,000 for the nine months ended September 30, 2020 and 2019, respectively. Depreciation expense was $15,000 and $10,000 for the three months ended September 30, 2020 and 2019, respectively.

Intangible assets, net of accumulated amortization was $361,000 and $467,000 as of September 30, 2020 and December 31, 2019, respectively, and are included in other assets. Amortization expense was $182,000 and $173,000 for the nine months ended September 30, 2020 and 2019, respectively. Amortization expense was $64,000 and $46,000 for the three months ended September 30, 2020 and 2019, respectively.

NOTE 5 – ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2020	December 31, 2019
Clinical trials accrual	$ 6,015,876	$ 3,235,527
Payroll and bonus accrual	2,759,967	2,728,495
Professional fees accrual	2,369,729	1,070,589
Other	274,903	232,095
Total	$ 11,420,475	$ 7,266,706

NOTE 6 – STOCKHOLDERS' EQUITY AND PREFERRED STOCK

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

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

In June 2018, the Company entered into a sales agreement (the "ATM agreement") with Cowen and Company, LLC ("Cowen") under which the Company may offer and sell in "at the market offerings," from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $50.0 million through Cowen acting as sales agent. In 2019, the Company sold 6,893,888 shares of its common stock under the ATM agreement for net proceeds of $22.3 million after deducting sales agent commissions and other offering expenses payable by the Company. The Company did not sell any shares of its common stock under the ATM agreement during the nine months ended September 30, 2020.

There were 5,506 and 7,762 shares of Series A Preferred Stock outstanding as of September 30, 2020 and December 31, 2019, respectively. Each share of Series A Preferred Stock is convertible into 1,000 shares of common stock at any time at the holder's option. However, the holder will be prohibited, subject to certain exceptions, from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than, at the written election of the holder, either 9.99% or 14.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holder's election to any other number less than or equal to 19.99% upon 61 days' notice to the Company; provided, however, that effective 61 days after delivery of such notice, such beneficial ownership limitations shall not be applicable to any holder that beneficially owns either 10.0% or 15.0%, as applicable based on the holder's initial written election noted above, of the total number of shares of common stock issued and outstanding immediately prior to delivery of such notice. In the event of a liquidation, dissolution, or winding up of the Company, holders of Series A Preferred Stock will receive a payment equal to $0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of common stock.

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

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

In October and November 2019, the Company sold 10,350,000 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, and 4,000 shares of Series A Preferred Stock at a public offering price of $2.50 and $2,500 per share, respectively, for net proceeds of $33.5 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In September 2019, the Company entered into an exchange agreement with entities affiliated with Biotechnology Value Fund, L.P. (the "Exchanging Stockholders"), pursuant to which the Company exchanged an aggregate of 1,262,000 shares of the Company's common stock owned by the Exchanging Stockholders for an aggregate of 1,262 shares of the Company's Series A Preferred Stock (the "Exchange Shares"). The Exchange Shares were issued without registration under the Securities Act of 1933, as amended, in reliance on the exemption from registration contained in Section 3(a)(9) of the Securities Act.

In February 2019, the Company sold 13,993,778 shares of its common stock and 2,500 shares of Series A Preferred Stock at a public offering price of $2.00 and $2,000 per share, respectively, for net proceeds of $30.5 million after deducting underwriting discounts and commission and other offering expenses payable by the Company (the "February 2019 Offering").

Dividends

No dividends on the common stock shall be declared and paid unless dividends on the Preferred Stock have been declared and paid. Through September 30, 2020, the Company has not declared any dividends.

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 Company's Board of Directors adopted and the Company's stockholders approved the 2017 equity incentive plan ("2017 Plan"), which became effective immediately on May 4, 2017. The initial reserve of shares of common stock under the 2017 Plan was 3,052,059 shares. The 2017 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance-based stock awards, and other forms of stock-based awards. Additionally, the 2017 Plan provides for the grant of performance cash awards. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2017 Plan. Upon the adoption of the 2017 Plan, no further awards will be granted under the 2014 Plan. Pursuant to the terms of the 2017 Plan, on each January 1st, the plan limit shall be increased by the lesser of (x) 5% of the number of shares of common stock outstanding as of the immediately preceding December 31 and (y) such lesser number as the Board of Directors may determine in its discretion. On January 1, 2020 and January 1, 2019, respectively, an additional 2,735,516 and 1,232,705 shares were reserved for issuance under the 2017 Plan. As of September 30, 2020, there were 3,649,226 shares of the Company's common stock reserved and available for issuance under the 2017 Plan.

The Company's Board of Directors adopted, and the Company's stockholders approved the 2017 employee stock purchase plan (the "2017 ESPP"), which became effective immediately prior to the execution of the underwriting agreement related to the Company's initial public offering on May 4, 2017. The initial reserve of shares of common stock that may be issued under the 2017 ESPP was 279,069 shares. On March 20, 2017, the

Company's Compensation Committee approved an offering period under the 2017 ESPP, which began on October 20, 2017. The ESPP allows employees to purchase common stock of the Company at a 15% discount to the market price on designated purchase dates. During the three months ended September 30, 2020 and 2019, 61,721 and 35,416 shares were purchased under the ESPP and the Company recorded expense of $36,111 and $34,865, respectively. During the nine months ended September 30, 2020 and 2019, 105,464 and 80,542 shares were purchased under the ESPP and the Company recorded expense of $107,712 and $99,791, respectively The number of shares of common stock reserved for issuance under the 2017 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2018 and continuing through and including January 1, 2027, by the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (ii) 550,000 shares or (iii) such lesser number of shares determined by our Board. On January 1, 2019, an additional 246,541 shares were reserved for issuance under the 2017 ESPP. The Board acted prior to January 1, 2020 to provide that there be no increase in the number of shares reserved for issuance under the 2017 ESPP. As of September 30, 2020, there were 553,552 shares of the Company's common stock reserved for issuance under the 2017 ESPP.

Unless specified otherwise in an individual option agreement, stock options granted under the 2014 Plan and 2017 Plan generally have a ten-year term and a four-year graded vesting period. The vesting requirement is generally conditioned upon the grantee's continued service with the Company during the vesting period. Once vested, all awards are exercisable from the date of grant until they expire. The option grants are non-transferable. Vested options generally remain exercisable for 90 days subsequent to the termination of the option holder's service with the Company. In the event of option holder's death or disability while employed by or providing service to the Company, the exercisable period extends to 12 months.

Performance-based option awards generally have similar terms, with vesting commencing on the date the performance condition is achieved and expire in accordance with the specific terms of the agreement. At September 30, 2020, there were 953,310 performance-based options outstanding and unvested that include options to be granted upon the achievement of certain research and development milestones.

The fair value of options granted during the nine months ended September 30, 2020 and 2019 was estimated using the Black-Scholes option valuation model. The inputs for the Black-Scholes option valuation model require management's significant assumptions and are detailed in the table below. The risk-free interest rates were based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life was based on the simplified method in accordance with the SEC Staff Accounting Bulletin No. Topic 14D. The expected volatility was estimated based on historical volatility information of peer companies that are publicly available.

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

The Company granted 10,000 and 175,000 stock options to nonemployee consultants for services rendered during the nine months ended September 30, 2020 and 2019, respectively. There were 139,688 and 152,073 unvested nonemployee options outstanding as of September 30, 2020, and 2019, respectively. Total expense recognized related to the nonemployee stock options for the three months ended September 30, 2020 and 2019 was $134,004 and $35,007, respectively. Total expense recognized related to the nonemployee stock options for the nine months ended September 30, 2020 was $205,643. During the nine months ended September 30, 2019, the Company recognized a credit of $17,000 related to the nonemployee stock options including the modification of certain options in connection with the separation and consulting agreement with Dr. During (see Note 11), respectively. Total unrecognized compensation expenses related to the nonemployee stock options was $238,670 as of September 30, 2020. During the nine months ended September 30, 2020 and 2019, the Company recognized $98,726 and zero expense for nonemployee performance-based option awards.

The Company granted 1,636,660 and 1,781,115 stock options to employees during the nine months ended September 30, 2020 and 2019 respectively. There were 4,418,152 and 2,615,208 unvested employee options outstanding as of September 30, 2020, and 2019, respectively. Total expense recognized related to the employee stock options for the three months ended September 30, 2020 and 2019 was $2.4 million and $1.1 million, respectively. Total expense recognized related to the employee stock options for the nine months ended September 30, 2020 and 2019 was $5.2 million and $4.0 million, respectively. Total unrecognized compensation expense related to employee stock options was $9.6 million as of September 30, 2020. During the nine months ended September 30, 2020 and 2019, the Company recognized $1.6 million and $9,000, respectively, in expenses for employee performance-based option awards.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 1,083,786	$ 545,742	$ 2,162,685	$ 1,872,617
General and administrative	1,532,454	638,740	3,311,819	2,206,312
Total	$ 2,616,240	$ 1,184,482	$ 5,474,504	$ 4,078,929

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Stock options	$ 2,580,129	$ 1,149,617	$ 5,366,792	$ 3,979,138
Employee Stock Purchase Plan	36,111	34,865	107,712	99,791
Total	$ 2,616,240	$ 1,184,482	$ 5,474,504	$ 4,078,929

The fair value of employee options granted during the three and nine months ended September 30, 2020 and 2019 was estimated by utilizing the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
Volatility	81.79%	76.55%	80.58%	84.38%
Expected term in years	5.61	6.08	5.73	6.07
Dividend rate	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	0.39%	1.72%	0.67%	2.43%
Fair value of option on grant date	$ 3.10	$ 1.44	$ 2.97	$ 1.52

The fair value of nonemployee options granted during the three and nine months ended September 30, 2020 and 2019 was estimated by utilizing the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
Volatility	73.90%	-	74.37%	74.56%
Expected term in years	5.88	-	5.64	5.30
Dividend rate	0.00%	-	0.00%	0.00%
Risk-free interest rate	2.36%	-	2.32%	2.37%
Fair value of option on measurement date	$ 1.15	-	$ 1.18	$ 1.07

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding December 31, 2019	7,405,295	$ 5.82	8.01	$ 4,488,930
Granted	1,646,660	4.82	9.65	
Exercised	(113,436)	2.45	-	$ 488,384
Forfeited or expired	(360,605)	5.12	-	
Options outstanding September 30, 2020	8,577,914	$ 5.70	7.31	$ 10,465,784
Vested and exercisable at September 30, 2020	4,020,074	$ 7.45	5.52	$ 1,772,932

At September 30, 2020 there was approximately $9.9 million of unamortized share–based compensation expense related to employee and nonemployee grants, which is expected to be recognized over a remaining average vesting period of 2.30 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 from 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.

During the nine months ended September 30, 2020, the Company recorded a $500,000 refundable tax credit towards future New York State tax expense as a reduction to operating expenses. The credit was granted under the NYS Life Sciences Research and Development Tax Credit Program.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

License Agreements

On March 26, 2015, the Company entered into an exclusive agreement with H. Lundbeck A/S ("Lundbeck") for a worldwide perpetual licensing right related the research, development and commercialization of OV101 (the "Lundbeck Agreement"). On May 10, 2019, the parties amended the Lundbeck License.

Pursuant to the amended Lundbeck license agreement, the Company agreed to make milestone payments totaling up to $189.0 million upon the achievement of certain development, regulatory and sales milestones. The first payment of $1.0 million is due upon the successful completion of the first Phase 3 trial for a product in which OV101 is an active ingredient. In addition, the agreement calls for the Company to pay royalties for an initial term based on a low double-digit percentage of sales and provides for the reduction of royalties in certain limited circumstances.

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

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

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

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

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

As of September 30, 2020, none of these contingent payments were considered probable.

Contingencies

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

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

Pursuant to the Northwestern agreement, Northwestern granted the Company an exclusive license to certain patent rights and know-how, including a patent application covering a specified composition of matter (the "Patent Application"). Northwestern previously entered into a license agreement with Catalyst Pharmaceuticals, Inc. ("Catalyst"), dated August 27, 2009, pursuant to which Northwestern granted Catalyst rights under certain intellectual property rights covering a different composition of matter (the "Catalyst License"). In addition, the Company is a party to a confidential disclosure agreement with Catalyst, dated September 16, 2016 (the "CDA"). On June 25, 2018, Catalyst sent a letter to Northwestern and the Company alleging, among other things, that Northwestern breached the Catalyst License by licensing the Patent Application to the Company. Catalyst's letter also asserted that the Company had breached its obligations under the CDA by allegedly failing to disclose that the

Company had a license to the Patent Application, and that a further breach would occur if the Company makes any use of information obtained under the CDA in connection with its development program arising from the rights granted under the license agreement. Catalyst has asserted that the combined conduct of Northwestern and the Company gives rise to various claims, including breach of contract, fraud, and tortious interference. The Company believes that Catalyst's claims are without merit and responded by letter dated June 28, 2018, which denies any and all liability to Catalyst, and further denies that Catalyst has been damaged in any way. On May 20, 2019, the Company entered into a Settlement Agreement with Catalyst, pursuant to which Catalyst released the Company from any and all claims, known or unknown, arising from or related to the dispute between Catalyst and Northwestern, the License Agreement, and/or the claims that Catalyst asserted against the Company in the June 25, 2018 letter. Under the settlement, the Company retains all rights and privileges previously granted to the Company under the Northwestern Licensing Agreement.

NOTE 10 – COLLABORATION AGREEMENTS

Angelini Collaboration

On July 9, 2020, the Company entered into the Angelini License Agreement with Angelini, pursuant to which the Company granted to Angelini exclusive rights to develop and commercialize OV101, a selective agonist of the $GABA_A$ receptor, for the treatment of Angelman syndrome in the European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey (the "European Territory"). The licenses granted to Angelini include sublicenses under the Lundbeck Agreement, as well as licenses under the Company's patents and know-how covering OV101. Angelini will be responsible for conducting any clinical trials necessary to obtain regulatory approval for OV101 for Angelman syndrome in the European Territory, and the Company will be responsible for bearing a portion of the costs for such trials. The Company will also be responsible, at its expense, for the completion of certain ongoing clinical trials for OV101, to the extent applicable to obtaining regulatory approval for OV101 in the European Territory. Angelini has the exclusive right, at its election, to develop and commercialize OV101 for the treatment of Fragile X Syndrome in the European Territory. The parties may also mutually agree to pursue additional indications for OV101 in the European Territory, and in such case, Angelini would have the exclusive rights to commercialize in such additional indications. Angelini is required to use commercially reasonable efforts to conduct development activities for OV101, and following regulatory approval, to commercialize OV101 in each approved indication.

In conjunction with the entry into the Angelini License Agreement, the parties entered into a separate supply agreement, pursuant to which the Company will be responsible for supply of OV101 to Angelini for development and commercialization in the European Territory, through its existing supply relationship with Lundbeck. The Angelini License Agreement also provides for a transfer, at Angelini's expense, of the relevant manufacturing technology from the Company and Lundbeck to Angelini, in order to enable Angelini to assume responsibility for its own manufacture and supply of OV101 in the future.

Under the Angelini License Agreement, Angelini made an upfront payment to the Company of $20.0 million during the three months ended September 30, 2020. In addition, Angelini will be required to make milestone payments to the Company upon the completion of the specified components of the technology transfer, transfer of a specified amount of compound and related information, and achievement of specified regulatory milestones for OV101 in Angelman syndrome of up to $60.0 million in the aggregate, as well as up to $162.5 million in sales milestone payments for achievement of specified levels of net sales in the European Territory. In addition, Angelini will be required to pay tiered royalties on net sales by Angelini, its affiliates or sublicensees at double-digit percentages above the teens, subject to certain standard reductions and offsets. Royalties will be payable on a product-by-product and country-by-country basis until the latest of the expiration of the licensed patents covering such product in such country, the expiration of market exclusivity for such product in such country, and fifteen years from first commercial sale of such product in such country.

Either party may terminate the Angelini License Agreement for an uncured material breach of the other party or in the case of insolvency. The Company may terminate the Angelini License Agreement if Angelini challenges any of the licensed patents. Angelini may terminate the Angelini License Agreement for convenience on specified notice periods, which are determined based upon whether the product has been commercially launched in the European Territory.

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

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

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

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

Upon the transfer of the specified amount of compound and related information and acceptance by Angelini, Angelini will be required to make a payment towards the $60.0 million aggregate tech transfer and regulatory milestone payments. This fulfillment is out of the Company's control, is subject to reversal and was not probable as of September 30, 2020 therefore this variable consideration is constrained and not part of the upfront transaction price. At this time, the Company cannot estimate if or when this milestone-related performance obligations might be achieved.

Angelini will be required to make another payment towards the $60.0 million aggregate tech transfer and regulatory milestone payments upon the successful completion of the manufacturing process technology transfer. The Company earning this is fully dependent on performance and cooperation of Angelini and Lundbeck in implementing the Technology Transfer. At this time, the Company cannot estimate if or when this milestone-related performance obligation might be achieved.

During the three and nine months ended September 30, 2020, the Company recognized $6.1 million of license revenue and $0.8 million relating to the progress of the ongoing trials. The portion of the upfront payment allocated to License Revenue was recognized in full as it was non-refundable and not contingent on any future performance and require no consequential continuing involvement by the Company. The Company did not have any such revenue during the three and nine months ended September 30, 2019. In addition, the Company recorded deferred revenue in the amount of approximately $13.1 million as of September 30, 2020 which will be recognized over the term of the ongoing trials based on the portion of total estimated expenses incurred.

The milestone payments in the Angelini License Agreement are considered contingent variable consideration which are not accounted for until the contingency is met. There were no milestones met during the quarter ended September 30, 2020 and such there was no revenue recognized related to any milestones.

Takeda Collaboration

On January 6, 2017, the Company entered into a license and collaboration with Takeda Pharmaceutical Company Limited (“Takeda”), to jointly develop and commercialize the compound TAK-935, which the Company has licensed from Takeda and now refers to as OV935 (soticlestat), in certain territories. 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 (including preferred stock on an as-converted basis) on the issuance date or (b) $50.0 million divided by the applicable share price. 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. In the event a payment settled in shares of the Company’s common stock would cause Takeda to own over 19.99% of the Company’s outstanding capital stock or certain other events occur, such payment must be paid in cash. None of these potential milestone payments mentioned above are deemed probable at September 30, 2020.

During the nine months ended September 30, 2020, the Company recognized a credit in research and development expenses of $1.3 million and expenses of $0.3 million in general and administrative representing costs to be reimbursed to the Company from Takeda. During the nine months ended September 30, 2019, the Company recognized a credit of $3.6 million in research and development expenses representing costs to be reimbursed to the Company from Takeda. During the three months ended September 30, 2020, the Company recognized a credit of $0.2 million in research and development expenses and expenses of $0.1 million in general and administrative representing costs reimbursed to the Company from Takeda. During the three months ended September 30, 2019, the Company recognized a credit of $0.7 million in research and development expenses representing costs reimbursed to the Company from Takeda.

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 the Company, and Takeda will grant the Company 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 part of the Company’s collaboration agreement with Takeda the Company recognized a long-term liability representing long-term prepaid expenses to be reimbursed to Takeda.

On March 24, 2019, the Company entered into a separation and consulting agreement with Dr. Matthew During in connection with Dr. During’s resignation as President and Chief Scientific Officer with the Company effective as of April 1, 2019. Pursuant to the separation and consulting agreement, Dr. During agreed to non-solicit and non-compete covenants through such time as he remains a consultant to the Company, as well as a general release of claims in connection therewith. Dr. During agreed to a three-year consulting arrangement, pursuant to which he will be paid, amongst other specific milestone and meeting related fees, $150,000 per year for his role as the Chairman of the Company’s Scientific Advisory

Board and $150,000 per year for other advisory and consulting services. Further, Dr. During was granted options to acquire 100,000 shares of common stock at an exercise price of $1.76 per share, the fair market value on April 1, 2019, which options shall vest in full upon completion of a specific clinical milestone, subject to Dr. During's continued service through such vesting date. In the event such option does not vest by December 31, 2020, the stock option will expire. Provided further, in recognition of Dr. During's service on the Scientific Advisory Board, Dr. During was granted options to acquire 75,000 shares of common stock at an exercise price equal to $1.76 per share, the fair market value on April 1, 2019. Either Dr. During or the Company may terminate the consulting arrangements pursuant to the Consulting Agreement in accordance with its terms, at any time and for any reason, upon thirty (30) days written notice to the other party. Upon such termination, the Company will have no further obligations to Dr. During, including any obligation to pay further consulting fees.

In February 2019, the Company issued and sold an aggregate of 6,325,000 shares of common stock and 2,500 shares of Series A Preferred Stock to entities affiliated with Takeda, its collaboration partner and an existing stockholder, entities affiliated with Biotechnology Value Fund, L.P., an existing stockholder, and Dr. Jeremy M. Levin, its Chief Executive Officer and Chairman, for aggregate gross proceeds of $17.7 million.

In October and November 2019, the Company issued and sold an aggregate of 4,058,000 shares of common stock and 2,000 shares of Series A Preferred Stock to entities affiliated with Takeda, its collaboration partner and an existing stockholder, entities affiliated with Biotechnology Value Fund, L.P., an existing stockholder, and Dr. Jeremy M. Levin, its Chief Executive Officer and Chairman, for aggregate gross proceeds of $10.2 million.

In September 2019, the Company entered into an exchange agreement with the Exchanging Stockholders pursuant to which the Company exchanged an aggregate of 1,262,000 shares of the Company's common stock owned by the Exchanging Stockholders for an aggregate of 1,262 shares of the Company's Series A Preferred Stock.

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

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

NOTE 12 – NET LOSS 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 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. Under the terms of the Series A Preferred Stock issued in 2019, Preferred stockholders do not share in losses of the Company and have no obligation to fund losses or transfer assets. Since there is a loss, diluted EPS should be computed in the same manner as basic EPS and because no potential common shares shall be included in the computation of any diluted per-share amounts when a loss exists, the Series A Preferred Stock should be excluded from the computation of basic and diluted EPS.

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

	September 30,	
	2020	2019
Stock options to purchase common stock	8,577,914	5,878,758
Series A convertible preferred stock	5,506	3,762

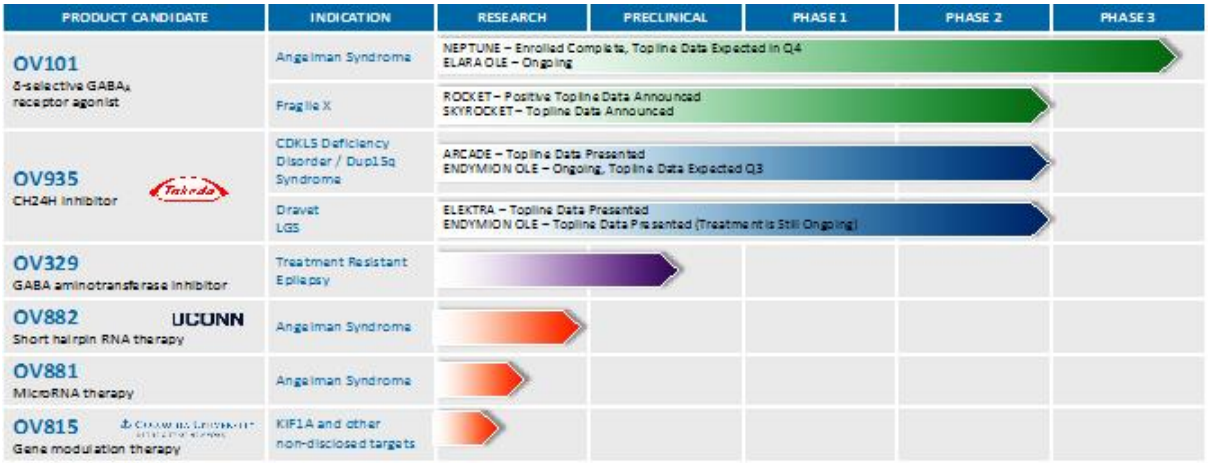
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited condensed consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission ("SEC") on March 11, 2020. In addition to historical financial information, the following discussion contains forward-looking statements based upon our current plans, expectations and beliefs that involve risks, uncertainties and assumptions. Our actual results may differ materially from those described in or implied by these forward-looking statements because of many factors, including those set forth under the section titled "Risk Factors" in Part II, Item 1A. Such factors may be amplified by the ongoing COVID-19 pandemic and its potential impact on our business and the global economy.

Overview

We are a late-stage clinical 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 and only now is being appreciated 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. Based on recent scientific advances in genetics and the biological pathways of the brain, we created a proprietary map of disease-relevant pathways and used it to identify and acquire novel compounds for the treatment of rare neurological disorders. We are also building a deep knowledge of the diseases and the clinically meaningful endpoints required for development of a compound in these rare neurological disorders. We continue to execute on our strategy by in-licensing and collaborating with leading biopharmaceutical companies and academic institutions. We have developed a robust pipeline of first-in-class and only-in-class clinical assets with an initial focus on neurodevelopmental disorders and developmental and epileptic encephalopathies, or DEE.

The following table sets forth the status and mechanism of action of our product candidates:



Our most advanced candidate is OV101 (gaboxadol). We have successfully completed a Phase 2 trial in adults and adolescents with Angelman syndrome, which we refer to as the STARS clinical trial. As previously announced, the STARS clinical trial achieved its primary endpoint of safety and tolerability and showed a statistically significant improvement in the once-daily OV101 dosing group on the pre-specified physician-rated Clinical Global Impressions-Improvement ("CGI-I") exploratory endpoint as well as improvements in relevant symptoms such as sleep, motor function and behavior. Following the STARS study we conducted a post hoc analysis of the STARS data which demonstrated that the study subjects in the once-daily dosing group of OV101 showed (i) improvements on the CGI-I scale increasing over time for the once-daily dosing group versus placebo, and (ii) improvements on the CGI-I scale being more robust in younger patients for the once-daily dosing group.

Following discussion of the STARS clinical trial with the U.S. Food and Drug Administration ("FDA") and German regulatory authorities, we designed and initiated a pivotal Phase 3 clinical trial in OV101 for Angelman syndrome in June 2019, which we refer to as the NEPTUNE clinical trial. NEPTUNE is a 12-week, two-arm, double-blind, placebo-controlled trial originally designed with approximately 60 patients aged 4 to 12 years randomized to either once daily, weight-based dose of OV101 or to placebo. Five patients aged 2-3 years will also be enrolled for safety assessments only. The primary endpoint is the change in the overall CGI-I-AS score at 12-weeks versus baseline between the OV101 and placebo groups. In March 2019, we announced that the first patient had been randomized in NEPTUNE. Due to mandated closures of clinical sites in the U.S., Europe, Israel and Australia in response to the ongoing COVID-19 pandemic, we had experienced delays in the enrollment of the Phase 3 NEPTUNE trial. In addition, after scientific advice from the European Committee for Medicinal Products for Human Use (CHMP), we have decided to expand the NEPTUNE trial sample size from 60 to 90 participants. The expansion of the trial will allow for the inclusion of a responder analysis of the primary endpoint (CGI-I-AS) specifically requested by the European regulatory authorities. We expect that increasing the trial sample size will enable us to provide additional data to support an EU regulatory filing of OV101 for the treatment of Angelman syndrome. Enrollment was completed for the NEPTUNE trial in the third quarter of 2020, and we expect to report topline data in the fourth quarter of 2020.

Based on the STARS clinical trial data, we also initiated ELARA, an open-label extension trial which enrolled its first patient in February 2019, and enrollment is ongoing. In June 2019, the European Commission granted OV101 orphan drug designation for the treatment of Angelman syndrome based on the results of the STARS clinical trial.

We also completed a Phase 2 trial evaluating OV101 in adolescent and young male adults with Fragile X syndrome, which we refer to as the ROCKET clinical trial. The trial met its primary objective and OV101 appeared to be well tolerated over 12 weeks of treatment with no serious adverse events reported across all three dose cohorts. OV101 demonstrated a statistically significant effect on secondary behavioral endpoints in the three combined study groups as follows: 26.2% mean improvement in the Aberrant Behavior Checklist for Fragile X (ABC-C_{FXS}) total score from baseline to week 12 (p=0.002); and a 21.6% mean improvement in the Anxiety, Depression and Mood Scale (ADAMS) total score from baseline to week 12 (p=0.004). Statistically significant improvements were also observed across various ABC-FXS and ADAMS subscales. In addition, OV101 demonstrated a statistically significant mean reduction of 0.4 in the Clinical Global Impressions Scale-Severity (CGI-S) total score (p=0.002) from baseline to week 12. These topline results support the continued development of OV101 for the treatment of Fragile X syndrome.

The participating clinicians and caregivers were aware that the trial was non-interventional. The mean changes from baseline to week 12 were evaluated in the ABC total and subscale scores, the ADAMS subscale scores, and the CGI-S subscale scores as well as the mean change in CGI-I score at week 12. Other exploratory scales were also assessed. High variability was seen among caregiver-administered assessments (ABC-c, ADAMS) compared to clinician-assessed scales (CGI-I, CGI-S). The caregiver-administered assessments showed a placebo response as seen with previous Fragile X syndrome trials. In these other trials, placebo response rates were highly variable. Therefore, the SKYROCKET trial data will help inform future study design, including potential endpoints and measures to mitigate placebo response.

In addition, we are in a license and collaboration with Takeda Pharmaceutical Company Limited (“Takeda”) to jointly develop and commercialize TAK-935, which we have licensed from Takeda and refer to as OV935 (soticlestat). We are initially studying OV935 for those suffering from severe and often intractable forms of DEE, including Dravet syndrome (“DS”), Lennox-Gastaut syndrome (“LGS”) and CDKL5 Deficiency Disorder, or CDD, and Duplication 15q, or Dup15q, syndrome. Each of these disorders either has limited or no therapeutic options. We completed a Phase 1b/2a clinical trial of OV935 in a mixed group of adults with DEE and announced the results in December 2018. The trial achieved its primary endpoint of safety and tolerability, dose proportional reduction in a potential plasma biomarker called 24HC, and a robust reduction in seizure frequency (61% at day 92), with two patients becoming seizure-free at the end of the treatment period.

Following this trial, we reported the initial data from the ENDYMION Phase 2 open-label extension study of OV935 in six study subjects who previously completed our 12-week Phase 1b/2a clinical trial of OV935 in adults with DEE. The longer-term data from ENDYMION out to 48 weeks suggest increased seizure reduction with prolonged treatment of OV935 and is consistent with the believed mechanism of action of OV935. Median seizure frequency reductions were 84% following 25 to 36 weeks (n=6) and 90% following 37 to 48 weeks (n=4) of treatment. In general, a greater reduction in seizure frequency was observed in those with higher baseline seizure frequency.

The FDA has granted orphan drug designation for OV935 for the treatment of DS and LGS. We and Takeda have completed two additional clinical trials: ELEKTRA and ARCADE.

ELEKTRA was an international, multi-center, randomized, double-blind, placebo-controlled study designed to evaluate treatment with soticlestat in pediatric patients, aged 2 to 17 years, with highly refractory epileptic seizures associated with DS (convulsive seizures) or LGS (drop seizures). The study consisted of a four- to six-week screening period to establish baseline seizure frequency, followed by a 20-week double-blind treatment period, including an 8-week dose optimization period and a 12-week maintenance period. During the 8-week dose optimization period, patients were titrated from 100mg twice daily (BID), to 200mg BID to 300mg BID (mg/kg dosing for <60 kg) of orally administered soticlestat.

A total of 141 patients were enrolled in ELEKTRA and 126 completed the study. A modified intent-to-treat, or mITT, analysis of 139 patients was performed to evaluate the efficacy endpoints, which includes any patient who enrolled in the study and received at least one dose of study drug. Patients in the study were allowed to be on one to four concomitant anti-epileptic drugs, or AEDs, with the majority of patients concomitantly treated with at least three AEDs. The most common AEDs taken by the patients were valproate, clobazam, levetiracetam and topiramate. Further, all patients who completed ELEKTRA enrolled in the ENDYMION open-label extension study.

On August 25, 2020, we and Takeda announced positive topline results from ELEKTRA and updated findings from ENDYMION. The ELEKTRA study achieved its primary endpoint with high statistical significance, demonstrating a 27.8% median reduction from baseline in convulsive seizure (DS) and drop seizure (LGS) frequency compared to a 3.1% median increase in patients taking placebo during the 12-week maintenance period (median placebo-adjusted reduction=30.5%; p=0.0007, based on the efficacy analysis set of 120 patients with seizure data in the maintenance period). In addition, DS and LGS patients treated with soticlestat demonstrated a 29.8% median reduction in convulsive seizure (DS) and drop seizure (LGS) frequency compared to 0.0% change in median seizure frequency in patients taking placebo during the full 20-week treatment period (titration plus maintenance) of the ELEKTRA study (placebo-adjusted reduction=25.1%; p=0.0024). Soticlestat was generally well-tolerated in the ELEKTRA study and demonstrated a safety profile consistent with those of previous studies, with no new safety signals identified. All patients who completed the ELEKTRA study elected to enroll into the ENDYMION open-label extension study and findings from ENDYMION were also reported on August 25, 2020.

All patients who completed the ELEKTRA trial elected to roll over into the ENDYMION open-label extension study, and data were supportive of results in the core study. The data indicate maintenance of effect over six months in those patients originally randomized to soticlestat, and similarly reduced seizure frequency as compared to baseline in those patients previously assigned to the placebo arm. No new safety signals were identified in ENDYMION.

ARCADE is a Phase 2 open-label, signal-finding pilot study designed to inform the potential for future development of soticlestat in CDD and Dup15q syndrome. The study enrolled 20 patients, ages 2 to 55 years, with refractory epileptic seizures associated with CDD (n=12) or Dup15q (n=8) and consisted of a four- to six-week screening period to establish baseline seizure frequency, followed by a 20-week treatment period, including an eight-week titration/dose optimization period and a 12-week maintenance period. Patients in the study were allowed to be on one to six concomitant anti-epileptic drugs (AEDs), with the majority of patients concomitantly treated with at least four AEDs, representing a highly refractory patient population. The primary objective of the ARCADE study was to determine percent change from baseline in motor seizure frequency during the 12-week maintenance period. Further, all patients who completed ARCADE enrolled in the ENDYMION open-label extension study.

On September 30, 2020, we announced results from ARCADE and updated findings from ENDYMION. Together, data from the ARCADE and ENDYMION studies showed seizure frequency reduction over time. In CDD patients (n=12), median motor seizure frequency reduction was 24% during the 12-week maintenance period in the ARCADE study, increasing to a 50% reduction in the ENDYMION long-term extension study in the five CDD patients who reached nine months of continuous treatment. In Dup15q patients (n=8), there was an increase in median motor seizure frequency in the ARCADE study during the 12-week maintenance period; however, longer-term data from the four Dup15q patients who reached nine months of continuous treatment showed a 74% reduction in median motor seizure frequency. Soticlestat was generally well tolerated in both studies and continues to demonstrate a favorable safety profile.

Additionally, Takeda elected to initiate a placebo-controlled trial of TAK-935 to treat study subjects with chronic complex regional pain syndrome (“CRPS”). This trial will look at the efficacy, safety and tolerability of TAK-935 as an adjunctive therapy in participants with CRPS. Pursuant to our agreement with Takeda, we have a one-time right to opt into this program but until we exercise our opt in rights we are not responsible for funding this trial. We also have early research programs exploring OV329 in infantile spasm/rare epilepsies and OV881 as a potential microRNA gene therapy for the treatment of Angelman syndrome.

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, developing our drug candidates and raising capital.

We have generated limited revenue through our Collaboration and License Agreement, or the Angelini License Agreement, with Angelini Pharma Rare Diseases AG, or Angelini, and have funded our business primarily through the sale of our capital stock. Through September 30, 2020, we have raised net proceeds of $275.4 million from the sale of common stock and convertible preferred stock. As of September 30, 2020, we had $86.9 million in cash and cash equivalents. We recorded net losses of $59.0 million and $43.5 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of approximately $272.2 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 development, 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, manufacturing, commercial and scientific personnel.

Recent Developments

Collaboration and License Agreement with Angelini Pharma Rare Diseases AG

On July 9, 2020, we entered into the Angelini License Agreement with Angelini, pursuant to which we granted to Angelini exclusive rights to develop and commercialize OV101 in the European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey, or the European Territory. The licenses granted to Angelini include sublicenses under our existing license agreement with H. Lundbeck A/S, or Lundbeck, as well as licenses under our patents and know-how covering OV101. Angelini will be responsible for conducting any clinical trials necessary to obtain regulatory approval for OV101 for Angelman syndrome in the European Territory, and we will be responsible for bearing a portion of the costs for such trials. We will also be responsible, at our expense, for the completion of certain ongoing clinical trials for OV101, to the extent applicable to obtaining regulatory approval for OV101 in the European Territory. Angelini has the exclusive right, at its election, to develop and commercialize OV101 for the treatment of Fragile X Syndrome in the European Territory. We and Angelini may also mutually agree to pursue additional indications for OV101 in the European Territory, and in such case, Angelini would have the exclusive rights to commercialize in such additional indications. Angelini is required to use commercially reasonable efforts to conduct development activities for OV101, and following regulatory approval, to commercialize OV101 in each approved indication.

In conjunction with the entry into the Angelini License Agreement, We and Angelini entered into a separate supply agreement, pursuant to which we will be responsible for supply of OV101 to Angelini for development and commercialization in the European Territory, through our existing supply relationship with Lundbeck. The Angelini License Agreement also provides for a transfer, at Angelini's expense, of the relevant manufacturing technology from us and Lundbeck to Angelini, in order to enable Angelini to assume responsibility for its own manufacture and supply of OV101 in the future.

Under the Angelini License Agreement, Angelini made an upfront payment to us of $20.0 million during the three months ended September 30, 2020. In addition, Angelini will be required to make milestone payments to us upon the completion of the specified components of the technology transfer, and achievement of specified regulatory milestones for OV101 in Angelman syndrome of up to $60.0 million in the aggregate, as well as up to $162.5 million in sales milestone payments for achievement of specified levels of net sales in the European Territory. Angelini also will be required to pay tiered royalties on net sales by Angelini, its affiliates or sublicensees at double-digit percentages above the teens, subject to certain standard reductions and offsets. Royalties will be payable on a product-by-product and country-by-country basis until the latest of the expiration of the licensed patents covering such product in such country, the expiration of market exclusivity for such product in such country, and fifteen years from first commercial sale of such product in such country.

Either party may terminate the Angelini License Agreement for the uncured material breach of the other party or in the case of insolvency. We may terminate the Angelini License Agreement if Angelini challenges any of the licensed patents. Angelini may terminate the Angelini License Agreement for convenience on specified notice periods, which are determined based upon whether the product has been commercially launched in the European Territory.

License Agreement with the University of Connecticut

On July 22, 2020, we entered into a license agreement (the "UConn License") with the University of Connecticut ("UConn"), pursuant to which we licensed from UCONN certain intellectual property to accelerate the development of a next-generation short hairpin RNA (shRNA)-based therapeutic for the treatment of Angelman syndrome and potentially other indications. We will work closely with UConn's Stormy J. Chamberlain, Ph.D., and gain exclusive access to identified genetic sequences for a shRNA-based therapeutic for potential future use alone or in combination with OV101 in Angelman syndrome.

Rare Disease Designation for OV101

On June 19, 2020, we announced that the FDA has granted Rare Pediatric Disease Designation to OV101 for the treatment of Angelman syndrome.

COVID-19 Update

We have implemented business continuity plans designed to address and mitigate the impact of the ongoing COVID-19 pandemic on our employees and our business. We continue to operate normally with the exception of enabling all of our employees to work productively at home and abiding by travel restrictions issued by federal and local governments. Our current plans to return to the office remain fluid as federal, state and local guidelines, rules and regulations continue to evolve. We also continue to expect to report topline data from the pivotal Phase 3 NEPTUNE trial in the fourth quarter of 2020.

Financial Operations Overview

Revenue

We have generated limited revenue under the Angelini License Agreement and expect to recognize additional revenue as we satisfy our performance obligations. We have not generated any revenue from commercial drug sales and do not expect to generate any further 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 including under the Angelini License Agreement.

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

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

General and Administrative Expenses

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

We expect that general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates.

Other (Expense) Income, net

Other income consists of interest income earned on our cash and cash equivalents maintained in money market funds and short-term investments that were maintained in U.S. treasury notes. Other expense consists primarily of foreign exchange losses incurred in the ordinary course of business.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

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

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Change
	(in thousands)		
Revenue:			
License revenue	$ 6,914	$ -	$ 6,914
Operating expenses:			
Research and development	$ 15,875	$ 11,598	4,277
General and administrative	7,442	5,168	2,274
Total operating expenses	23,318	16,766	6,552
Loss from operations	(16,404)	(16,766)	362
Other (expense) income, net	(21)	131	(152)
Net loss	$ (16,425)	$ (16,635)	$ 210

Revenue

Total revenue was $6.9 million for the three months ended September 30, 2020. We did not generate any revenue during the three months ended September 30, 2019. The increase in total revenue was due to $6.9 million of revenue recorded in connection with the Angelini License Agreement.

Research and Development Expenses

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Change
	(in thousands)		
Preclinical and development expense	$ 10,713	$ 7,885	$ 2,828
Payroll and payroll-related expenses	4,097	2,828	1,269
Other expenses	1,065	885	180
Total research and development	$ 15,875	$ 11,598	$ 4,277

Research and development expenses were $15.9 million for the three months ended September 30, 2020 compared to $11.6 million for the three months ended September 30, 2019. The increase of $4.3 million included an increase in preclinical and development expenses and payroll and payroll-related expenses for the clinical studies of OV101 and our Takeda collaboration expenses related to OV935. During the three months ended September 30, 2020, total research and development expenses consisted of $10.7 million in preclinical and development expenses, including a credit of $0.2 million representing costs to be reimbursed to us from Takeda in respect of the Takeda collaboration, $4.1 million in payroll and payroll-related expenses, of which $1.1 million related to stock-based compensation, and $1.1 million in other expenses. During the three months ended September 30, 2019, total research and development expenses consisted of $7.9 million in preclinical and development expenses, including a credit of $0.7 million representing costs to be reimbursed to us from Takeda in respect of the Takeda collaboration, $2.8 million in payroll and payroll-related expenses, of which $0.5 million related to stock-based compensation, and $0.9 million in other expenses.

General and Administrative Expenses

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Change
	(in thousands)		
Payroll and payroll-related expenses	$ 3,588	$ 2,259	$ 1,329
Legal and professional fees	2,908	1,802	1,106
General office expenses	946	1,107	(161)
Total general and administrative	$ 7,442	$ 5,168	$ 2,274

General and administrative expenses were $7.4 million for the three months ended September 30, 2020 compared to $5.2 million for the three months ended September 30, 2019. The increase of $2.3 million was primarily due to an increase in legal fees, compliance and pre-commercialization expenses and professional fees of $1.1 million and an increase in payroll and payroll-related expenses of $1.3 million offset by a decrease in general office expenses of $0.2 million.

Other (Expense) Income, net

Other expense was $0.02 million for the three months ended September 30, 2020. Other income was $0.1 million for the three months ended September 30, 2019.

Comparison of the Nine Months Ended September 30, 2020 and 2019

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

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Change
		(in thousands)	
Revenue:			
License revenue	$ 6,914	$ -	$ 6,914
Operating Expenses:			
Research and development	$ 46,534	$ 30,052	16,482
General and administrative	20,220	14,090	6,130
Total operating expenses	66,754	44,142	22,612
Loss from operations	(59,840)	(44,142)	(15,698)
Other income, net	834	650	184
Net loss	$ (59,006)	$ (43,492)	$ (15,514)

Revenue

Total revenue was $6.9 million for the nine months ended September 30, 2020. We did not generate any revenue during the nine months ended September 30, 2019. The increase in total revenue was due to $6.9 million of revenue related to the Angelini License Agreement.

Research and Development Expenses

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Change
		(in thousands)	
Preclinical and development expense	$ 31,963	$ 18,619	$ 13,344
Payroll and payroll-related expenses	11,683	8,598	3,085
Other expenses	2,888	2,835	53
Total research and development	$ 46,534	$ 30,052	$ 16,482

Research and development expenses were $46.5 million for the nine months ended September 30, 2020 compared to $30.1 million for the nine months ended September 30, 2019. The increase of $16.5 million included an increase in preclinical and development expenses and payroll and payroll-related expenses for the clinical studies of OV101 and our Takeda collaboration expenses related to OV935. During the nine months ended September 30, 2020, total research and development expenses consisted of $32.0 million in preclinical and development expenses, including a credit of $1.3 million representing costs to be reimbursed to us from Takeda in respect of the Takeda collaboration, $11.7 million in payroll and payroll-related expenses, of which $2.2 million related to stock-based compensation, and $2.9 million in other expenses. During the nine months ended September 30, 2019, total research and development expenses consisted of $18.6 million in preclinical and development expenses, including a credit of $3.6 million representing costs to be reimbursed to us from Takeda in respect of the Takeda collaboration, $8.6 million in payroll and payroll-related expenses, of which $1.9 million related to stock-based compensation, and $2.8 million in other expenses.

General and Administrative Expenses

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Change
		(in thousands)	
Payroll and payroll-related expenses	$ 9,305	$ 7,537	$ 1,768
Legal and professional fees	8,009	4,015	3,994
General office expenses	2,906	2,538	368
Total general and administrative	$ 20,220	$ 14,090	$ 6,130

General and administrative expenses were $20.2 million for the nine months ended September 30, 2020 compared to $14.1 million for the nine months ended September 30, 2019. The increase of $6.1 million was primarily due to an increase in legal fees, compliance and pre-commercialization expenses and professional fees of $4.0 million, an increase in general office expenses of $0.4 million, and an increase in payroll and payroll-related expenses of $1.8 million.

Other Income, net

Other income included interest income of $0.8 million for the nine months ended September 30, 2020 and $0.7 million for the nine months ended September 30, 2019.

Liquidity and Capital Resources

Overview

As of September 30, 2020, we had total cash and cash equivalents of $86.9 million as compared to $76.7 million of cash, cash equivalents and short-term investments as of December 31, 2019. The $10.2 million increase in total cash, cash equivalents and short-term investments was due primarily to proceeds of $46.7 million from the August 2020 Offering (as defined below) offset by the net loss of $59.0 million for the nine months ended September 30, 2020.

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

On July 9, 2020, we entered into the Angelini License Agreement with Angelini, pursuant to which we granted to Angelini exclusive rights to develop and commercialize OV101 in the European Territory. Under the Angelini License Agreement, Angelini made an upfront payment to the Company of $20.0 million during the three months ended September 30, 2020. In addition, Angelini will be required to make milestone payments to us upon the completion of the specified components of the technology transfer, and achievement of specified regulatory milestones for OV101 in Angelman syndrome of up to $60.0 million in the aggregate, as well as up to $162.5 million in sales milestone payments for achievement of specified levels of net sales in the European Territory. Angelini also will be required to pay tiered royalties on net sales by Angelini, its affiliates or sublicensees at double-digit percentages above the teens, subject to certain standard reductions and offsets.

Similar to other development stage biotechnology companies, we have generated limited revenue, which has been through the Angelini License Agreement. We have incurred losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the next several years. We incurred net losses of approximately $59.0 million and $43.5 million for the nine months ended September 30, 2020 and 2019, respectively. These losses are expected to continue for an extended period of time. As of September 30, 2020, we had an accumulated deficit of approximately $272.2 million and working capital of $72.4 million.

Management has identified certain conditions or events, which, considered in the aggregate, could raise substantial doubt about our ability to continue as a going concern including the risk that we will be unable to raise adequate additional capital to fund its operations through at least the next 12 months from the date of filing of the this Quarterly Report on Form 10-Q. Management believes it can pursue implementing various cost cutting measures in order to generate additional liquidity. The Company's management believes that these actions alleviate the substantial doubt referred to above and therefore have concluded that the Company remains a going concern.

Our plans to alleviate the substantial doubt about our ability to continue as a going concern may not be successful. The failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategy. If we are unable to raise capital, we 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 us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently.

We plan to finance our cash needs through either equity offerings, debt financings, collaborations, strategic alliances, or licensing agreements or a combination of any such transactions. To the extent that we raise additional capital through future equity offerings or debt financings, ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. There can be no assurance that such financings will be obtained on terms acceptable to us, if at all. The ongoing COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. If we raise additional funds through collaborations, strategic

alliances or licensing agreements with third parties for one or more of our current or future drug candidates, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy.

Cash Flows

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

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (37,075)	$ (34,202)
Investing activities	34,739	4,968
Financing activities	47,305	30,653
Net increase in cash and cash equivalents	$ 44,969	$ 1,419

Net Cash Used in Operating Activities

Net cash used in operating activities was $37.1 million for the nine months ended September 30, 2020, which consisted of a net loss of $59.0 million offset by a net of $22.0 million of non-cash charges and indirect cash changes, primarily related to $5.5 million of stock-based compensation expense and $13.1 million of deferred revenue. Net cash used in operating activities was $34.2 million for the nine months ended September 30, 2019, which consisted of a net loss of $43.5 million offset by a net of $9.3 million of non-cash charges and indirect cash changes, primarily related to $4.1 million of stock-based compensation expense.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $34.7 million for the nine months ended September 30, 2020, compared to $5.0 million of net cash provided by investing activities for the nine months ended September 30, 2019. The change in net cash provided by investing activities was primarily due to the higher maturities of short-term investments during the nine months ended September 30, 2020 compared to maturities during the nine months ended September 30, 2019.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $47.3 million for the nine months ended September 30, 2020 was primarily due to proceeds from August 2020 Offering. Net cash provided by financing activities of $30.7 million for the nine months ended September 30, 2019 was primarily due to net proceeds from our public offering in February 2019.

Contractual Obligations and Commitments

As of September 30, 2020, we agreed to continue certain studies that were ongoing at the time of signing the Angelini License Agreement. We had no other material contractual obligations or commitments. We had no long-term debt or capital leases and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase order basis. We excluded any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under license agreements we have entered into with various entities pursuant to which we have in-licensed certain intellectual property as contractual obligations or commitments, including agreements with H. Lundbeck A/S, Northwestern, and our Takeda license agreement. Pursuant to these license agreements, we have agreed to make milestone payments up to an aggregate of $279.3 million upon the achievement of certain development, regulatory and sales milestones. We excluded these contingent payments given that the timing, probability, and amount, if any, of such payments cannot be reasonably estimated at this time.

Off-Balance Sheet Arrangements

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

Emerging Growth Company Status and Smaller Reporting Company Status

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

- reduced disclosure about our executive compensation arrangements;

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

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

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the revenue and expenses incurred during the reported periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2020, we recognized license revenue resulting in a change to our critical accounting policies as reported for the year ended December 31, 2019 as part of our Annual Report on Form 10-K, which was filed with the SEC on March 11, 2020. In addition, see Note 2 of our Condensed Consolidated Financial Statements under the heading "Recent Accounting Pronouncements" for new accounting pronouncements or changes to the accounting pronouncements during the nine months ended September 30, 2020.

We recognize license revenue under certain of our sublicense agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. We evaluate these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, up-front fees that are not contingent on any future performance and require no consequential continuing involvement by us, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if the performance obligations are not satisfied.

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from collaboration.

If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on its relative standalone selling price. The transaction price was allocated based on the standalone selling price of the license and ongoing trials. The portion of the upfront payment allocated to License Revenue was recognized in full as it was non-refundable and not contingent on any future performance and require no consequential continuing involvement by the Company. Revenue related to ongoing trials is recognized by measuring the progress toward complete satisfaction of the performance obligations over time based on the portion of estimated total trial costs to be incurred. Milestone payments are considered contingent variable consideration which are not accounted for until the contingency is met.

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 September 30, 2020, we had cash and cash equivalents of $86.9 million that were held in an interest-bearing money market account. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and short-term investments and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short-term investments. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are comprised of U.S. Treasury and U.S. Treasury-backed repurchase agreements as well as treasury notes and high quality short-term corporate bonds.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

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

As of September 30, 2020, 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 September 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2020, we recognized revenue under the Angelini License Agreement resulting in the adoption of new internal controls over financial reporting.

Except for the changes related to the revenue recognition, there have been no changes in our internal control over financial reporting during our most recent fiscal quarter ended September 30, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since inception and expect to continue to incur substantial operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern if we are unsuccessful raising additional capital.

Since inception in April 2014, we have incurred significant operating losses. Our net loss was $59.0 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of $272.2 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 hiring employees and building our 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;
- experience further delays in our preclinical studies and clinical trials due to the ongoing COVID-19 pandemic;
- seek marketing approvals for our current and future drug candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any drug candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- implement operational, financial and management systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

Management has identified certain conditions or events, which, considered in the aggregate, could raise substantial doubt about our ability to continue as a going concern, including the risk that we will be unable to raise adequate additional capital to fund our operations through at least the 12 months following the filing date of the this quarterly report on Form 10-Q. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock. If we are unable to raise capital, we 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 us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently. In addition, if we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations.

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

Our operations have consumed substantial amounts of cash since our inception in April 2014, primarily due to organizing and staffing our company, business planning, raising capital, acquiring assets and undertaking the development of OV101 and OV935. We have not yet demonstrated the ability to, obtain marketing approvals, manufacture a commercial-scale drug or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had more experience developing drug candidates.

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, ("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 continue to incur additional costs associated with operating as a public company.

As of September 30, 2020, our cash and cash equivalents was $86.9 million we had an accumulated deficit of $272.2 million. Management has identified certain conditions or events, which, considered in the aggregate, could raise substantial doubt about our ability to continue as a going concern, including the risk that we will be unable to raise adequate additional capital to fund our operations through at least the 12 months following the filing date of this quarterly report on Form 10-Q. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock. If we are unable to raise capital, we 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 us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently. In addition, if we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations.

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

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

Until such time as we can generate substantial revenue from drug sales, if ever, we expect to finance our cash needs through a combination of equity and debt financings, strategic alliances, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we issue additional equity securities, our stockholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition, we may issue equity or debt securities as consideration for obtaining rights to additional compounds. 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, issuing additional equity, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. For example, on July 9, 2020, we entered into a collaboration and license agreement (the “Angelini License Agreement”) with Angelini Pharma Rare Diseases AG, pursuant to which we granted to Angelini exclusive rights to develop and commercialize OV101 in the European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey. The licenses granted to Angelini include sublicenses under our existing license agreement with H. Lundbeck A/S (“Lundbeck”), as well as licenses under our patents and know-how covering OV101.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise develop and market ourselves.

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

Our NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2020 is subject to certain limitations. It is uncertain if and to what extent various states will conform to the Tax Act.

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

Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

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, or our licensees, 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 would prevent us from commercializing and marketing our current and future drug candidates. An inability to effectively develop and commercialize our current and future drug candidates, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, could have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

Even if we obtain approval from the FDA and comparable foreign regulatory authorities for our current and future drug candidates, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of that drug candidate or any other drug candidate that we may in-license, develop or acquire in the future. In certain circumstances, including under our license agreement with Angelini for OV101, our third-party licensees are responsible for obtaining regulatory approvals in the countries covered by the license, and we are dependent on their efforts in order to achieve the necessary approvals in order to commercialize our products. If Angelini, or any future licensees fail to perform their obligations to develop and obtain regulatory approvals for the licensed products, we may not be able to commercialize our products in the affected countries, or our ability to do so may be substantially delayed.

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

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

Success in preclinical testing and early clinical trials does not ensure that subsequent clinical trials will generate similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. Frequently, drug candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. For instance, our STARS trial was the first clinical trial evaluating efficacy of OV101 in patients with Angelman syndrome and OV101 has not been evaluated in a clinical trial to treat Fragile X syndrome. We may be unable to demonstrate efficacy in any future trials, including any future clinical trials of OV101 to treat Angelman syndrome. Similarly, our Phase 1b/2a adult study in OV935 showed exploratory signals of efficacy in seizure frequency reduction, but we may be unable to demonstrate efficacy in future trials in patients with DEE, or the related indications of Dravet syndrome, Lennox-Gastaut syndrome, CDKL5 Deficiency Disorder or Duplication 15q ("Dup15q") syndrome, and the FDA has not yet made any determination regarding safety and efficacy of OV935 in any of these indications. The results from preclinical studies of OV101 and OV935 in animal models and the results from our STARS clinical trial of OV101 in patients with Angelman syndrome and clinical trials of OV101 in patients with primary insomnia may not be predictive of the effects of these compounds in later stage clinical trials. Our approach of targeting the extrasynaptic $GABA_A$ receptor with OV101, and cholesterol 24-hydroxylase (CH24H) 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 one of our drug candidates, we may decide to delay or abandon clinical development of that drug candidate. Any such delay or abandonment could harm our business, financial condition, results of operations and prospects.

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

From time to time, we have and may in the future publish or report preliminary or interim data from our clinical trials, such as the initial data we announced from the ENDYMION open label extension trial for OV935 in September 2019, which involved data from the first six patients enrolled in that extension trial which showed promising signs of efficacy over the treatment period, or the topline data from the ELEKTRA trial for OV935 in August 2020. Preliminary or interim data from our clinical trials and those of our partners may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published or reported. As a result, preliminary or interim data should be considered carefully and with caution until final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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. Further, delays and interruptions to ongoing trials related to the COVID-19 pandemic may also increase the duration and costs of such trials. 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 ("CROs") and clinical trial sites;
- delays in opening investigational sites;
- delays or difficulty in recruiting and enrollment of suitable patients to participate in our clinical trials, whether as a result of the COVID-19 pandemic or otherwise;
- imposition of a clinical hold by regulatory authorities because of a serious adverse event, concerns with a class of drug candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters and public health epidemics

In addition, our clinical trials may be affected by the COVID-19 pandemic. For example, we have experienced delays in enrollment in our Phase 3 NEPTUNE trial in Angelman syndrome as a result of mandated closures of investigational sites in response to the COVID-19 pandemic. As a result, we now expect to report topline data from this trial in the fourth quarter of 2020.

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

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 ("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 ("IRB") may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice ("GCP") regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug ("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 treatments approved by the U.S. Food and Drug Administration, and the primary clinical endpoint, CGI-I-AS, has not previously been used as a sole primary endpoint in a pivotal clinical trial.

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 may 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 and/or our label may be limited. Based on feedback from the FDA, we developed acceptable endpoints and obtained the FDA's agreement before initiating the Phase 3 NEPTUNE trial. For Europe, based on an on-going dialogue with European regulatory authorities, we have increased enrollment in the NEPTUNE study from 60 to 90 patients to allow for inclusion of a responder analysis of the primary endpoint (CGI-I-AS), which has been specifically requested by the European regulatory authorities. We may experience delays in finishing the NEPTUNE trial and ultimately our ability to gain approval for OV101.

We may need to develop a new liquid formulation of OV101 for use in infant patients if our existing formulation in capsules that can be opened and sprinkled on semi-solid foods is not acceptable to the regulatory authorities, and we may be unable to successfully develop an appropriate liquid formulation.

Our existing formulation of OV101 is an oral capsule. We have recently developed lower strength capsules that can be opened and sprinkled on applesauce or similar semi-solid foods. However, we may need to develop an oral liquid formulation of OV101 for use in very young pediatric patients. While we have begun developing this formulation, 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 that may affect 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.

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. The COVID-19 pandemic could also impact our ability to do in-person due diligence, negotiations, and other interactions to identify new opportunities. Even if we identify drug candidates that initially show promise, we may fail to in-license or acquire these assets and may also fail to successfully develop and commercialize such drug candidates for many reasons, including the following:

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

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.

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 ("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 DEE, such as Dravet syndrome, Lennox-Gastaut syndrome, Dup15q syndrome and CDKL5 deficiency disorder is small and has not been established with precision. If the actual number of patients with these disorders is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our drug candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial, any such enrollment issues could cause delays or prevent development and approval of our drug candidates. Because we are focused on addressing rare neurological disorders, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our drug candidates, or could render further development impossible. For example, the impact of public health pandemics, such as COVID-19, may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us or our partners from completing our clinical trials at all, and harm our ability to obtain approval for such product candidate. 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 insomnia. In addition, some patients treated with OV101 in the Lundbeck Phase 3 trials experienced headaches, nausea and dizziness. In the STARS study, the most frequent adverse events for OV101 treated arms that were greater than placebo arm included pyrexia, rash, seizure, enuresis, myoclonic epilepsy, otitis media and viral infection. Patients in our ongoing or planned clinical trials may experience similar or other adverse events after treatment with OV101. In the Phase 1b/2a OV935 trial, adverse events that occurred more frequently in the OV935-treatment group versus the placebo group were dysarthria, insomnia, lethargy, seizure cluster, and upper respiratory infection. If additional clinical experience indicates that any of our current drug candidates, including OV101 and OV935, or any future drug candidates has adverse events or causes serious or life-threatening adverse events, the development of that drug candidate may fail or be delayed, or, if the drug candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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. In certain cases, including under our license with Angelini, which covers the European Economic Area as well as Switzerland, the United

Kingdom, Russia and Turkey, we are dependent on third parties to obtain such foreign regulatory approvals, and any delay or failure of performance of such third parties could delay or prevent our ability to commercialize our products in the affected countries. Due to the ongoing COVID-19 pandemic, it is possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

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

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

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by 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 Licensing and Collaboration Arrangements

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 submission of the IND to the FDA. 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 upon six 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 are dependent on our relationship with Angelini for the development and commercialization of OV101 in European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey. Any disruption in our relationship with Angelini could lead to delays in the development and achievement of regulatory approval in these countries, which would materially harm our business.

Under our license agreement with Angelini, Angelini obtained exclusive rights to develop and commercialize OV101 in the European Economic Area as well as Switzerland, the United Kingdom, Russia and Turkey. The development and commercialization of OV101 is highly dependent upon our relationship with Angelini, and on Angelini's performance of its obligations under the agreement, including with respect to the preparation and submission of applications for marketing approval in Europe and the other licensed countries. If for any reason Angelini fails to perform its obligations, we may not be able to achieve regulatory approval for OV101 in the licensed countries, or may be materially delayed in doing so, and our business would be adversely affected.

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 Lundbeck in March 2015 (the "Lundbeck Agreement"), as amended on May 10, 2019. Under the Lundbeck Agreement, as amended, 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 $189.0 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 (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. 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. In the event a payment settled in shares of our common stock would cause Takeda to own over 19.99% of our outstanding capital stock or other events occur, such payment must be paid 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.

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

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

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

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

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

Risks Related to Regulatory Compliance

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

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 healthcare 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 by the Health Care and Education Reconciliation Act (collectively, 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 in order to have committed a violation;
- 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 ("HIPAA"), which created additional 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 ("HITECH"), and their 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, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform certain services on behalf of a covered entity that involves the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- 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 ("CMS"), information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- 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/or information regarding drug pricing, 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, state laws and regulations that require drug manufacturers to file reports relating to drug pricing and marketing information, and state and local laws that require the registration of pharmaceutical sales representatives; 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 regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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

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

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

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

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

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.

There remain judicial, Congressional and executive branch challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance, delaying the implementation of certain PPACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to

determine whether the remaining provisions of the PPACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, which are expected to occur in the fall of 2020. It is unclear how such litigation and other efforts to repeal and replace the PPACA will impact the PPACA and 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 due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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.

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 ("MACRA"), which ended the use of the statutory formula and established a quality payment program, also referred to as the Quality Payment Program. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the 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 and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Moreover, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. On July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie certain Medicare Part B drug prices to international drug prices, the details of which were released on September 13, 2020 and expanded the policy to cover certain Part D drugs; one that directs the U.S. Department of Health and Human Services ("HHS") to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and EpiPen's to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Although some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs.

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.

It is possible that additional governmental action is taken to address the ongoing COVID-19 pandemic. For example, on April 18, 2020, CMS announced that Qualified Health Plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus. Further, on August 6, 2020, President Trump issued an executive order that instructs the federal government to develop a list of "essential" medicines and then buy them and other medical supplies from U.S. manufacturers instead of companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and promote the production of drug products in the United States.

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.

For OV101, the FDA granted orphan drug designation for OV101 for the treatment of Angelman syndrome and for the treatment of Fragile X syndrome in September 2016 and October 2017, respectively. The EMA granted orphan designation for OV101 for the treatment of Angelman syndrome in June 2019. The FDA granted orphan drug designation for OV935 for the treatment of Dravet syndrome and Lennox-Gastaut syndrome both in December 2017. 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.

We have received Fast Track designations for OV101 for the treatment of Angelman syndrome and Fragile X syndrome, but such designations may not actually lead to a faster development or regulatory review or approval process.

The FDA granted Fast Track designations to OV101 for the treatment of Angelman syndrome and Fragile X syndrome in December 2017 and March 2018, respectively. If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for such condition, a sponsor may apply for FDA Fast Track designation. Even though we received Fast Track designations for OV101, such Fast Track designations do not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe for any of these fast track-designated indications. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Although the FDA has granted Rare Pediatric Disease Designation for OV101 for the treatment of Angelman Syndrome, an NDA for OV101, if approved, may not meet the eligibility criteria for a priority review voucher.

Rare Pediatric Disease Designation has been granted for OV101 for the treatment of Angelman Syndrome. In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval. For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2020. However, if a drug candidate receives Rare Pediatric Disease Designation before October 1, 2020, it is eligible to receive a voucher if it is approved before October 1, 2022.

However, OV101 for the treatment of Angelman Syndrome may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that an NDA will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease Designation does not lead to faster development or regulatory review of the product, or increase the likelihood that it will receive marketing approval. We may or may not realize any benefit from receiving designation or a voucher.

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.

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

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

In addition, the FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process, or suspend or restrict regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and drug candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and any future drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future development programs and drug candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Pursuant to the Lundbeck Agreement, as amended, we obtained an exclusive, worldwide license to develop, manufacture and commercialize OV101 for the treatment of human disease. However, the Lundbeck Agreement, as amended, 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, as amended, 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 December 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business and financial condition.

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

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

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. See the section herein titled "Legal Proceedings" for additional information.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

We do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage and distribution, or testing. We 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 of 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 good laboratory practices ("GLPs") and good clinical practices ("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

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

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

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

In addition, our clinical trials may be affected by the COVID-19 pandemic. For example, prior to reaching full enrollment of our Phase 3 NEPTUNE trial in Angelman syndrome, we had experienced delays in enrollment as a result of mandated closures of investigational sites in response to the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be willing or able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations. As a result of the COVID-19 pandemic, we have faced and may to continue face delays in meeting our anticipated timelines for our ongoing and planned clinical trials.

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

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

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

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

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

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

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

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

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

As of September 30, 2020, we had 65 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, our ability to commercialize drug candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

We are exposed to the risk that our employees, consultants, distributors, and collaborators may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of pharmaceuticals, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Further, because of the work-from-home policies we implemented due to COVID-19, information that is normally protected, including company confidential information, may be less secure. If actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

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

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

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

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

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

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

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

Risks Related to Being a Public Company

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

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

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

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

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

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

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

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

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

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

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

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

- results of clinical trials of our current and any future drug candidates or those of our competitors;
- the success of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our current and any future drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;

- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. In June 2018, we filed a shelf registration statement on Form S-3 (Registration No. 333-225391) that allows us to sell up to an aggregate of $200 million of our common stock, preferred stock, debt securities and/or warrants (the “S-3 Registration Statement”), which includes a prospectus covering the issuance and sale of up to $50.0 million of common stock pursuant to an at-the-market (“ATM”) offering program. As of September 30, 2020, we had $107.0 million available under our S-3 Registration Statement, including $27.0 million available pursuant to our ATM program. Financing activities may have an adverse impact on our stockholders’ rights as well as on our operations, and such additional funding may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it may result in dilution to our existing stockholders and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as redeeming our shares, making investments, issuing additional equity, limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any of these events could significantly harm our business, financial condition and prospects.

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

As of September 30, 2020, we had outstanding options to purchase an aggregate of 8,557,914 shares of our common stock at a weighted average exercise price of $5.70 per share and 5,506,000 shares of common stock issuable upon conversion of outstanding Series A convertible preferred stock for no additional consideration. Such Series A convertible preferred stock is convertible any time at the option of the holder thereof subject to the beneficial ownership limitations described in Note 6 to the financial statements contained in this Quarterly Report on Form 10-Q. The exercise of such options and conversion of the Series A convertible preferred stock for shares of our common stock will result in further dilution of your investment and could negatively affect the market price of our common stock. In addition, you may experience further dilution if we issue common stock, or securities convertible into common stock, in the future. As a result of this dilution, you may receive significantly less than the full purchase price you paid for the shares in the event of liquidation.

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

Based upon our shares of our common stock outstanding as of November 5, 2020, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 33.5% 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. We do currently have research coverage offered by several industry or financial analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

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

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

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

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

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

Additionally, the Takeda standstill provisions and transfer restrictions in the Takeda 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on May 10, 2017).
3.2	Corrected Amended and Restated Certificate of Designation of Series A Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on September 24, 2019).
3.3	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on May 10, 2017).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-217245), filed with the Commission on April 25, 2017).
4.2	Form of Series A Preferred Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-38085), filed with the Commission on February 21, 2019).
4.3	Second Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated January 6, 2017 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-217245), filed with the Commission on April 10, 2017).
10.1	Collaboration and License Agreement, by and between the Company and Angelini Pharma Rare Diseases AG, dated July 9, 2020.
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.

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: November 12, 2020

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

Date: November 12, 2020

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

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.1

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "**Agreement**") is entered into as of July 8, 2020 (the "**Effective Date**"), by and between **Ovid Therapeutics Inc.**, a Delaware company having an address at 1460 Broadway, Suite 15021 New York, NY 10036, USA ("**Ovid**") and **Angelini Pharma Rare Diseases AG**, a Swiss company under direction and control of Angelini Pharma S.p.A. and having an address at Consulting GmbH Sumpfstrasse 26 6312 Steinhausen, Zurich, Switzerland ("**Licensee**"). Ovid and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

Recitals

Whereas, Ovid, a biopharmaceutical company, owns or controls certain patents, know-how, and other intellectual property relating to its proprietary compound known as OV101, a selective agonist of the GABAA receptor, including certain intellectual property rights in-licensed from H. Lundbeck A/S, which Ovid has been developing for the treatment of Angelman syndrome and Fragile X syndrome and potentially other Rare Diseases indications;

Whereas, Licensee is a subsidiary, 100% under direction and control of Angelini Pharma S.p.A., an Italian pharmaceutical company, which is experienced in the development and commercialization of pharmaceutical products; and

Whereas, Licensee and Ovid desire to form a collaboration for the continued development and commercialization of OV101, with the status of Orphan Medicine and with Final Label 1a, 1b and/or 2, all on the terms and conditions set forth below.

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Ovid and Licensee hereby agree as follows:

1. Definitions

1.1 "**Additional Development Activities**" has the meaning set forth in Section 4.3(a).

1.2 "**Additional Indications**" means any Rare Diseases Indication other than the Initial Indication and the Second Indication that has been submitted to and approved by the CGB.

1.3 "**Additional Pivotal Trial**" means the additional Phase 3 Clinical Trial of the Product for the Initial Indication, if required by the EMA or by Licensee at its own discretion, for the purpose of seeking or maintaining MAA Approval of the Product for the Initial Indication in the Licensee Territory, as described in **Exhibit H**.

1.4 "**Affiliate**" means, with respect to any party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such party, but for only so long as such control exists. As used in this Section 1.4, "control" means

(a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

1.5 "**Allocated Quantity of Compound**" means [***] of the Compound in Ovid's control as of the Effective Date, which Ovid has agreed, under the Supply Agreement, to allocate exclusively for the purpose of fulfilling Licensee's or Licensee Affiliate's Purchase Orders under the Supply Agreement.

1.6 "**Allowable Increases**" has the meaning set forth in Section 4.5(b).

1.7 "**Amended Development Budget**" has the meaning set forth in Section 4.2.

1.8 "**Amended Development Plan**" has the meaning set forth in Section 4.2.

1.9 "**Angelini Commercially Reasonable Efforts**" means, with respect to Licensee and its obligations under this Agreement, commercially reasonable efforts and resources as commonly used by a similar size pharmaceutical company to Develop and Commercialize a product controlled by Licensee or to which it has exclusive rights, which product is at similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved and/or anticipated labelling, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, likelihood of regulatory approval given the regulatory structure involved, the profitability of the product, [***] and other relevant factors, including technical, legal, scientific and/or medical factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis and indication-by-indication basis for a particular Product, and it is anticipated that the level of effort will change over the time, reflecting changes in the status of the Product and the country(s) involved. [***].

1.10 "**Applicable Laws**" means the applicable provisions (including Data Protection Legislation) of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, Regulatory Authority, or governmental agency or authority having jurisdiction over or related to the subject item.

1.11 "**Auditor**" has the meaning set forth in Section 9.4.

1.12 "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

1.13 "**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31.

1.14 "**cGCP**" means the current good clinical practice standards as set out in (a) ICH Harmonized Guidance on current Good Clinical Practice (CPMP/ICH/135/95), (b) U.S. 21 C.F.R.

Parts 50, 54, 56, 58, 210, 211 and 312, and (c) the equivalent law or regulation in any other applicable jurisdiction in the Territory, each as may be amended from time to time.

1.15 "**cGLP**" means current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other comparable regulatory standards in jurisdictions outside the U.S.), as may be amended from time to time.

1.16 "**cGMP**" means the current standards for systems to assure the proper design, monitoring, and control of processes and facilities to be used for the manufacture, processing, packing, or holding of a drug as specified by applicable laws of the relevant countries at the time of manufacturing conducted in accordance with this Agreement, defined under (a) U.S. 21 C.F.R. Parts 210 and 211 and (b) the equivalent law or regulation in any other applicable jurisdiction in the Territory, each as may be amended from time to time.

1.17 "**Claim**" has the meaning set forth in Section 12.3.

1.18 "**Clawback**" means post sales clawback policies applied to manufacturers, requiring them to pass a part of their revenues in respect of a product to a national health service or other Governmental Authority.

1.19 "**Clinical Trial**" or "**Clinical Trials**" means Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, or Phase 4 Clinical Trial, as the context dictates.

1.20 "**Collaboration Governance Board**" or "**CGB**" has the meaning set forth in Section 3.1.

1.21 "**Combination Product**" means any pharmaceutical product containing the Compound as an active pharmaceutical ingredient in combination with one or more other therapeutically active ingredients, in any and all forms, presentations, dosages, and formulations.

1.22 "**Commercialization**" means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, sales, marketing, medical and patient support and services, and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling, and delivering Products to customers) of Products in the Field, including sales force efforts, detailing, advertising, market research, market access (including price and reimbursement activities), medical education and information services, publication, scientific and medical affairs, advisory and collaborative activities with opinion leaders and professional societies including symposia, marketing, sales force training, and sales (including receiving, accepting and filling Product orders) and distribution. "**Commercialize**" and "**Commercializing**" have correlative meanings.

1.23 "**Commercialization Plan**" has the meaning set forth in Section 6.2.

1.24 "**Committee**" means the CGB, JPT, or any other subcommittee established by the CGB, as applicable.

1.25 **"Committee for Medicinal Products for Human Use (CHMP)"** means the EMA committee responsible for human medicines.

1.26 "**Competing Acquirer**" means a Third Party that, as of the closing date of the applicable transaction, is engaged in [***] of products, other than Products, for [***].

1.27 "**Competing Product**" means any product or compound, other than the Compound and Products and the Current Licensee Pipeline Products, (a) [***], or (b) [***].

1.28 "**Compound**" means the δ-selective extrasynaptic GABAA receptor agonist known internally by Ovid as OV101, having the chemical structure set forth in **Exhibit A**.

1.29 "**Compound Invention**" has the meaning set forth in Section 10.1(b)(i).

1.30 "**Compounding**" or "**Compounding Activities**" means [***].

1.31 "**Confidentiality Agreement**" means that certain Confidential Disclosure Agreement between Ovid and Licensee dated as of July 8, 2019.

1.32 "**Confidential Information**" means all Know-How and other proprietary scientific, marketing, financial, or commercial information or data that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, or formulae in relation to this Agreement; provided that all Ovid Technology will be deemed Ovid's Confidential Information, all Licensee Technology will be deemed Licensee's Confidential Information, and all Joint Inventions and Joint Patents will be deemed both Parties' Confidential Information.

1.33 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents, or other intellectual property rights, the legal authority or right (whether by ownership, license, or otherwise, but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license, or a sublicense of or under such Know-How, Patents, or other intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.34 "**Cost of Goods**" means, with respect to the Drug Product, the fully burdened cost to manufacture and supply such Drug Product, which means: (a) in the case of products and services acquired from Third Parties, [***]; and (b) in the case of manufacturing services performed by a Party or its Affiliates, including manufacturing services to support products and services acquired from Third Parties as contemplated in subsection (a), [***].

1.35 "**Current Licensee Pipeline Products**" means, in each case as of the Effective Date, Licensee's pipeline for products related to (a) [***], (b) [***], and (c) [***], in each case as better defined in **Exhibit I**.

1.36 "**Data**" means any and all scientific, technical, test, marketing, or sales data pertaining to any Product that is generated by or on behalf of Ovid, Licensee, and their respective

Affiliates and (sub)licensees, including research data, clinical pharmacology data, pre-clinical data, clinical data, clinical study reports, or submissions made in association with an IND or MAA with respect to any Product.

1.37 "**Data Protection Legislation**" means all applicable legislation relating to the protection and processing of personal data, data privacy and the privacy of electronic communications in any relevant jurisdiction, including the General Data Protection Regulation ((EU) 2016/679), and any national implementing laws, regulations and secondary legislation, as amended or updated from time to time.

1.38 "**Development**" means all non-clinical and clinical drug development activities, including toxicology, pharmacological, and other non-clinical efforts, statistical analysis, the performance of Clinical Trials, including the Manufacturing of the Products for use in the Clinical Trials, Manufacturing Development or other activities reasonably necessary in order to obtain or maintain Regulatory Approval of Products in the Field in the Territory, as detailed in a Development Plan for the Products. "Development" shall exclude all Commercialization activities. When used as a verb, "Develop" means to engage in Development activities.

1.39 "**Development Budget**" means the initial reasonably detailed budget estimated by the Parties for all Development activities set forth in the Development Plan.

1.40 "**Development Costs**" means the costs incurred by a Party or for its account or by the Parties jointly, during the Term and pursuant to this Agreement, that are specifically directed (or reasonably allocable) to the Development of a Product. The Development Costs shall include amounts that a Party pays to Third Parties involved in the Development of a Product (at cost), and all internal costs (calculated on an FTE basis at the then-current FTE Rate) and out-of-pocket costs incurred by or on account of a Party in performing Development in accordance with the Development Plan. For clarity, [***].

1.41 "**Development Plan**" means the initial plan of Development activities for the Product set forth in **Exhibit C**.

1.42 "**Drug Product**" means the Compound, filled and finished into unit doses, but not packaged or labelled.

1.43 "**Elara Trial**" means the open-label extension study for patients with Angelman Syndrome who have previously been enrolled in a Clinical Trial of the Product (including the Neptune Trial) as of the Effective Date, as further described in **Exhibit J**. [***].

1.44 "**EMA**" means the European Medicines Agency, and any successor agency or authority having substantially the same function.

1.45 "**Executive Officers**" means the [***] of Ovid and the [***] of Licensee.

1.46 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services,

including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, in each case, as amended.

1.47 "**Extended Commercialization Term**" means the period commencing on the expiration of the Royalty Term and continuing for so long as Ovid continues to supply to Licensee or Licensee Affiliate the Product under the terms of the Lundbeck License Agreement.

1.48 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.49 "**FDA**" means the U.S. Food and Drug Administration, and any successor agency or authority having substantially the same function.

1.50 "**Field**" means the treatment of (a) the Initial Indication, (b) the Second Indication (subject to Section 4.2(e)) and (c) any Additional Indication(s) for which the Parties agree to incorporate Additional Development Activities into the Development Plan and Development Budget in accordance with Section 4.3.

1.51 "**Final Label**" refers to the information regarding an approved Indication and population target that is included with a prescription drug as approved by an applicable Regulatory Authority.

1.52 "**Final Label 1a**" means the Final Label for a population from two (2) years of age up to twelve (12) years of age.

1.53 "**Final Label 1b**" means the Final Label for a population from four (4) years of age up to twelve (12) years of age.

1.54 "**Final Label 2**" means the Final Label for the population from twelve (12) years of age up to, at least seventeen (17) years of age or more.

1.55 "**First Commercial Sale**" means, on a Product-by-Product and country-by-country basis, the first sale of such Product in such country by Licensee or its Affiliates or Sublicensees to a Third Party after Regulatory Approval for such Product has been obtained in such country.

1.56 "**FTE**" means the equivalent of a full-time individual's work for a twelve (12) month period, consisting of a total of [***] hours per year of dedicated effort. Any person who devotes more or less than [***] hours per year on the applicable activities shall be treated as an FTE on a pro-rata basis, based upon the actual number of hours worked by such person on such activities, divided by [***]. For clarity, the hours spent by temporary workers and contractors on applicable activities may be treated as FTE on a pro-rata basis.

1.57 "**FTE Rate**" means an initial rate of (a) with respect to Ovid's personnel, [***] per FTE per year and (b) with respect to Licensee's personnel, [***] per FTE per year, which rates shall apply through [***]. Thereafter, the FTE Rate shall be changed annually on a Calendar Year

basis to reflect any year-to-year percentage increase or decrease (as the case may be) (i) with respect to Ovid, in the Consumer Price Index for All Urban Consumers for the U.S., as published by the U.S. Department of Labor, Bureau of Labor Statistics, and (ii) with respect to Licensee, in the Italy Consumer Price Index as published by the Italian National Statistical Institute (both changes based on the change from the most recent applicable index available as of the Effective Date to the most recent applicable index available as of the date of the calculation of such revised FTE Rate).

1.58 "**Generic Product**" means, (a) any pharmaceutical product which has received Regulatory Approval [***] of the Product; and/or (b) any other pharmaceutical product, approved under an Abbreviated New Drug Application, or ANDA, in the United States, under Section 505(b)(2) of the Food Drug and Cosmetic Act, or similar regulatory pathways outside of the U.S., in any case, with the Product as the reference product.

1.59 "**Generic Product Competition**" with respect to a Product, on a country-by-country basis, Generic Product Competition shall exist if [***] there are one or more Generic Products sold [***] in such country and the sales of such Generic Product(s) account for [***] or more of the sales revenue of the Product and its Generic Product(s) in the given country during such [***] as determined by reference to applicable sales data obtained from IMS Health, Verispan, or from such other reputable source for such sales data as may be used and relied upon by the Parties from time to time, provided however if sale of such Generic Product(s) [***], Generic Product Competition shall no longer exist.

1.60 "**Governmental Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization, or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.61 "**ICH**" means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.62 "**IND**" means an application filed with a Regulatory Authority for authorization to commence Clinical Trials, including (a) an Investigational New Drug Application or any successor application or procedure filed with the FDA, (b) a Clinical Trial Application or any successor application or procedure filed with the EMA, (c) any equivalent of the applications in (a) and (b) in countries or regulatory jurisdictions outside the U.S. and EU, and (d) all supplements, amendments, variations, extensions, and renewals thereof that may be filed with respect to the foregoing.

1.63 "**Indemnitee**" has the meaning set forth in Section 12.3.

1.64 "**Indemnitor**" has the meaning set forth in Section 12.3.

1.65 "**Independent Development Activities**" has the meaning set forth in Section 4.3(d).

1.66 "**Independent Development Costs**" has the meaning set forth in Section 8.2(b).

1.67 "**Indication**" means a separate and distinct disease, disorder, illness, or health condition and all of its associated signs, symptoms, stages, or progression (including precursor conditions), in each case for which a separate MAA may be filed. Subpopulations or patients with a primary disease or condition, however stratified (including stratification by stages or progression, particular combinations of symptoms associated with the primary disease or condition, prior treatment courses, response to prior treatment, family history, clinical history, phenotype, or other stratification) shall not be deemed to be separate "Indications" for the purposes of this Agreement.

1.68 "**Initial Indication**" means Angelman syndrome (AS).

1.69 "**International Transparency Reporting Requirements for Europe**" means EFPIA consolidated Code for Pharmaceutical Companies to report transfers of value related to HCPs: donations and grants, contribution to costs related to events, fees for service and consultancy, research and development.

1.70 "**Inventions**" means all inventions, whether or not patentable, discovered, made, conceived, or reduced to practice in the course of activities contemplated by this Agreement.

1.71 "**JPT**" has the meaning set forth in Section 3.2.

1.72 "**Joint Development Activities**" has the meaning set forth in Section 4.2(d).

1.73 "**Joint Inventions**" has the meaning set forth in Section 10.1(b)(ii).

1.74 "**Joint Patents**" has the meaning set forth in Section 10.1(b)(ii).

1.75 "**Know-How**" means all technical and scientific information, know-how, and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models, and other physical, biological, or chemical materials, expertise, and other technology applicable to development, registration, use, or marketing or to methods of assaying or testing them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, and analytical safety, nonclinical, and clinical data, regulatory documents, data and filings, instructions, processes, formulae, expertise, and information relevant to the research, development, use, importation, offering for sale, or sale of, or which may be useful in studying, testing, developing, Products. Know-How excludes Patents.

1.76 "**Licensee Data**" has the meaning set forth in Section 10.1(a).

1.77 "**Licensee Indemnitee**" has the meaning set forth in Section 12.1.

1.78 "**Licensee Know-How**" means all Know-How that Licensee or its Affiliate(s) Controls as of the Effective Date or during the Term, including any Joint Inventions, that is necessary or reasonably useful for the research, Development, manufacture, use, importation, offer for sale, or sale of the Compound or any Product in the Field. For clarity, subject to Section 8.2(b)

in the case of any Licensee Data generated as a result of Licensee's Independent Development Activities, the Licensee Know-How includes the Licensee Data.

1.79 "**Licensee Patents**" means all Patents that Licensee or its Affiliate(s) Controls as of the Effective Date or during the Term (including any Joint Patents) that would be infringed, absent a license or other right to practice granted under such Patents, by the research, Development, manufacture, use, importation, offer for sale, or sale of any Compound or Product (considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Licensee or its Affiliate).

1.80 "**Licensee Technology**" means the Licensee Know-How and the Licensee Patents, including Licensee's interest in the Joint Inventions and Joint Patents.

1.81 "**Licensee Territory**" or "**Licensed Territory**" means Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.

1.82 "**Licensee Territory Development Activities**" has the meaning set forth in Section 4.2(b).

1.83 "**Losses**" has the meaning set forth in Section 12.1.

1.84 "**Lundbeck License Agreement**" means the License Agreement by and between Ovid and H. Lundbeck A/S ("**Lundbeck**") dated 25 March, 2015, and amended on July 7, 2020 to clarify certain sights of sublicensees upon termination of such agreement (such amendment, the "**Lundbeck Sublicense Amendment**").

1.85 "**MAA**" means a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in any country or jurisdiction. For clarity, MAA does not include any application for Pricing and Reimbursement Approval.

1.86 "**MAA Approval**" means approval of an MAA by the applicable Regulatory Authority for marketing and sale of a Product in the applicable country or jurisdiction, but excluding any Pricing and Reimbursement Approval.

1.87 "**Major European Market**" means [***].

1.88 **Manufacturing Development**" means any of the following with respect to the Compound or a Product: manufacturing process development, process improvements and any analytical development or validation associated with such development or improvements.

1.89 "**Market Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by a Regulatory Authority with respect to a Product other than patents, including Directive 2001/83/EC and 2004/27/EC (as amended) in the EU and rights equivalent to those

conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity).

1.90 "**Medical Affairs**" or "**Medical Affairs Activities**" means activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, the Product, including by way of example: (a) activities of medical scientific liaisons/medical advisors who, among their other functions, may: (i) conduct service based medical activities including providing input and assistance with consultancy meetings, proposing investigators for clinical trials sponsored or co-sponsored by a Party or Affiliate, and providing input in the design of such trials and other research related activities; and/or (ii) deliver non-promotional communications and conduct non-promotional activities; (b) grants to support continuing medical education, symposia, or Third Party research related to the Product; (c) development, publication, and dissemination of original and literature review data relating to the Products; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call, or email; (e) conducting advisory board meetings, international advisory board activities, or other consultant programs, including the engagement of key opinion leaders and health care professional in individual or group advisory and consulting arrangements; and (f) the evaluation of applications submitted for support of investigator-initiated trials.

1.91 "**Neptune Trial**" means the Phase 3 Clinical Trial of the Product for Angelman Syndrome ongoing as of the Effective Date and for which Ovid is the sponsor, as further described in **Exhibit J**.

1.92 "**Net Sales**" means, with respect to any Product, the aggregate gross amount invoiced by Licensee, its Affiliates, or Sublicensees for the sale of the Product to a Third Party, less the following deductions to the extent allowed and actually taken on such sales:

(a) transportation charges relating to the Product to the extent actually invoiced to Licensee's, its Affiliate's, or Sublicensee's customers, including handling charges and insurance premiums relating thereto;

(b) sales taxes, excise taxes, use taxes, VAT, and duties paid by Licensee, its Affiliate, or Sublicensee in relation to the Product and any other equivalent governmental charges imposed on the importation, use, or sale of the Product;

(c) government-mandated rebates (including any Paybacks or Clawbacks charged with respect to the Product) and other rebates or fees;

(d) customary trade, quantity, and case discounts allowed on the Product;

(e) allowances or credits to customers on account of retrospective price reductions affecting the Product; and

(f) customary rebates (including confidential discount agreements Success Fee and Performance based Payments).

The transfer of Product between Licensee and its Affiliates and Sublicensees shall not be considered a sale unless the Affiliate or Sublicensee is a bona fide purchaser at fair market value for resale. If the Affiliate or Sublicensee is not an end user, Net Sales shall be determined based on the invoiced sale price by the Affiliate or Sublicensee to the first Third Party trade purchaser, less the deductions allowed under this Section 1.92. Disposal of Product for or use of Product in Clinical Studies or as free samples in quantities common in the industry for this sort of Product shall not give rise to any deemed sale under this definition.

Net Sales shall be calculated and accounted for in accordance with accounting standards during the Term (i.e., IFRS), consistently applied.

If Product is sold for other than cash payment, Net Sales of the Product shall be deemed to be the cash value of such other payment.

If the Product is sold as part of a Combination Product, Net Sales of such Product shall be deemed to be an amount equal to the following:

(X divided by Y) multiplied by Z,

where "**X**" is the average sales price during the applicable reporting period achieved for the relevant Product in the country in which such sale occurred when the Product contains only the Compound and no other active pharmaceutical ingredient;

"**Y**" is the sum of the average sales price as a single entity during the applicable reporting period achieved in that country (as applicable) of each product included in the Combination Product when such product is sold as a separate product and not as part of a Combination Product; and

"**Z**" is the single price at which the relevant Combination Product was actually sold.

In the event that no separate sale of either (a) the Product comprising the Compound as the sole active pharmaceutical ingredient, or (b) a product containing the other active pharmaceutical ingredient(s) included in the Combination Product, are made during the accounting period in which the sale was made or if the price for a particular therapeutically active ingredient cannot otherwise be determined for an accounting period, Net Sales allocable to the Product shall be determined by mutual agreement of the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the Territory, variations in potency, the relative contribution of each therapeutically active ingredient in the Combination Product, and relative value to the end user of each therapeutically active ingredient; provided, that if the Parties cannot reach mutual agreement prior to the end of the applicable accounting period, such matter shall be resolved in accordance with Article 15.

1.93 "**Orphan Drug Designation**" means a status assigned to a medicine intended for use against a rare condition. The medicine must fulfil certain criteria for designation as an orphan medicine so that it can benefit from incentives such as protection from competition once on the market.

1.94 "**Orphan Drug Designation of the Product**" means the EMA orphan drug designation obtained for the Product.

1.95 "**Orphan Medicine**" means a medicine that continues to meet the criteria for maintaining its orphan status in parallel with the assessment of an application for marketing authorisation by the European Medicines Agency (EMA).

1.96 "**Ovid Commercially Reasonable Efforts**" means, with respect to Ovid and its obligations under this Agreement, commercially reasonable efforts and resources as commonly used by a similar size pharmaceutical company to Develop and Commercialize a product controlled by Ovid or to which it has exclusive rights, which product is at similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved and/or anticipated labelling, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, likelihood of regulatory approval given the regulatory structure involved, the profitability of the product, [***], and other relevant factors, including technical, legal, scientific and/or medical factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis and indication-by-indication basis for a particular Product, and it is anticipated that the level of effort will change over the time, reflecting changes in the status of the Product and the country(s) involved.

1.97 "**Ovid Data**" has the meaning set forth in Section 10.1(a).

1.98 "**Ovid Indemnitee**" has the meaning set forth in Section 12.2.

1.99 "**Ovid Know-How**" means all Know-How that Ovid Controls as of the Effective Date or, subject to Section 2.7(b), during the Term, including any Joint Inventions, that is necessary or reasonably useful for the Development, use, importation, offer for sale, or sale of any Compound or Product in the Field in the Licensee Territory. For clarity, any Ovid Data generated during Ovid's Independent Development Activities will be included within the Ovid Know-How following reimbursement by Licensee of its share of Development Costs in accordance with Section 8.2(b).

1.100 "**Ovid Ongoing Trials**" means the Rocket Trial, Elara Trial, and Neptune Trial.

1.101 "**Ovid Patents**" means all Patents in the Licensee Territory that Ovid Controls as of the Effective Date or, subject to Section 2.7(b), during the Term (including any Joint Patents) that would be infringed, absent a license or other right to practice granted under such Patents, by the Development, use, importation, offer for sale, or sale of any Compound or Product in the Field in the Licensee Territory (considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Ovid). The Ovid Patents existing as of the Effective Date are set forth in **Exhibit B**.

1.102 "**Ovid Technology**" means the Ovid Know-How and the Ovid Patents, including Ovid's interest in the Joint Inventions and Joint Patents.

1.103 "**Ovid Territory**" means the world outside the Licensee Territory.

1.104 "**Paediatric Investigational Plan (PIP)**" is the development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for use in children. Any Applicants must obtain EMA approval of the PIP before MAA.

1.105 "**Patents**" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings, provisional patent applications and patent applications, and (b) any renewals, divisions, or continuations (in whole or in part) of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, supplementary protection certificates, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.106 "**Payback**" means payback policies which require manufacturers to pay back a share of their revenue in respect of a product, if a prespecified budget ceiling for public pharmaceutical expenditures is exceeded.

1.107 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.4.

1.108 "**Phase 1 Clinical Trial**" means a human clinical trial of a pharmaceutical product that satisfies the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.109 "**Phase 2 Clinical Trial**" means a human clinical trial of a pharmaceutical product that satisfies the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.110 "**Phase 3 Clinical Trial**" means a human clinical trial of a pharmaceutical product for an indication on a sufficient number of subject that is designed to establish that the pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions and adverse reactions that are associated with the pharmaceutical product in the dosage range to be described, and to support Regulatory Authority to market such Product in patients having the indication being studied and that satisfies the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.111 "**Phase 4 Clinical Trial**" means a product support clinical trial of a Product that is commenced after receipt of MAA Approval in the country where such trial is conducted. Phase 4 Clinical Trial may include epidemiological studies, modeling and pharmacoeconomic studies, and post-marketing surveillance trials.

1.112 "**PIP Compliance Check**" means that PIP has been checked by EMA for compliance with all the measures mentioned in the PIP decision, including the timelines for the conduct of the studies or collection of the data.

1.113 "**Pricing and Reimbursement Approval**" means, with respect to a Product, the approval, agreement, determination, or decision of any applicable Governmental Authority

establishing the price or reimbursement level for such Product, as required in a given country or jurisdiction prior to sale of such Product in such country or jurisdiction.

1.114 "**Product**" means any pharmaceutical product containing the Compound as an active ingredient, alone or in combination with one or more other active pharmaceutical ingredients, in any form, presentation, dosage, or formulation, and for any mode of administration.

1.115 "**Product Infringement**" has the meaning set forth in Section 10.3(a).

1.116 "**Promotional Materials**" has the meaning set forth in Section 6.4(c).

1.117 "**Proposal**" has the meaning set forth in Section 4.3.

1.118 "**Proposing Party**" has the meaning set forth in Section 4.3.

1.119 "**Public Official or Entity**" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality, or subdivision of any government, military, or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party, or any official of a political party.

1.120 "**Rare Disease**" means a disease that affects one person per two thousand (2,000).

1.121 "**Recall**" has the meaning set forth in Section 5.7.

1.122 "**Regulatory Approval**" means, with respect to a country or jurisdiction, any and all approvals (including MAA Approval and, if required by Applicable Law, Pricing and Reimbursement Approval), licenses, registrations, permits, notifications and authorizations (or waivers) of any Regulatory Authority that are necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of a Product in such country or jurisdiction.

1.123 "**Regulatory Authority**" means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given jurisdiction. For countries where Pricing and Reimbursement Approval is required, Regulatory Authority shall also include any Governmental Authority whose grant of Pricing and Reimbursement Approval of the Product is required.

1.124 "**Regulatory Filing**" means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the testing, Development, manufacture, or Commercialization of any Product made to or received from any Regulatory Authority in a given country, including INDs and MAAs.

1.125 "**Regulatory Meeting**" has the meaning set forth in Section 5.1(c)(ii).

1.126 "**Regulatory Milestone Event**" has the meaning set forth in Section 8.3(a).

1.127 "**Rocket Trial**" means the Phase 2 Clinical Trial of the Product for Fragile X Syndrome ongoing as of the Effective Date and for which Ovid is the sponsor, as further described in **Exhibit J**.

1.128 "**Safety Data**" means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities. Safety Data also includes "adverse events", "adverse drug reactions", and "unexpected adverse drug reactions" as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

1.129 "**SEC**" means the U.S. Securities and Exchange Commission, or any successor entity or its foreign equivalent, as applicable.

1.130 "**Safety Reason**" has the meaning set forth in Section 4.15.

1.131 "**Sales Milestone Event**" has the meaning set forth in Section 8.4(a).

1.132 "**Scientific Advice**" means any report of the advice provided by EMA to medicine developers on the most appropriate way to generate robust evidence on a medicine's benefits and risks.

1.133 "**Second Indication**" means Fragile X syndrome (FXS).

1.134 "**Second Indication Opt-In**" means the election by Licensee, following the Licensee's exercise of the Second Indication Opt-Out, to resume the Licensee's rights granted to Licensee according to Section 2.1 with respect to the Second Indication.

1.135 "**Second Indication Opt-Out**" means the election by Licensee, in accordance with the terms hereof, not to participate in Development and/or Commercialization activities for the Product for the Second Indication.

1.136 "**Segregate**" means, with respect to a Competing Product, to [***] segregate the Development, Manufacturing and Commercialization of such Competing Product in the Field from Development, Manufacture and Commercialization activities with respect to Compounds and Products under this Agreement, including [***]; provided that, [***].

1.137 "**Sponsor**" means the Party that takes the ultimate responsibility for the initiation, performance, and management of, including financing or arranging the financing for, the applicable Clinical Trial.

1.138 "**Sublicensee**" means a Third Party to whom Licensee grants a sublicense to Develop, use, import, promote, offer for sale, or sell any Product in the Field in the Licensee Territory. In no event shall Ovid or any of its Affiliates be deemed a Sublicensee.

1.139 "**Success Fee**" or "**Performance Based Payments**" means the returned part of the Product-generated revenues for those cases where outcomes are not meeting pre-defined clinical

goals set by National Health Authority (e.g.QoL Gain, Survival, Progression, Course of Disease Modification).

1.140 "**Sunshine Reporting Laws**" has the meaning set forth in Section 5.8.

1.141 "**Supply Agreement**" means the supply agreement between Ovid and Licensee attached hereto as **Exhibit K**.

1.142 "**Take the Lead**" means, with the respect to a particular Party and a particular activity, that such Party is primarily responsible for, and has the authority to make, all day-to-day operational decisions, in accordance with the Development Plan and Commercialization Plan and the terms of this Agreement; provided that [***]; and provided further that [***]. For clarity, [***].

1.143 "**Technology Transfer Completion Date**" means the earlier of (a) the date on which the activities [***], as set forth in the Technology Transfer Plan, has been completed, but for clarity, excluding [***] and (b) the [***].

1.144 "**Technology Transfer Agreement**" has the meaning set forth in Section 11.4(e).

1.145 "**Technology Transfer Plan**" has the meaning set forth in Section 11.4(e).

1.146 "**Term**" has the meaning set forth in Section 14.1.

1.147 "**Third Party**" means any entity other than Ovid or Licensee or an Affiliate of Ovid or Licensee.

1.148 "**Threshold Price Sale**" means, on a Product-by-Product and country-by-country basis, the first sale of such Product in such country (after Regulatory Approval for such Product has been obtained in such country) for which Licensee or its Affiliate or Sublicensee, as applicable, invoices a Third Party (a) [***], or (b) [***].

1.149 "**Total Supply Price**" means, for any Product, [***].

1.150 "**U.S.**" means the United States of America, including its territories and possessions (including Puerto Rico).

1.151 "**Valid Claim**" means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise, or (b) a claim of a pending patent application that has not been cancelled, withdrawn, or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

2. GRANT OF LICENSES

2.1 Licenses Granted to Licensee. Subject to the terms and conditions of this Agreement, Ovid hereby grants to Licensee, during the Term:

(a) an exclusive (even as to Ovid, except as expressly set forth herein), royalty-bearing license, with the right to grant sublicenses (through multiple tiers) solely as provided in Section 2.2, under the Ovid Technology to use and have used, sell, offer for sale, import, and otherwise Commercialize and have Commercialized (but not to make or have made, unless otherwise provided herein) the Products in the Field in the Licensee Territory;

(b) a non-exclusive license, with the right to grant sublicenses (through multiple tiers) solely as provided in Section 2.2, under the Ovid Technology to Develop (but not to make or have made unless otherwise provided herein) the Products on a worldwide basis in accordance with the Development Plan, and to use the Products for that purpose; and

(c) a non-exclusive, royalty-bearing license, with the right to grant sublicenses (through multiple tiers) solely as provided in Section 2.2, under the Ovid Technology to make or have made the Products solely for use in the Field in the Licensee Territory in accordance with the licenses granted in Sections 2.1(a) and 2.1(b), provided that, for clarity, Licensee's rights under any Patents and Know-How Controlled by Lundbeck that are included within the Ovid Technology shall be subject to the completion of the Technology Transfer and the terms of the Lundbeck License Agreement; and

(d) solely as and to the extent provided in Section 14.5, an exclusive (even as to Ovid, except as expressly set forth herein), royalty-bearing license, with the right to grant sublicenses (through multiple tiers) solely as provided in Section 2.2, under the Ovid Technology to Develop, have developed, use and have used, sell, offer for sale, import, and otherwise Commercialize and have Commercialized the Products in the Field in the Licensee Territory.

2.2 Sublicenses. Licensee shall have the right to grant sublicenses under the licenses granted in Section 2.1:

(a) to an Affiliate of Licensee without Ovid's express prior written consent but with written notice to Ovid, provided that such sublicense will terminate if such sublicensee no longer qualifies as an Affiliate of Licensee**.**

(b) to a Third Party other than as set forth in Section 2.2(a) with Ovid's express prior written consent (not to be unreasonably withheld, conditioned or delayed).

All sublicenses granted under the licenses granted in Section 2.1 shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement and shall provide that any such Sublicensee (including any distributor) shall not further sublicense except with the written consent of Licensee and Ovid. Licensee shall ensure that each agreement with a Sublicensee grants Ovid all rights with respect to Data, Inventions, and Regulatory Filings made or generated by such Sublicensee as if such Data, Inventions, and Regulatory Filings were made or generated by Licensee. Licensee shall be responsible for the compliance of its Affiliates,

Sublicensees (including any distributors), and subcontractors with the terms and conditions of this Agreement. Licensee shall provide written notice to Ovid of each sublicense granted to a Third Party hereunder, specifying the name of the Sublicensee, the territory, and the duration of the sublicense.

2.3 Reserved Rights. Ovid hereby expressly reserves:

(a) the right under the Ovid Technology to exercise its rights and perform its obligations under this Agreement, whether directly or through one or more licensees or subcontractors; and

(b) all rights to practice, and to grant licenses under, the Ovid Technology outside of the scope of the licenses granted in Section 2.1.

2.4 Licenses Granted to Ovid. Subject to the terms and conditions of this Agreement, including Section 2.8, Licensee hereby grants to Ovid:

(a) a non-exclusive, royalty-free, fully paid-up license, with the right to sublicense (through multiple tiers), under the Licensee Technology to use, sell, offer for sale, import, and otherwise Commercialize the Products in the Ovid Territory; and

(b) a non-exclusive, worldwide, royalty-free, fully paid-up license, with the right to sublicense (through multiple tiers), under the Licensee Technology to (i) Develop the Compound and Products on a worldwide basis under the Development Plan, and (ii) to make and have made the Compound and Products anywhere in the world.

2.5 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How, or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or (sub)licensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6 Disclosure of Know-How. For as long as the Parties are conducting Development activities under the Development Plan, upon Licensee's written request no more frequently than [***], Ovid shall disclose and make available to Licensee, in electronic form where possible, all Ovid Know-How that comes into existence after the Effective Date and that was not previously provided to Licensee, promptly after the earlier of the development, making, conception, or reduction to practice of such Ovid Know-How. For as long as the Parties are conducting Development activities under the Development Plan, upon Ovid's written request no more frequently than [***], Licensee shall, and shall cause its Affiliates to, disclose and make available to Ovid, in electronic form where possible, any Licensee Know-How not previously provided to Ovid, promptly after the earlier of the development, making, conception, or reduction to practice of such Licensee Know-How. The CGB shall establish a mechanism for the reciprocal disclosure of such Know-How.

2.7 Third Party Licenses.

(a) Notice. Licensee shall promptly notify Ovid if it becomes aware of any Third Party Know-How or Patent that is necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale, or import the Compound or Product in the Field in the Licensee Territory, and [***].

(b) Sublicense under Third Party License. If Ovid enters into any agreement with a Third Party after the Effective Date that includes a license from such Third Party to Ovid under any Know-How or Patents that are necessary to Develop, use, sell, offer for sale, or import the Products in the Field in the Licensee Territory, and Ovid has the right to grant a sublicense under such Know-How or Patents to Licensee, then Ovid shall notify Licensee and identify the relevant Know-How or Patents and provide Licensee with the substantive terms of the applicable Third Party license agreement to Licensee, in each case to the extent applicable to the rights that would be sublicensed to Licensee. Such Know-How and Patents, to the extent falling within the definition of Ovid Technology, will be sublicensed to Licensee only if Licensee provides Ovid with written notice in which (i) Licensee consents to adding such Patents and Know-How to the definition of Ovid Technology and (ii) Licensee acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement.

(c) Licensee Restriction. Except with the prior written consent of Ovid, Licensee shall not obtain a license to any Third Party Patent or Know-How that is necessary to Develop, make, have made, use, sell, offer for sale, or import the Products in the Ovid Territory.

2.8 Exclusivity.

(a) Exclusivity. Subject to Section 2.8(c), for the period starting from the Effective Date and for [***] in the Licensee Territory, neither Party shall, directly or indirectly (including through an Affiliate or a Third Party), develop or commercialize any Competing Product that is directed to the treatment of the Initial Indication or Second Indication in the Licensee Territory.

(b) Competing Program Exclusivity. If a Third Party becomes an assignee of this Agreement from a Party, or becomes an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation, or other similar transaction, and such Third Party, as of the closing date of such transaction, is engaged in the development or commercialization of a Competing Product in the Licensee Territory (a "**Competing Program**"), then such Competing Program shall not be a breach of Section 2.8(a), so long as (i) such Third Party, or such Party or its Affiliates, [***], and (ii) [***] such Competing Product. [***] of such Competing Program.

(c) Territory Exclusivity. During the Term, Licensee shall not, directly or indirectly (including through an Affiliate or a Third Party), Commercialize the Product in the Ovid Territory. Ovid shall not, directly or indirectly (including through an Affiliate or a Third Party), Commercialize the Product in the Licensee Territory, except as provided in Section 2.3(a).

(d) Effect of Triggering Acquisition. In the event of an acquisition of Ovid by a Competing Acquirer that closes prior to [***] (a "**Triggering Acquisition**"), then Ovid shall

provide notice to Licensee of such Triggering Acquisition within [***] after the date upon which the Triggering Acquisition closes or otherwise becomes effective. On or before the date that is [***] after the date on which Licensee receives notice of a Triggering Acquisition, Licensee shall have the right to elect to Take the Lead on any or all then current Joint Development Activities and future Licensee activities in the Licensee Territory, [***] remaining in full force and effect. For sake of clarity, [***].

2.9 Licensee's access to Ovid Data, Know-How and Patents

(a) Ovid hereby agrees to provide to Licensee, within [***] following the Effective Date, a list of (a) [***] the Ovid Know-How [***] and (b) [[***] the Compound and/or Product necessary for Licensee's Development, use, manufacture, and Commercialization of the Product in the Field in the Licensee Territory, [***].

(b) Promptly following the Effective Date, Ovid shall transfer to Licensee information in its possession and control that relate to [***].

(c) From time to time during the Term, and at no additional cost to Licensee (subject to Section 4.5), Ovid shall provide to Licensee [***] the Ovid Know-How solely relating to the Compound and/or the Product, reasonably requested by Licensee and necessary for Licensee's Development, use, manufacture, and Commercialization of the Product.

(d) Ovid hereby agrees that, [***] following the Effective Date, Ovid will provide to Licensee the Ovid Know-How [***] for Licensee to Develop, manufacture, use, and Commercialize the Compound and the Product in the Field in the Licensee Territory in accordance with the terms of this Agreement. Licensee shall reimburse Ovid all out of pocket costs and reasonable, internal cost related to such technology transfer.

2.10 Licensee's Access to Ovid Personnel. The Parties acknowledge the significant contribution and experience of Ovid and Ovid employees to the Development, manufacture, use, and Commercialization of the Compound and Product prior the Effective Date and that these contributions and experience may be valuable to Licensee. Accordingly, Licensee is entitled to meet with employees of Ovid who hold significant experience or expertise in the Development activities, and manufacture, use, and Commercialization of the Compound and Product. Licensee shall provide reasonable notice to Ovid requesting such a meeting and Ovid's approval of date and agenda of meeting shall not be unreasonably withheld. Each Party shall bear its own cost in relation to such meetings.

3. GOVERNANCE

3.1 Collaboration Governance Board. As of the Effective Date, the Parties have established a board to govern their collaboration under this Agreement (the "**Collaboration Governance Board**" or the "**CGB**"), composed of an equal number of up to [***] employees of each Party, to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The CGB shall act as a joint consultative body and, to the extent expressly provided herein, a joint decision-making body. The CGB shall in particular:

(a) review and discuss the strategy for the Development of the Product worldwide, coordinate and oversee the overall implementation of the Development Plan;

(b) provide a forum for discussion of the Development and Commercialization of the Compound and Products in the Licensee Territory;

(c) monitor performance of Development activities in and for the Licensee Territory, including performance against agreed budgets, and discuss and approve any budget overruns;

(d) oversee the activities of the JPT, and serve as a forum for resolution of disputes arising at the JPT;

(e) review and discuss any proposed amendments to the Development Plan, including corresponding budgets, and approve any proposed amendments to Joint Development Activities under the Development Plan;

(f) review, discuss, and approve Clinical Trial protocols for jointly-conducted Clinical Trials, and monitor the progress of all Clinical Trials in the Licensee Territory;

(g) review Clinical Trial Data from jointly-conducted Clinical Trials to determine whether progress to the next phase Clinical Trial is merited;

(h) review, discuss, and approve Proposals, including amendments to the Development Plan with respect to activities directed to Additional Indications;

(i) monitor and coordinate regulatory strategy and activities for the Licensee Territory, including activities directed to obtaining Regulatory Approval in Additional Indications;

(j) coordinating reporting of pharmacovigilance and safety matters for the Product worldwide (monitoring and coordinating of pharmacovigilance and safety matters will conducted in accordance with the pharmacovigilance agreement);

(k) oversee and coordinate Medical Affairs Activities for the Product in all Indications in the Licensee Territory;

(l) review and discuss the Commercialization Plan for the Licensee Territory, including any amendments proposed thereto, and oversee the Commercialization of Products in the Licensee Territory in accordance with the global commercialization strategy for Products;

(m) provide a forum for discussion regarding launch sequencing, pricing and reimbursement strategy for Products in the Licensee Territory and discuss potential international pricing reference by relevant Regulatory Authorities;

(n) oversee the manufacturing and supply strategy and monitor supply of Products for the Licensee Territory;

(o) oversee and facilitate the Parties' communications and activities with respect to publications under Section 13.4;

(p) establish joint subcommittees as it deems necessary or advisable to further the purpose of this Agreement, including as set forth in Section 3.7; and

(q) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties' written agreement, including providing financial oversight of the activities conducted pursuant to this Agreement.

3.2 Joint Project Team. No later than [***] following the Effective Date, the Parties will establish a cross-functional joint project team (the "**JPT**"), composed of an equal number of up to [***] employees of each Party, to (a) design and implement the Development Plan (subject to CGB review and approval), and (b) oversee the commercial strategy and Commercialization of the Products in the Licensee Territory. The JPT shall in particular:

(a) oversee the conduct of activities under the Development Plan in the Licensee Territory and report to the CGB on such activities;

(b) provide a forum for, and facilitate communications between the Parties with respect to the Development of Products in the Licensee Territory, including sharing of Data in accordance with Section 4.7;

(c) prepare and submit to the CGB for approval protocols for jointly-conducted Clinical Trials;

(d) prepare amendments to the Development Plan as needed (including corresponding changes to the Development Budget) and submit such amendments to the CGB for approval;

(e) review and discuss Proposals and make recommendations to the CGB with respect thereto;

(f) review and discuss the CMC components of the Regulatory Filings in the Licensee Territory, and oversee and coordinate the manufacture and supply of Drug Product to Licensee for use in Clinical Trials for which Licensee is the Sponsor in the Licensee Territory;

(g) prepare and submit to the CGB for approval a plan for manufacture and supply of Drug Product for commercialization in the Licensee Territory;

(h) review the Commercialization Plan prepared by Licensee for alignment with the global commercialization strategy for Products, and provide comments thereto;

(i) monitor the conduct of Commercialization of Products in the Licensee Territory; and

(j) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Development of Products.

3.3 Committee Membership and Meetings.

(a) Committee Members. Each Committee representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of such Committee's responsibilities. Each Party may replace its representatives on a Committee on written notice to the other Party. The CGB chairperson shall be one of the representatives appointed by Ovid. The chairperson of the JPT shall alternate between one of the representatives appointed by Ovid and one of the representatives appointed by Licensee. The chairperson shall prepare and circulate agendas to Committee members at least [***] before each Committee meeting and shall direct the preparation of reasonably detailed notes for each such Committee meeting, which shall be approved by the chairperson and circulated to Committee members within [***] after such meeting. If not determined as of the Effective Date, the Parties shall determine their respective initial members of each Committee promptly following the Effective Date.

(b) Meetings. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall meetings of the JPT be held less frequently than [***], and meetings of the CGB once every [***]. The first CGB meeting and first JPT meeting shall be held within [***] after the Effective Date. Committee meetings may be held in person or by audio or video teleconference. In-person Committee meetings shall be held at locations alternately selected by the Parties. Each Party shall be responsible for all of its own expenses of participating in any Committee meeting. No action taken at any Committee meeting shall be effective unless at least one (1) representative of each Party is participating. In addition, upon written notice to the other Party, either Party may request that a special *ad hoc* meeting of a Committee be convened for the purpose of resolving any disputes in connection with, or for the purpose of reviewing or making a decision pertaining to any material subject-matter within the scope of such Committee, the review or resolution of which cannot be reasonably postponed until the following scheduled Committee meeting. Such *ad hoc* meeting shall be convened at such time as may be mutually agreed by the Parties, but no later than [***] following the notification date of request that such meeting be held.

(c) Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend Committee meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

3.4 Decision-Making.

(a) All decisions of a Committee shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter, the representatives of the Parties

cannot reach an agreement as to such matter within [***] after such matter was first considered, then if such disagreement arose within the JPT, it shall be referred to the CGB for resolution. If the CGB cannot resolve such matter within a further [***], or if the disagreement first arose within the CGB, then prior to any formal dispute resolution process such issue shall be referred to the Executive Officers for resolution.

(b) If the Executive Officers cannot resolve such matter within [***] after such matter has been referred to them, then:

(i) Ovid shall have the final decision making authority, which shall be exercised in its reasonable discretion, with respect to (A) Ovid's Independent Development Activities, (B) the Ovid Ongoing Trials, (C) all manufacturing matters outside the Licensee Territory, and (D) Joint Development Activities necessary for obtaining Regulatory Approvals for Products in any Indication in the Licensee Territory for which Ovid is the sponsor (including any necessary updates to the Development Plan and Development Budget pursuant to Section 4.2, but subject in all cases to Sections 3.4(b)(i)(1) and 3.4(b)(i)(2)), except for:

(1) the addition of new Clinical Trials to the Development Plan as Joint Development Activities (the cost of which would be shared by the Parties); and

(2) any material modification to a previously agreed upon Clinical Trial that is set forth in the Development Plan as Joint Development Activities (unless such modification is required by a Regulatory Authority or any local or regional IRB/ethics committee, or is reasonably necessary to protect patient safety); for the purpose of this Section 3.4(b)(i)(2), "material modification" means [***].

(ii) Licensee shall have the final decision making authority with respect to (A) Joint Development Activities necessary for obtaining Regulatory Approvals for Products in any Indication in the Licensee Territory for which Licensee is the sponsor (including any necessary updates to the Development Plan and Development Budget pursuant to Section 4.2, but subject in all cases to Sections 3.4(b)(i)(1) and 3.4(b)(i)(2)), (B) the determination of whether the Additional Pivotal Trial is necessary to obtain Regulatory Approval in the Licensee Territory (although [***] for the Additional Pivotal Trial) (C) Commercialization of the Product in the Licensee Territory, (D) Licensee Territory Development Activities and (E) Licensee's Independent Development Activities in the Licensee Territory, and (F) Phase 4 Clinical Trials for the Licensee Territory (but subject in all cases to Sections 3.4(b)(i)(1) and 3.4(b)(i)(2)), in each case (A) through (F) provided that Licensee's exercise of any such decision right does not adversely affect, the Development, manufacture, or Commercialization of the Product in the Ovid Territory, and complies with the terms and conditions of this Agreement. For clarity, [***].

(iii) Neither Party shall have the final decision making authority with respect to the matters in Sections 3.4(b)(i)(1) and (2), and the status quo shall persist with respect to such matter unless and until the Parties are able to agree.

3.5 Limitations on Authority. Each Committee shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, no Committee will have the power to amend this Agreement, and no Committee decision may be in contravention of any terms and conditions of this Agreement.

3.6 Discontinuation of the Committees. The activities to be performed by each Committee shall solely relate to governance under this Agreement and are not intended to be or involve the delivery of services. Each Committee shall continue to exist until the first to occur of (a) the Parties mutually agree to disband such Committee or (b) Ovid provides written notice to Licensee of its intention to disband and no longer participate in such Committee. Once the Parties mutually agree or Ovid has provided written notice to disband a Committee, such Committee shall have no further obligations under this Agreement and, thereafter, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through Alliance Managers, and decisions of such Committee shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement. [***].

3.7 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. The Alliance Manager will ensure communication to the CGB of all relevant matters raised at the JPT and any other subcommittee. Each Alliance Manager shall be permitted to attend meetings of the CGB and JPT, in each case as appropriate and as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Party shall bear its own costs of its Alliance Manager, which costs shall be excluded from the Parties' respective Development and manufacturing costs (including Cost of Goods) under this Agreement.

3.8 Supply Contacts. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of Drug Product under this Agreement ("**Supply Contacts**"). Each Party may replace its Supply Contact with an alternative representative at any time with prior written notice to the other Party. The Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of Drug Product under this Agreement. The Supply Contacts shall have decision-making authority with respect to the supply of Drug Product under this Agreement within the guidance of the JPT and subject to the review and approval of the CGB. Each Party shall bear its own costs of its Supply Contact, which costs shall be excluded from the Parties' respective Development and manufacturing costs (including Cost of Goods) under this Agreement.

4. DEVELOPMENT

4.1 Overview. Subject to the terms and conditions of this Agreement, the Parties will collaborate with respect to the Development of the Compound and Products and share the Data resulting from such collaboration as provided in this Article 4 to facilitate the Development of the Compound and Products throughout the Licensee Territory and the Ovid Territory.

4.2 Amendments to Development Plan. Any amendment to the Development Plan for the Compound and Products under this Agreement, including the Ovid Ongoing Trials, Licensee Territory Development Activities for registrational purposes, all Joint Development Activities, and all Independent Development Activities shall be conducted pursuant to a comprehensive written updated (from time to time) Development Plan (the "**Amended Development Plan**"), which shall be incorporated by reference into this Agreement. The Amended Development Plan will include Clinical Trials for the Initial Indications that the Parties have agreed to conduct jointly (unless modification is required by a Regulatory Authority or any local or regional IRB/ethics committee, or is reasonably necessary to protect patient safety), the Clinical Trials for the Second Indication that Ovid may conduct under its sole responsibility and cost if Licensee exercises the Second Indication Opt-Out and not the Second Indication Opt-In, as well as Clinical Trials for the Additional Indications that the Parties (through the CGB) mutually agree to conduct and include in accordance with Section 4.3. The Amended Development Plan will also include:

(1) any other Development activities approved by the CGB in accordance with Article 3; and

(2) the PIP for the Initial Indication; and

(3) the Additional Pivotal Trial, if applicable.

The Amended Development Plan shall also set forth the amendments to the detailed budget of the anticipated costs for all Development activities (the "**Amended Development Budget**") on a study-by-study or Clinical Trial-by-Clinical Trial basis. As of the Effective Date, the Parties have agreed upon an initial Development Plan and Development Budget, attached to this Agreement as **Exhibit C**. If the terms of the Development Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern. In addition, the following shall apply to the Development of the Compound and Products under the Development Plan:

(a) Neptune Trial, Rocket Trial and Elara Trial. Ovid shall be responsible for, and shall use Commercially Reasonable Efforts to conduct, at its own expense, (i) the Neptune Trial, (ii) the Rocket Trial, and (iii) the Elara Trial ((i)-(iii) collectively, the "**Ovid Ongoing Trials**").

(b) PIP. Ovid shall be responsible for the full applying process to obtain EMA agreement for the Paediatric Investigational Plan in order to allow the Licensee to submit the MAA for the Product for the Initial Indication in the Licensee Territory. Ovid shall discuss and agree with the Licensee the PIP before moving forward with the application process.

(c) Licensee Territory Development Activities for Initial Indication.

(i) Licensee shall be solely responsible for and shall use Angelini Commercially Reasonable Efforts to conduct, at its sole expense, all Development activities that are exclusively for the benefit of one or more countries within the Licensee Territory for the Initial Indication, including (A) any and all Development activities required or recommended by a Regulatory Authority for the exclusive benefit of the Licensee Territory, including any Phase 4 Clinical Trials for the Initial Indication in the Licensee Territory, and (B) any and all Development activities required for any Pricing and Reimbursement Approval in the Licensee Territory.

(ii) Licensee shall be solely responsible for the Additional Pivotal Trial, and for the Phase 4 Clinical Trials of the Product in the Licensee Territory, but Licensee shall bear [***] and Ovid shall bear [***] of the Development Costs for the Development Activities for the Additional Pivotal Trial, up to a total amount of [***], and for any Additional Pivotal Trial Development Costs in excess of [***] Licensee shall bear [***] and Ovid shall bear [***].

(iii) The activities specified in the foregoing subsections (i) and (ii) shall be referred to collectively as the "**Licensee Territory Development Activities**". Prior to commencing any Licensee Territory Development Activities, Licensee shall provide the CGB with a draft workplan therefor, and following review and approval of such Licensee Territory Development activities by the CGB, such Licensee Territory Development Activities shall be included in and conducted in accordance with the Development Plan, subject to the oversight of the CGB and JPT as set forth in Article 3. Notwithstanding anything to the contrary herein, Licensee shall consider in good faith and incorporate Ovid's reasonable comments on any proposed Licensee Territory Development Activities.

(d) Joint Development Activities for Initial Indication and Second Indication. The Development Plan shall set forth the timeline and details ([***]) of all preclinical (if any) and clinical Development activities ([***]) to be conducted jointly by the Parties in order to generate Data sufficient to meet the common requirements of the FDA, EMA, and other Regulatory Authorities agreed upon by the Parties for MAA Approval of the Compound and Products for each of the Initial Indication and eventually and separately for the Second Indication, ([***]) (such activities, the "**Joint Development Activities**"). All Joint Development Activities shall be included in and conducted in accordance with the Development Plan, subject to the oversight of the CGB and JPT as set forth in Article 3. The Development Plan shall also set forth the allocation of responsibility for all Joint Development Activities as between the Parties. All Development Costs Associated with Joint Development Activities shall be borne in accordance with Section 8.2(a).

(e) Second Indication Opt-Out and Second Indication Opt-In.

(i) Second Indication Opt-Out. If Licensee determines, at its sole and absolute discretion, within [***], not to pursue further additional Development activities with respect to the Second Indication, Licensee shall have the right to exercise the Second Indication Opt-Out, exercisable by written notice to Ovid. The Second Indication Opt-Out shall be effective as of the date of such notice. If Licensee exercises the Second Indication Opt-Out, then the definition of Field shall automatically be deemed to not include the Second Indication, provided

that if Ovid undertakes to submit an MAA for the Product for the Second Indication in the Licensee Territory it shall do so with a trademark other than the Trademark for the Initial Indication.

(ii) Second Indication Opt-In. In any case, after Licensee has made the Second Indication Opt-Out, Licensee will have the right, at any time as below and for any reason, to exercise the Second Indication Opt-In, exercisable by written notice to Ovid [***]. The Second Indication Opt-In shall be effective as of the date of such notice. If Licensee makes the Second Indication Opt-In, then Licensee shall reimburse to Ovid an amount equal to [***] of all Development Costs incurred by Ovid in the conduct of Development activities for the Second Indication during the period of Licensee's Second Indication Opt-Out, and [***] of all Development Costs incurred for such Development activities following the Second Indication Opt-In. Then the definition of Field shall automatically be deemed to include the Second Indication

(f) Regulatory Filings. The Development Plan shall include a coordinated Development and regulatory strategy, including the Parties' respective roles in the development of the registration dossier and Regulatory Filings for the Products, and the countries in which Clinical Trials of the Products will occur. All costs associated with regulatory activities in connection with Regulatory Filings and obtaining MAA Approval for Products in the Licensee Territory shall be borne solely by Licensee.

(g) Updates. During the Term (at least on a [***] basis), the JPT shall review the Development Plan and prepare updates and amendments, as appropriate, to the then-current Development Plan, including budgets, and submit such updates and amendments to the CGB for review and approval. If the CGB determines that any pre-clinical studies or Clinical Trials not included in the Development Plan are required in order to obtain or maintain MAA Approval for a Product for the Initial Indication in one or more countries in the Licensee Territory, then the CGB shall review and approve an amendment to the Development Plan reflecting such additional studies, including associated budget. Such additional Development activities for the Initial Indication shall be either Licensee Territory Development Activities or Joint Development Activities and the costs of such additional studies shall be borne by the Parties as provided in Section 4.5(a).

4.3 Additional Indications.

(a) Proposal. If either Party (the "**Proposing Party**") desires to pursue additional Development of a Product in order to seek Regulatory Approval of the Product in one or more Additional Indications for the benefit of (a) the Ovid Territory and Licensee Territory in the case of Ovid, or (b) the Licensee Territory in the case of Licensee, in each case beyond what is set forth in the then-current Development Plan, then such Party shall provide the other Party (the "**Reviewing Party**") with a written detailed plan and budget for such additional work (the "**Proposal**"). Within [***] after the Reviewing Party's receipt of the Proposal (or at such other time as the Parties may mutually agree), the JPT shall meet to review and discuss in good faith the Proposal and permit the Reviewing Party an opportunity to ask questions and request additional information from the Proposing Party related to the Proposal, including whether such Proposal is reasonably likely to have any adverse effect on the Development or Commercialization of the Product in the Reviewing Party's territory. No work under any Proposal shall proceed unless and until (i) the CGB determines in its reasonable discretion that such Proposal is not likely to

adversely affect the Development or Commercialization of the Product in the Reviewing Party's territory, and (ii) in the case of Licensee as the Proposing Party, Ovid consents in writing to such activities being included as Joint Development Activities, or to Licensee performing such additional Development as Licensee Territory Development Activities (where such Development Activities solely and specifically relate to the Licensee Territory), or as Independent Development Activities, such consent not to be unreasonably withheld. For clarity, (i) Licensee's final decision right under Section 3.4(b)(ii) shall not apply to Licensee Territory Development Activities proposed in connection of initiation of Development for any Additional Indication, but once Development Activities have been commenced in such Additional Indication in and for the Licensee Territory, any further Licensee Territory Development Activities proposed by Licensee in respect of such Additional Indication shall be subject to the process set forth in Section 4.2(b) and (ii) Ovid will not develop in the Licensee Territory any Product in additional indications other than Rare Diseases without Licensee's prior written consent. Following each such determination and, if applicable, consent, the CGB shall incorporate such additional Development activities and the corresponding budget into the Development Plan (the "**Additional Development Activities**").

(b) Costs. If the Parties jointly agree to conduct Additional Development Activities, such Additional Development Activities shall be included in the Development Plan and conducted as Joint Development Activities, subject to the allocation of responsibility for leading such activities set forth in Section 4.3(c), and the costs of such Joint Development Activities shall be shared as further set forth in Section 8.2(a). Notwithstanding the foregoing, for Additional Development Activities that would otherwise be Joint Development Activities (if the Parties agreed to conduct such activities together), the Reviewing Party may elect, at its discretion, and by written notice delivered to the Proposing Party within [***] following the receipt of the Proposal, to opt out of funding its share of the Development Costs for such Additional Development Activities. Upon such an election, such Additional Development Activities shall be deemed the "**Independent Development Activities**" of the Proposing Party and the Proposing Party may pursue such work subject to the remainder of this Section 4.3, and the Development Costs with respect thereto shall be Independent Development Costs subject to Section 8.2(b).

(c) Conduct of Additional Development Activities. In general, except as the Parties may agree in an amendment to the Development Plan, including to allocate specific activities to Licensee in the Licensee Territory, (i) Ovid shall be the lead Party responsible for conducting Additional Development Activities that relate to both the Ovid Territory and the Licensee Territory, provided that such activities shall be subject to the oversight of the CGB to the extent such activities impact the Licensee Territory, and (ii) Licensee shall be the lead Party responsible for conducting Additional Development Activities that relate to the Licensee Territory and not the Ovid Territory.

(d) Independent Development Activities. The CGB shall amend the Development Plan to include any Additional Development Activities in the Rare Diseases indications that are Independent Development Activities, and thereafter the Proposing Party may conduct such Independent Development Activities, provided that: (i) the Proposing Party shall have the right to make the final decision in the event of any dispute regarding the conduct of the Independent Development Activities, except to the extent that, where the Proposing Party is Licensee, Ovid reasonably believes that Licensee's exercise of such right would adversely impact Ovid's Development and Commercialization of Products outside the Licensee Territory, (ii) the

Proposing Party shall have the right to make the final decision in the event of any dispute regarding the conduct of the Independent Development Activities, except to the extent that, where the Proposing Party is Ovid, Licensee reasonably believes that Ovid's exercise of such right would adversely impact Licensee's Development and Commercialization of Products in the Licensee Territory, (iii) to the extent applicable to the Licensee Territory, Independent Development Activities shall be conducted in accordance with the amended Development Plan, (iv) the Proposing Party shall provide updates to the CGB with respect to such Independent Development Activities impacting the Licensee Territory at each regularly scheduled CGB meeting, and (v) neither Party shall conduct any Independent Development Activities in a manner that would have any adverse effect on the Development or Commercialization of the Product in either Party's territory. The Investigator initiated trials (IIT) proposed to each Party for the Licensee Territory shall be discussed and agreed between the Parties before providing feedback to the proposing Investigator. The Party receiving the proposal will be responsible for the costs to support the IIT unless a different specific agreement is entered among the Parties. For sake of clarity, Independent Development Activities shall not include indications other than Rare Disease.

(e) Ovid's Right to Develop. Notwithstanding anything to the contrary herein, Ovid shall have the right to conduct any Development activities with respect to the Compound or Product in or relating to the Ovid Territory outside the scope of the Development Plan. Such Development activities shall be at Ovid's expense and Licensee shall have the right of reference to the Safety Data generated in such Development activities as necessary for regulatory purposes without any reimbursement obligation to Ovid.

4.4 Annual Update to Development Budget. The CGB shall review, discuss, and, with respect to Joint Development Activities, agree upon the subsequent year's Development Budget on an annual basis no later than [***] of each year.

4.5 Development Costs.

(a) Licensee Territory Development Costs. Licensee shall be solely responsible for all Development Costs incurred in connection with Licensee Territory Development Activities, except as provided in Section 4.2(c)(ii) with respect to the Additional Pivotal Study.

(b) Joint Development Costs. The Development Costs associated with all Joint Development Activities that are shared by the Parties in accordance with Section 8.2(a) shall include Allowable Increases. "**Allowable Increases**" means increased Development Costs resulting from [***].

(c) Independent Development Costs. The Party conducting Independent Development Activities pursuant to Section 4.3 shall be solely responsible for all Independent Development Costs as provided in Section 8.2(b).

4.6 Development Responsibilities. Ovid shall be responsible for, and shall use Ovid Commercially Reasonable Efforts in connection with, the conduct of the Ovid Ongoing Trials. Licensee shall be responsible for the conduct of the Licensee Territory Development Activities, other than Additional Pivotal Study which shall be shared by the Parties as set forth in Section

4.2(c)(ii). The Parties shall each be responsible for the conduct of the Joint Development Activities, and the allocation of such agreed responsibility therefore (including which Party shall be the Sponsor for each applicable Clinical Trial), shall be set forth in the Development Plan. Each Party shall have the operational responsibility and be the Sponsor for its own Independent Development Activities.

4.7 Data Exchange and Use.

(a) General. With respect to all Joint Development Activities, Licensee Territory Development Activities, and Independent Development Activities (but subject to Section 4.7(c)), each Party shall promptly provide the other Party with [***]. The Parties shall cooperate [***] to facilitate the sharing of reports, Data, and other information on a routine basis.

(b) Joint Development Activities Data. Each Party shall have the right to use and reference, without additional consideration, any and all Data generated by or on behalf of the other Party (including by any Sublicensee) in the performance of Joint Development Activities for obtaining and maintaining Regulatory Approval for the Products and Commercializing the Products in its territory in accordance with the terms of this Agreement. Notwithstanding the foregoing, should Licensee fail to obtain the foregoing use and reference rights from any Sublicensee, Licensee shall not have the right to grant use and access or other rights to such Sublicensee to any Data or other documentation provided to Licensee by Ovid pursuant to Section 4.7(a).

(c) Independent and Licensee Territory Development Activities Data. The Party receiving Data resulting from the other Party's Independent Development Activities shall have the right to use such Data only to the extent reasonably necessary for the receiving Party to comply with its regulatory reporting and compliance obligations, including safety reporting obligations. Licensee shall have the right to use such Data only to support its own Development, Regulatory Approval, or Commercialization of the Product in the Field in such Party's territory for the Initial Indication unless Licensee reimburses Ovid for Licensee's share of Development Costs pursuant to Section 8.2(b). Ovid shall have the right to use Data resulting from the Licensee Territory Development Activities as necessary for Ovid or its Affiliates or licensees (other than Licensee) to comply with its regulatory reporting and compliance obligations, including safety reporting obligations, and to support its own Development, Regulatory Approval, or Commercialization of the Product in the Ovid Territory.

(d) Any data transfer between the Parties under this Agreement shall comply with the applicable data privacy laws of the EU and USA.

4.8 Diligence. Each Party shall use its Commercially Reasonable Efforts to perform the Development activities assigned to such Party under and in accordance with the Development Plan and the Amended Development Plan. In addition, Licensee shall use Commercially Reasonable Efforts to perform any Independent Development Activities of Licensee, and Licensee Territory Development Activities and file MAAs and seek and maintain Regulatory Approval (including Pricing and Reimbursement Approval, as applicable) for the Products throughout the Licensee Territory.

4.9 Compliance. Each Party shall perform Development activities for the Compound and Products in and for the Licensee Territory in compliance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.10 Development Records. Each Party shall maintain complete, current, and accurate records of all Development activities conducted by it hereunder, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and Clinical Trials and/or Studies in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH, GCP, GLP, and GMP).

4.11 Development Reports. At each regularly scheduled JPT meeting, each Party shall provide the JPT with regular reports detailing its Development activities for the Products under this Agreement, and the results of such activities. In addition, after the completion of any Clinical Trial or other study of the Products, the Party responsible for the conduct of such Clinical Trial or study shall promptly provide the other Party with a data package consisting of, at a minimum, [***], as well as any other Data specified in the Development Plan or otherwise agreed by the Parties. The Parties shall discuss the status, progress, and results of each Party's Development activities under this Agreement at such JPT meetings.

4.12 Use of Subcontractors. Each Party may perform its Development activities under this Agreement through one or more subcontractors, provided that (a) such Party will remain responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself, (b) each subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 13, (c) each subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work to such Party (or, in the event such assignment is not feasible, a license to such intellectual property with the right to sublicense to such other Party), and (d) in the case of Licensee engaging any subcontractor to conduct significant activities under this Agreement (e.g., a contract research organization to manage a Clinical Trial), Licensee will be responsible for the selection of the subcontractor and will inform Ovid on the selection process including the criteria applied and shall first obtain Ovid's written consent to such subcontractor, such consent not to be unreasonably withheld. The Parties may also subcontract work on terms other than those set forth in this Section 4.12 with the prior approval of the CGB.

4.13 Restrictions. During the Term, neither Party nor any of its Affiliates or Sublicensees shall, directly or through any Third Party, sponsor, conduct, cause to be conducted, otherwise assist in, supply any Product for use in connection with, or otherwise fund any research or Development of any Product in the Licensee Territory outside the scope of the Development Plan. For clarity and without limiting the foregoing, if Licensee wishes to perform or sponsor any study or test on the Compound or Products, including any pre-clinical or non-clinical study, toxicology study, CMC-related study, or comparator study, Licensee shall first prepare and provide to Ovid for Ovid's approval a Proposal detailing such study in accordance with Section 4.3.

4.14 Materials Transfer. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain biological materials or chemical compounds Controlled by the supplying Party (collectively, "**Materials**") for use by the other Party in furtherance of such Development activities. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, and will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except to subcontractors, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

4.15 Suspension and Termination for Safety Reasons. Each Party shall have the right, at any time, to request that the CGB meet promptly to discuss whether to suspend the continued Development and/or Commercialization of the Products in the Field in the Licensee Territory for a period of [***] (the "**Suspension**"), upon providing written notice to the other Party, if such Party reasonably determines in good faith that the Compound or any other Product caused or is likely to cause a safety issue (a "**Safety Reason**"). If the CGB does not come to a consensus with regard to such Safety Reason during the Suspension, either Party may terminate the Agreement (with the understanding that the other Party shall have the continuing right to Develop and Commercialize the Product; provided, however, that if the other Party is Licensee and Licensee wishes to continue the Development and Commercialization of the Product, this Agreement shall remain in force and effect, but the provisions of Section 14.5 shall apply) with immediate effect, upon written notice to the other Party if: (i) the Executive Officers meet (in person or otherwise) within [***] to resolve the dispute in good faith; and (ii) such Executive Officers are unable to resolve the dispute.

5. REGULATORY ACTIVITIES

5.1 Regulatory Responsibilities.

(a) General.

(i) The Development Plan shall set forth the regulatory strategy for seeking Regulatory Approval for the Compound and Products by the appropriate Regulatory Authorities in the Licensee Territory and Ovid Territory. Subject to the oversight of the CGB and except as otherwise set forth in the Development Plan and the remainder of this Section 5.1(a)(i), each Party shall be responsible for implementing such regulatory strategy in its territory. The Development Plan shall also specify which Party shall apply for and hold Regulatory Filings in each country with respect to the conduct of Development activities, provided that (1) Ovid shall apply for and hold all Regulatory Filings and Regulatory Approvals for the Ovid Ongoing Trials

and Ovid's Independent Development Activities and (2) Licensee shall apply for and hold all Regulatory Filings for the Licensee Territory arising from the Licensee Territory Development Activities, Licensee's Independent Development Activities, and Joint Development Activities. Except as otherwise provided herein or in the Development Plan or required by Applicable Law, each Party shall (A) be responsible for the preparation and submission of any and all Product registrations and MAAs in its territory and (B) own and hold all such Regulatory Filings (including Regulatory Approvals). For the avoidance of doubt, in no event shall Licensee submit any Regulatory Filing for the Product in the Ovid Territory.

(ii) Each Party shall be responsible for the costs of all regulatory activities in its territory, except that any costs incurred by Ovid in connection with regulatory activities in the Licensee Territory pursuant to Ovid's Independent Development Activities shall be Independent Development Costs of Ovid and subject to Section 8.2(b).

(iii) Licensee acknowledges that Ovid may be required from time to time to communicate with Regulatory Authorities in the Licensee Territory as a result of Development and manufacturing activities in such territory. Ovid shall notify Licensee as soon as reasonably practicable of such communication with Regulatory Authorities in the Licensee Territory.

(iv) Ovid will provide to Licensee [***]. Licensee shall have the right to use such information to [***] for the Product for the Initial Indication [***] under this Agreement.

(v) Prior to [***], Ovid will not, without Licensee's input, (A) withdraw the IND for the Product in the Licensee Territory for any reason other than a Safety Reason, (B) file an MAA for the Product in the Licensee Territory, or (C) finalize the PIP for the Initial Indication. Prior to [***], Ovid shall notify Licensee of any scheduled meeting with a Regulatory Authority in the Licensee Territory that relates to the any of the Ovid Ongoing Trials and, to the extent permitted by Applicable Law and the relevant Regulatory Authority, shall permit a representative of Licensee to attend such meeting, at Licensee's request and expense.

(vi) Ovid will, upon Licensee's reasonable request, cooperate with Licensee in [***] Product in the Initial Indication in the Licensee Territory.

(vii) Ovid shall [***] for the Compound [***]. Licensee shall have the right to perform a Scientific Advice with the applicable Regulatory Authorities in the Licensee Territory.

(b) Regulatory Filing Right of Reference. Except as set forth in Section 5.1(c), Ovid shall grant and hereby grants to Licensee a right of reference and access to all Regulatory Approvals and Regulatory Filings Controlled by Ovid in the Licensee Territory for the Compound and Product, in each case to the extent necessary for Licensee to submit Regulatory Filings and obtain MAA Approvals for Products in the Initial Indication in the Licensee Territory. For the purposes of this Agreement, "right of reference" means the "right of reference or use" as defined in 21 C.F.R. §314.3(b) and any equivalent regulation outside the U.S., as each may be amended.

(c) Licensee Regulatory Information Sharing and Right of Reference.

(i) Licensee shall promptly provide Ovid with copies of any Regulatory Filings prepared (including any drafts), submitted, or received by Licensee in the Licensee Territory pertaining to the Compound and Products, and Ovid shall have the right to comment on drafts of such Regulatory Filings. Licensee shall share with Ovid the following communications/correspondence with any Regulatory Authority: (1) [***], (2) [***], and (3) [***] relating to the Compound or Product. If any Regulatory Filing to be provided under this Section 5.1(c) was originally created in a language other than the English language, then Licensee shall provide an English translation along with the original document to Ovid. Licensee shall use Commercially Reasonable Efforts to grant to Ovid access and rights to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee. Should Licensee fail to obtain such access and rights from any Sublicensee despite the application of Commercially Reasonable Efforts, Licensee shall not have the right to grant access or rights to such Sublicensee to any Regulatory Filing or right of reference granted to Licensee by Ovid pursuant to Section 5.1(b).

(ii) Licensee hereby grants to Ovid a right of reference to all Regulatory Filings for the Compound and Products submitted by or on behalf of Licensee. Ovid may use such right of reference to seek, obtain, and maintain Regulatory Approval of the Products in the Ovid Territory, except that Ovid may use such right of reference to any Regulatory Filings based on Data resulting from Licensee's Independent Development Activities only to comply with its safety reporting obligations, unless Ovid reimburses Licensee for such work as set forth in Section 8.2(b).

5.2 Meetings with Regulatory Authorities. On a current and ongoing basis, each Party (through the JPT) shall provide the other Party with a list and schedule of any in-person meeting or material teleconference with Regulatory Authorities (or related advisory committees) in the Licensee Territory planned for [***] that relates to the Development of the Compound and Products under the Development Plan in the Licensee Territory (each, a "**Regulatory Meeting**"). In addition, each Party shall notify the other Party as soon as reasonably possible if such Party becomes aware of any additional Regulatory Meetings that become scheduled for such Calendar Quarter and will keep the other Party informed of any significant interface or communication with any Regulatory Authority which might affect efforts to obtain Regulatory Approval for the Product in the Licensee Territory. Each Party shall be solely responsible for any communications with any Regulatory Authorities occurring or required in connection with performing its regulatory responsibilities set forth in this Article 5 with respect to the Product in the Licensee Territory. With respect to Regulatory Meetings for which Licensee is the responsible Party, Ovid shall have the right to comment in preparation for all such Regulatory Meetings and the right, but not the obligation, to have its representatives attend any such Regulatory Meetings.

5.3 Regulatory Inspections. Licensee shall permit the Regulatory Authority(ies) in the Ovid Territory to conduct inspections of Licensee, its Affiliates, and its Sublicensees and subcontractors (including Clinical Trial sites) relating to the Development of the Product under the Development Plan, and shall ensure that such Affiliates and Sublicensees and subcontractors permit such inspections. In addition, Licensee shall promptly notify Ovid of any such inspection and shall supply Ovid with all information pertinent thereto. Ovid shall have the right to have a representative attend any such inspection. Ovid shall permit the Regulatory Authority(ies) in the

Licensee Territory to conduct inspections of Licensee, its Affiliates, and its Sublicensees and subcontractors (including Clinical Trial sites) relating to the Development of the Product in the Licensee Territory under the Development Plan, and shall ensure that such Affiliates and Sublicensees and subcontractors permit such inspections. In addition, Ovid shall promptly notify the Licensee of any such inspection in the Licensee Territory and shall supply the Licensee with all information pertinent thereto. The Licensee shall have the right to have a representative attend any such inspection.

5.4 Adverse Event Reporting; Pharmacovigilance Agreement. [***] after the Effective Date, the Parties shall enter into a pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to the Products, such as Safety Data sharing, adverse event reporting, and safety signal and risk management (the "**Pharmacovigilance Agreement**"), which agreement shall be amended by the Parties from time to time as necessary to comply with any changes in Applicable Laws or any guidance received from Regulatory Authorities. Such procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws (including, to the extent applicable, those obligations contained in ICH guidelines) to monitor patients' safety. Ovid has established, and shall continue to hold (either by itself or through a vendor engaged by Ovid) the global safety database for the Products, and shall maintain such global safety database for so long as such Product is under Development or Commercialization by the Parties. The Parties envision that Ovid will separately maintain the Product global safety database and Licensee will maintain its own Product safety database with respect to the Licensee Territory and the Parties will synchronize the Product databases in accordance with the Pharmacovigilance Agreement so that they each maintain all Product safety data; however, the Parties agree that the Ovid global safety database will be the source for all periodic reports. Ovid shall [***] from its database and Licensee will maintain [***] its own Product safety database. The CGB shall establish a safety subcommittee to draft the Pharmacovigilance Agreement to define the process for exchanging adverse event reports using the Ovid global safety database, as well as periodic reports, regulatory communication, and other key elements. The Parties will collaboratively agree on data cut points for periodic safety reports and Ovid will review and approve all such reports. The Parties will jointly review and approve such reports before submission to Regulatory Authorities in the Licensee Territory as required. Such safety subcommittee shall implement the Pharmacovigilance Agreement and coordinate with respect to any Safety Data reporting for the Products to the Regulatory Authorities in the Licensee Territory including, responding to safety issues, communicating with Regulatory Authorities related to the Products under any MAA or Regulatory Approval for the Product held by such Party and filed with such Regulatory Authorities, including maintaining the qualified person for Pharmacovigilance and individual case safety report processing, in each case at its own cost. Each Party agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees, and Sublicensees to comply with such obligations.

5.5 No Harmful Actions. If a Party reasonably believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse impact upon the regulatory status of such Product in such Party's territory, then such Party may bring the matter to the attention of the CGB and the Parties shall discuss in good faith to promptly resolve such concern.

5.6 Notification of Threatened Action. Each Party shall notify the other Party within twenty-four (24) hours of any information it receives regarding any threatened or pending action, inspection, or communication by any Regulatory Authority which may affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

5.7 Recalls. In the event that a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's territory is required by a Regulatory Authority of competent jurisdiction, or if any Regulatory Authority requires or advises either Party or such Party's Affiliates or sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product in a Party's territory, or if a recall, withdraw, or correction of a Product in its territory is deemed advisable by such Party in its sole discretion, such Party shall so notify the other Party no later than [***] in advance of the earlier of (a) [***], or (b) [***]. Any such recall, withdrawal, correction, or dissemination of information (e.g., "Dear Doctor" letter) shall be referred to herein as a "**Recall**". Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party. All costs and expenses in connection with a Recall [***]. Each Party shall handle exclusively the organization and implementation of all Recalls of Products in its territory. Notwithstanding the foregoing, any Recall related to the manufacture and supply of the Product by Ovid to Licensee shall be governed by the terms and conditions of the Supply Agreement.

5.8 Sunshine Reporting Laws and the International Transparency Reporting Requirements for Europe. Each Party acknowledges that the other Party may be subject to federal, state, local, and international laws, regulations, and rules related to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities, including, as applicable, International Transparency Reporting Requirements for Europe (collectively, "**Sunshine Reporting Laws**"), and agrees to provide the other Party with all information regarding such payments or transfers of value by such Party as necessary for such other Party to comply in a timely manner with its reporting obligations under the Sunshine Reporting Laws.

6. COMMERCIALIZATION

6.1 General. Subject to the terms and conditions of this Agreement, including this Article 6, Licensee shall have the sole and exclusive responsibility, at its own expense, for all aspects of the Commercialization of the Products in the Licensee Territory, including (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities and other payors regarding the price and reimbursement status of the Products, (c) marketing and promotion, (d) booking sales and distribution and performance of related services, (e) handling all aspects of order processing, invoicing and collection, inventory and receivables, (f) providing customer support, including handling medical queries, and performing other related functions, and (g) conforming its practices and procedures to Applicable Laws applying to the promotion, sales and marketing, access, and distribution of the Products in the Licensee Territory.

6.2 Commercialization Plan. As soon as reasonably practicable, but no later than [***], Licensee shall prepare and present to the CGB a reasonably detailed plan for the Commercialization of the Product in the Licensee Territory (the "**Commercialization Plan**"). The Commercialization Plan will include specific information on a country-by-country basis, as applicable, and shall be consistent with the global commercialization plan for branding and messaging. Licensee shall update and amend the Commercialization Plan [***] following the First Commercial Sale of the Product in the Licensee Territory and present such updates and any amendments to the CGB for review and discussion. Subject to the terms of this Agreement and compliance with the Commercialization Plan, Licensee shall have full Control and authority with respect to the day-to-day Commercialization of the Products and implementation of the Commercialization Plan.

6.3 Diligence.

(a) General. During the Term, Licensee shall use Commercially Reasonable Efforts to Commercialize the Products for each and every Indication that receives Regulatory Approval in the Licensee Territory.

(b) Product Launch. Licensee shall use Angelini Commercially Reasonable Efforts to launch the Product for each Indication that has received Regulatory Approval and, if required by Applicable Law, Pricing and Reimbursement Approval in the Licensee Territory (including any Indication that received Regulatory Approval as a result of Ovid's Independent Development Activities). As applicable, Licensee shall obtain all necessary Pricing and Reimbursement Approvals necessary to list and to launch such Product for such Indication following receipt of MAA Approval of such Product in a country. Without limiting the generality of the foregoing, Licensee shall use Angelini Commercially Reasonable Efforts to launch the Product in each country in the Licensee Territory within [***] after receiving Regulatory Approval, or, where required by Applicable Law, after the publication of the Pricing and Reimbursement Approval, of the Product for an Indication from the applicable Regulatory Authority in such country. Thereafter, Licensee shall utilize Commercially Reasonable Efforts in the ongoing support for such Product in such country.

(c) Commercial Updates. Licensee shall update the CGB on [***] basis regarding its Commercialization activities with respect to the Products in the Licensee Territory. Each such update shall be in a form to be agreed by the CGB and shall summarize Licensee's and its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Products in the Licensee Territory, and shall contain at least such information at a level of detail reasonably required by Ovid to determine Licensee's compliance with its diligence obligations set forth in this Section 6.3. Such updates shall include Licensee's sales activities, sales forecasts for at least the next [***], marketing activities, and Medical Affairs Activities.

6.4 Coordination of Commercialization Activities.

(a) Generally. The Parties, through the CGB (or JPT or other designated team), shall update each other on Commercialization strategies for the Product (e.g., for market and payor research, branding and messaging, international congresses, advisory boards) in their respective territories, and the Parties shall work together to identify and take advantage of any

potential global strategies and messaging. The foregoing shall not be construed as requiring either Party to seek the other Party's consent in connection with such first Party establishing or implementing any sales, marketing, or medical affairs practices in such first Party's territory.

(b) Pricing. Following the CGB discussion and processes, Licensee shall keep Ovid timely informed on the status of any application for Pricing and Reimbursement Approval or material updates to an existing Pricing and Reimbursement Approval in the Licensee Territory, including any discussion with a Regulatory Authority with respect thereto. Licensee and its Affiliates and Sublicensees shall [***] include a Product, [***] of the Product [***] and the Product [***].

(c) Sharing of Promotional Materials. Licensee shall, at its own expense, prepare, develop, produce, or otherwise obtain and utilize sales, promotional, advertising, marketing, website, educational, and training materials (the "**Promotional Materials**") to support its Commercialization activities in the Licensee Territory, and shall ensure that such Promotional Materials, as well as all information contained therein, comply with all Applicable Laws and are consistent with the Regulatory Approvals obtained for the Product in the applicable jurisdiction in the Licensee Territory. At Ovid's request, Licensee shall share samples of and updates to Promotional Materials with respect to the Commercialization of the Products with Ovid. If Ovid has such promotional materials available for the Product for the Ovid Territory prior to the commercial launch of such Product in the Licensee Territory, Ovid will share such materials with the Licensee upon its request.

(d) Commercialization in Ovid Territory. For clarity, Ovid shall have the exclusive right to Commercialize the Product in the Ovid Territory at its own expense, with or without Third Party(ies).

6.5 Medical Affairs Activities.

(a) Coordination of Global Medical Affairs Activities. Ovid shall be responsible for all Medical Affairs Activities for the Product in the Ovid Territory in accordance with the medical affairs portion of the Development Plan. Licensee shall be responsible for Medical Affairs Activities in the Licensee Territory in accordance with the medical affairs portion of the Development Plan, provided, however, that Ovid shall have the right, but not the obligation, to also conduct Medical Affairs Activities in the Licensee Territory in global support of the Product, consistent with the medical affairs portion of the Development Plan and in coordination and agreement with Licensee, such agreement not to be unreasonably withheld, conditioned, or delayed. Licensee will not undertake Medical Affairs Activities in the Ovid Territory without Ovid's prior written consent, to be given on a case-by-case basis in Ovid's sole discretion.

(b) Advisory Panels. To the extent practicable, each Party shall give the other Party written notice at least [***] in advance of any major market or international level advisory panel meetings with key opinion leaders with respect to the Commercialization of the Products in the Licensee Territory and the Ovid Territory that are held, sponsored, or attended by either Party or its Affiliate or sublicensee, and each Party shall have the right to attend and participate in such meetings with the consent of the other Party.

(c) Medical Information. Ovid will provide Licensee with any relevant materials developed by Ovid for the Product in the Ovid Territory for medical information, including reports of collected and answered inquires, which Licensee may use in connection with medical affairs activities in the Licensee Territory. For clarity, Ovid shall provide such materials in the form used by Ovid in the Ovid Territory.

(d) Scientific Training. At times reasonably agreed by the Parties, Ovid will deliver the onboarding scientific training to Licensee's medical and commercial team and to share updates with respect to the Commercialization of the Product. Each Party shall bear its own cost in relation to such meetings.

6.6 Diversion. To enforce the Parties' respective rights and obligations set forth in Sections 2.1, 2.4, and 2.8 of the Agreement, to the extent permitted by Applicable Law, each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its sublicensees not to, directly or indirectly, promote, market, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receives any order for a Product for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product for use in the other Party's territory.

6.7 Ovid's Right to Commercialize. Notwithstanding anything to the contrary herein, if Ovid conducts Development activities for the Product in the Licensee Territory as provided in Section 2.3(a) for any Additional Indication(s) for which Licensee has elected to not share Development Costs as provided in Section 8.2(a) and/or Section 8.2(b), as applicable, then prior to filing for Regulatory Approval for the Product in any Additional Indication, the Parties shall discuss in good faith whether Licensee wishes to include such Additional Indication within the Field and to Commercialize such Product in such Additional Indications. For clarity, neither Party may file for Regulatory Approval or Commercialize Products in (i) any Additional Indication for which Licensee has elected not to share Development Costs or (ii) any additional indication other than Rare Diseases unless the Parties mutually agree to do so.

7. MANUFACTURE AND SUPPLY

7.1 Upon Licensee's request, Ovid will manufacture and supply, itself or through a Third Party contract manufacturer, all Drug Product for use in the Development and Commercialization of the Products under this Agreement and according to the Supply Agreement. All Drug Product supplied by Ovid to Licensee or Licensee Affiliate for use for Development and Commercial purposes shall be supplied at [***], provided that [***] ("**Total Supply Price Threshold**"). In case the Total Supply Price will be [***], the Cost of Good for such Drug Product

will be [***] the Total Supply Price Threshold. For clarity, the Total Supply Price Threshold [***]. Payment shall be due within [***] after Licensee's receipt from Ovid of an invoice for such Drug Product. Drug Product shall be delivered EXW (Incoterms 2020) at supplier facility (or that of its Third Party contract manufacturer), and Licensee shall be responsible for all costs of freight, insurance, taxes and duties associated with shipment of Drug Product to Licensee's designated delivery point. Licensee shall be responsible, at its expense, for the final packaging and labeling of the Product for all countries in the Licensee Territory. Licensee shall also be responsible, at its sole expense, for any specific manufacturing requirements, such as stability studies or development of finished Product presentations, necessary to obtain MAA Approval of the Product in the Licensee Territory. If Licensee is manufacturing Drug Product following the Technology Transfer Completion Date, Ovid may request, and Licensee or Licensee Affiliate will supply Drug Product to Ovid, on the same terms as set forth above, pursuant to a mutually agreed supply agreement.

8. FINANCIAL PROVISIONS

8.1 Upfront and Technology Transfer Financials.

(a) Upfront Payment. Licensee shall make a one-time, non-refundable, non-creditable upfront payment to Ovid of twenty million dollars ($20,000,000) within five (5) business days after the Effective Date.

(b) Technology Transfer and Compound Delivery Payment.

(i) Within [***] following (A) the transfer to Licensee of [***], (B) the delivery ([***]) to Licensee or to Licensee Affiliate of [***] and (C) [***], Licensee shall pay to Ovid a one-time, non-refundable, non-creditable payment of (1) [***] if [***], or (2) [***] if [***]. Licensee shall use Angelini Commercially Reasonable Efforts to cooperate with Ovid and Lundbeck to implement the foregoing transfers within the timelines set forth in this Section 8.1(b)(i).

(ii) Within [***] following the Technology Transfer Completion Date, Licensee shall make a one-time, non-refundable, non-creditable technology transfer payment of [***]. Licensee shall use Angelini Commercially Reasonable Efforts to cooperate with Ovid and Lundbeck to implement the Technology Transfer Agreement within [***] after the Effective Date.

8.2 Sharing/Reimbursements of Development Costs.

(a) Shared Development Costs. With respect to Joint Development Activities conducted pursuant to Section 4.2(b) or Section 4.3 directed to obtaining Regulatory Approval for any Indication, excluding the Ovid Ongoing Trials, Ovid shall bear [***] and Licensee shall bear [***] of all Development Costs for such Joint Development Activities. No later than [***] after the beginning of each Calendar Quarter during which a Party will perform any Joint Development Activities pursuant to Section 4.2(b) or Section 4.3 in such Calendar Quarter, such Party shall submit to the other Party a statement setting forth the Development Costs incurred, including the other Party's share (calculated in accordance with the foregoing sentence) of (i) estimated Development Costs for the then current quarter; (ii) variances from prior invoiced estimates and

actual Development Costs; and (iii) Development Costs incurred by or on account of such Party in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such Development Costs, including reasonable supporting documents. The other Party shall pay the amount invoiced within [***] after the receipt of the invoice, subject to the other Party's right to audit the invoicing Party's records and books related to such costs as provided in Section 9.4. If both Parties will perform Joint Development Activities pursuant to Section 4.2(b) or Section 4.3 under the Development Plan in such Calendar Quarter, the Parties shall consolidate the payments for such Calendar Quarter into a single payment from one Party to the other Party, as applicable.

(b) Independent Development Costs. In general, each Party shall bear all Development Costs incurred by or on account of such Party in performing its own Independent Development Activities (the "**Independent Development Costs**"). After the completion of such Independent Development Activities, such Party shall provide the other Party (the "**Non-Funding Party**") with a report of such Independent Development Costs. If a Non-Funding Party desires to submit any portion of the Data, or reference any portion of a Regulatory Filing, resulting from Independent Development Activities conducted by the other Party to support any Regulatory Approval in the Non-Funding Party's territory, then such Non-Funding Party may notify the other Party in writing of such request at any time following the completion of such Independent Development Activities. Within [***] after its receipt of such notice, the Party having conducted such Independent Development Activities shall submit to the other Party a reasonably detailed invoice for, [***] of the Independent Development Costs incurred [***] in connection with the performance of such Independent Development Activities, with such invoiced amount representing the Non-Funding Party's base share of Development Costs ([***]), had such Party originally opted in, plus [***], provided that in no event will either Party be required to pay, as a result of the application of such premium, more than [***] the costs actually incurred in conducting such Independent Development Activities. If the Non-Funding Party subsequently uses or references such Data, in whole or in part to support Regulatory Approval of the Product in the applicable Indication in its territory, then such Party shall notify the conducting Party in writing of such decision and pay the amount set forth in the invoice within [***] after its submission of a Regulatory Filing including or referencing such Data.

(c) Internal Development Cost. Each Party shall record and calculate its Development Costs for the Development Activities implemented from the Effective Date on an FTE basis at the applicable FTE Rate. The Parties agree that [***] from the Effective Date.

8.3 Development Milestone Payments.

(a) Development Milestones. Subject to the remainder of this Section 8.3, Licensee shall pay to Ovid the one-time, non-refundable, non-creditable payments set forth in the table below upon the achievement of the applicable milestone event (whether by or on behalf of Licensee or its Affiliates or Sublicensees or Ovid or its Affiliates or licensee(s) (other than Licensee)).

Regulatory Milestone Event	Regulatory Milestone Amount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Notice and Payment. Each Party shall notify the other Party in writing within [***] after the achievement of any milestone event set forth in this Section 8.3 by such Party or its Affiliates or Sublicensees. Licensee shall pay to Ovid the applicable development milestone payment within [***] after the delivery or receipt of such notice.

(c) One-time Payment. Each of the above Regulatory Milestone amounts shall only be payable once no matter how many times the corresponding Regulatory Milestone Event is achieved.

(d) For clarity, Licensee shall pay to Ovid each Regulatory Milestone amount the first time that the corresponding Regulatory Milestone Event is achieved.

8.4 Sales Milestones Payments.

(a) Licensee shall pay to Ovid the one-time, non-refundable, non-creditable payments set forth in the table below when the aggregated Net Sales of all Products in the Licensee Territory in any Calendar Year first reach the values indicated in the table below. For clarity, each payment in this Section 8.4 shall be payable once only upon first achievement of the applicable milestone event, regardless of the number of times such milestone is subsequently achieved.

Aggregate Net Sales of all Products in the Licensee Territory in a Calendar Year	Sales Milestone Payment Amount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Notice and Payment. As part of the report in Section 9.1, Licensee shall provide written notice to Ovid if the aggregated Net Sales of all Products in the Licensee Territory in any Calendar Year first reach the values set forth in Section 8.4(a), and Licensee shall pay to Ovid the corresponding Net Sales milestone payment along with its payment of royalties in accordance with Section 9.1, following the end of the Calendar Quarter in which such Net Sales milestone is achieved.

(c) One-time Payment. Each of the above Sales Milestone amounts shall only be payable once during the Term of this Agreement no matter how many times the corresponding Sales Milestone Event is achieved. For clarity, Licensee shall pay to Ovid each Sales Milestone amount the first time that the corresponding Sales Milestone Event is achieved.

8.5 Royalty During the Royalty Term.

(a) Royalty Rate. Subject to the remainder of this Section 8.5, during the Royalty Term, Licensee shall make quarterly non-refundable, non-creditable royalty payments to Ovid on the annual Net Sales of all Products sold in the Licensee Territory at the applicable rate to the relevant portion of annual Net Sales as set forth below:

Annual Net Sales of all Products in the Licensee Territory	**Royalty Rate**
Portion of annual Net Sales up to [***]	[***]%
Portion of annual Net Sales greater than [***] and less than or equal to [***]	[***]%
Portion of annual Net Sales greater than [***] and less than or equal to [***]	[***]%
Portion of annual Net Sales greater than [***]	[***]%

For example purposes only, [***].

(b) Royalty Term. Royalties shall be paid on a Product-by-Product and country-by-country basis in the Licensee Territory from the First Commercial Sale of such Product in such country by or on behalf of Licensee, its Affiliates, or Sublicensees, until the last to occur of (i) the expiration of the last-to-expire Valid Claim of the Ovid Patents (ii) the expiration of all Market Exclusivity covering such Product in such country, and (iii) fifteen (15) years after the First Commercial Sale of such Product in such country (the "**Royalty Term**").

(c) Royalty Stacking Reduction. If it is necessary for Licensee to obtain a license from a Third Party under any Patent in a particular country in the Licensee Territory in order to sell the Compound or the Compound incorporated into a Product for the Initial Indication or, if Licensee does not exercise the Second Indication Opt-Out, the Second Indication in such country and Licensee obtains such a license, then solely during the Royalty Term, Licensee may

deduct from the royalty payment that would otherwise have been due pursuant to Section 8.5(a) with respect to Net Sales of such Product in such country in a particular Calendar Quarter an amount equal to [***] of the royalties paid by Licensee to such Third Party pursuant to such license on account of the sale of such Product in such country during such Calendar Quarter.

(d) Royalty Floor. Notwithstanding the foregoing Sections 8.5(c) and Section 8.7 with respect to any Product in any Calendar Quarter, the royalties that would otherwise have been due under Section 8.5(a) with respect to Net Sales of such Product in the applicable country(ies) during such Calendar Quarter shall not be reduced by more than [***] as a result of all such reductions.

8.6 Royalties During the Extended Commercialization Term. During the Extended Commercialization Term, Licensee shall pay to Ovid a quarterly non-refundable, non-creditable royalty of [***] on the annual Net Sales of all Products sold in the Licensee Territory, as calculated by multiplying the foregoing royalty rate by the amount of Net Sales of the Product in the Territory in the applicable Calendar Quarter.

8.7 Royalty Reduction for Generic Competition. If at any time Generic Product Competition exists in a given country with respect to a Product, then the royalty rate set forth in Section 8.5(a) with respect to sales of such Product in such country shall be reduced by [***]. For clarity, if Generic Product Competition ceases to exist, then the royalty rate shall no longer be reduced.

8.8 Upstream License Agreement Payments. Any and all payments that become due under the Lundbeck License Agreement as a result of activities under this Agreement, whether by or on behalf of Ovid or by Licensee or its Affiliate or Sublicensee, shall be the responsibility of Ovid and Ovid shall make such payment in accordance with the terms of the Lundbeck License Agreement.

9. PAYMENT; RECORDS; AUDITS

9.1 Payment; Reports. All royalty payments due under this Agreement shall be accompanied by a report setting forth, on a country-by-country basis, Net Sales of the Products by Licensee and its Affiliates and Sublicensees in the Licensee Territory in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including, for each country, the number of Products sold, the gross sales and Net Sales of Products, including the deductions from gross sales to arrive at Net Sales, the royalty payable, the exchange rates used, any adjustments to the royalty paid during the Royalty Term pursuant to Section 8.5(c), and whether any Net Sales milestone under Section 8.4 has been achieved. Within [***] following the end of each Calendar Quarter during the Royalty Term and Extended Commercialization Term, Licensee shall provide Ovid with the foregoing report and the payment due for such Calendar Quarter. For clarity, royalty payments during the Extended Commercialization Term shall not be subject to any offsets or reductions whatsoever, including those set forth in Section 8.5(c). Prior to the First Commercial Sale of the Product in the Licensee Territory, the Parties will agree on the form of royalty report. Licensee shall submit a single report for all Net Sales during a Calendar Year, including all of Licensee's and its Affiliates' and Sublicensees' Net Sales, but shall separately identify the Net Sales and other information applicable to each entity.

9.2 Exchange Rate; Manner and Place of Payment. All references to dollars and "$" herein shall refer to U.S. dollars. Unless otherwise specified herein, all payments due under this Agreement shall be payable in U.S. dollars. When conversion of Net Sales from any currency other than U.S. dollars is required, such conversion shall be at the exchange rate equal to the conversion rate for the U.S. dollar for the currency of the country in which the applicable Net Sales were made as published by [***]. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Ovid, unless otherwise specified in writing by Ovid.

9.3 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of the milestone payments, royalty payments, and other payments made by Licensee to Ovid under this Agreement. To the extent that Licensee is required by Applicable Laws to deduct and withhold taxes on any payment to Ovid, Licensee shall withhold the amount of such taxes otherwise payable to Ovid and, if and when necessary pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Ovid an official tax certificate or other evidence of such payment sufficient to enable Ovid to claim such payment of taxes. Ovid shall provide Licensee any tax forms that may be reasonably necessary in order for Licensee to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, to the extent legally able to do so. Ovid shall use reasonable efforts to provide any such tax forms to Licensee in advance of the due date. Licensee shall provide Ovid with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Ovid. Licensee shall have the right to deduct any such tax, levy, or charge actually paid from payment due to Ovid. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

(c) Taxes Resulting From Licensee's Action. If a Party takes any action of its own discretion (not required by a Regulatory Authority and without consent of the other Party), including any assignment, sublicense, change of place of incorporation, or failure to comply with Applicable Laws or filing or record retention requirements, which results in a withholding or deduction obligation (a "**Withholding Tax Action**"), then such Party shall pay the sum associated with such Withholding Tax Action. For clarity, if Licensee undertakes a Withholding Tax Action, then the sum payable by Licensee (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Ovid receives a sum equal to the sum which it would have received had no such Withholding Tax Action occurred. If a change in Applicable Laws results in a withholding or deduction obligation absent either Party taking a Withholding Tax Action, then the amount of such withholding or deduction obligation shall be paid by Licensee to the applicable Governmental Authority on behalf of Ovid, provided that Licensee shall assist Ovid in minimizing or recovering such withholding or deduction obligation.

The Parties shall use commercially reasonable efforts to invoke the application of any applicable bilateral income tax treaty that would reduce or eliminate otherwise applicable taxes with respect to payments payable pursuant to this Agreement.

9.4 Records; Audit. Each Party shall maintain complete and accurate records in sufficient detail in relation to this Agreement to permit the other Party to confirm the accuracy of the amount of Development Costs to be reimbursed or shared, achievement of Net Sales milestones, and the amount of royalty and other payments payable under this Agreement. Each Party will keep such books and records for at least [***] following the Calendar Year to which they pertain. Upon reasonable prior notice, such records shall be inspected during regular business hours at such place or places where such records are customarily kept by an independent certified public accountant (the "**Auditor**") selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party pursuant to this Agreement. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits may occur no more often than [***]. Each Party shall only be entitled to audit the books and records from the [***] in which the audit request is made. The Auditor shall not disclose the audited Party's Confidential Information to the auditing Party, and shall only verify the accuracy or inaccuracy of the financial reports furnished by the audited Party or the amount of payments by such Party under this Agreement, and, in the case of any inaccuracy, the amount of such inaccuracy. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment, the underpaid or overpaid amount shall be settled within [***] after the Auditor's report. The auditing Party shall bear the full cost of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party, which underpayment or overpayment was more than [***], in which case the audited Party shall reimburse the auditing Party for the costs for such audit. For clarity, the foregoing audit rights may also be exercised by Ovid on behalf of Lundbeck pursuant to the terms of the Lundbeck License Agreement.

9.5 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due [***]; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

10. INTELLECTUAL PROPERTY

10.1 Ownership.

(a) Data. All Data generated in connection with any Development or Commercial activities with respect to any Product conducted solely by or on behalf of Ovid and its Affiliates and licensees (other than Licensee) (the "**Ovid Data**") shall be the sole and exclusive property of Ovid or such Affiliates or licensees, as applicable. All Data generated in connection with any Development or Commercial activities with respect to any Product conducted solely by or on behalf of Licensee or its Affiliates or Sublicensees (the "**Licensee Data**") shall be the sole

and exclusive property of Licensee or such Affiliates or Sublicensees, as applicable. All Data generated in connection with any Joint Development Activities or joint Commercial activities with respect to any Product and for which the Parties are sharing Development Costs pursuant to Section 8.2(a) shall be jointly owned by the Parties. For clarity, each Party shall have access and right to use and reference the other Party's Data as and to the extent set forth in this Agreement.

(b) Inventions. Inventorship of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. The Parties will work together to resolve any issues regarding inventorship or ownership of Inventions. Ownership of Inventions will be allocated as follows:

(i) Ovid shall solely own all data, Inventions, and Patents claiming such Inventions that relate to the composition, formulation, manufacture, dosing, new indications or method of use of the Compound, or any improvement of any such composition, manufacture, or use, including in combination with other agents or components (each, a "**Compound Invention**"). All Compound Inventions will be included in the Ovid Know-How, and Patents in the Licensee Territory claiming such Inventions will be included in the Ovid Patents. To the extent that any Compound Invention is made by Licensee, whether solely or jointly with Ovid, Licensee shall, and hereby does, transfer and assign to Ovid, without additional consideration, all of its right, title, and interest in such Compound Invention. To effectuate the foregoing assignment, Licensee shall ensure that all entities and individuals that perform any Development under this Agreement are under a written or other legally enforceable obligation to assign all of its right, title, and interest in such Invention to Licensee or to an entity that is obligated to assign all right, title, and interest to Licensee.

(ii) Except for Compound Inventions, each Party shall solely own any Inventions made solely by it and its Affiliates' employees, agents, or independent contractors, and the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party and its Affiliates together with employees, agents, or independent contractors of the other Party and its Affiliates ("**Joint Inventions**"). All Patents claiming patentable Joint Inventions shall be referred to herein as "**Joint Patents**". Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign, and otherwise exploit its interest under the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party.

10.2 Patent Prosecution and Maintenance.

(a) Ovid Patents.

(i) Subject to the remainder of this Section 10.2(a), and as between the Parties, Ovid shall have the sole right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings and defense of validity or enforceability challenges) of the Ovid Patents (other than Joint Patents) worldwide, using counsel of its own choice. Subject to the terms of the Lundbeck License Agreement, Ovid shall (A) keep Licensee informed of material

progress with regard to the preparation, filing, prosecution, and maintenance of the Ovid Patents in the Licensee Territory, sufficiently in advance for Licensee to be able to review any material documents, including content, timing, and jurisdiction of the filing of such Ovid Patents in the Licensee Territory, (B) consult with, and consider in good faith the requests and suggestions of, Licensee with respect to strategies for filing, prosecuting, and defending, if any, the Ovid Patents in the Licensee Territory, and (C), [***].

(ii) In the event that Ovid desires to abandon or cease prosecution or maintenance of any Ovid Patent in any country in the Licensee Territory, Ovid shall provide reasonable prior written notice to Licensee of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Ovid Patent in the relevant patent office). In such case, upon Licensee's written election provided no later than [***] after such notice from Ovid, Ovid shall continue prosecution and maintenance of such Ovid Patent at Licensee's direction and expense. If Licensee does not provide such election within [***] after such notice from Ovid, Ovid may, in its sole discretion, continue prosecution and maintenance of such Ovid Patent or discontinue prosecution and maintenance of such Ovid Patent.

(b) Licensee Patents.

(i) Subject to the remainder of this Section 10.2(b), Licensee shall have the first right, but not the obligation, to control the preparation, filing, prosecution and maintenance (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of all Licensee Patents (other than Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice in the Licensee Territory and by counsel mutually agreed to by the Parties in the Ovid Territory. Licensee shall keep Ovid informed of the status of filing, prosecution, maintenance, and defense, if any, of the Licensee Patents, and Licensee shall consult with, and consider in good faith the requests and suggestions of, Ovid with respect to strategies for filing, prosecuting, and defending the Licensee Patents.

(ii) In the event that Licensee desires to abandon or cease prosecution or maintenance of any Licensee Patent, Licensee shall provide reasonable prior written notice to Ovid of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Licensee Patent in the relevant patent office). In such case, upon Ovid's written election provided no later than [***] after such notice from Licensee, Ovid shall have the right to assume prosecution and maintenance of such Licensee Patent at Ovid's expense and Licensee shall assign to Ovid all of its rights, title, and interest in and to such Licensee Patent. If Ovid does not provide such election within [***] after such notice from Licensee, Licensee may, in its sole discretion, continue prosecution and maintenance of such Licensee Patent or discontinue prosecution and maintenance of such Licensee Patent.

(c) Joint Patents.

(i) Subject to the remainder of this Section 10.2(c), Ovid shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain (including any

interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) Joint Patents using a patent counsel selected by Ovid in the Ovid Territory and counsel mutually agreed to by the Parties in the Licensee Territory.. Ovid shall keep Licensee informed of material progress with regard to the preparation, filing, prosecution, maintenance, and defense, if any, of the Joint Patents, including content, timing, and jurisdiction of the filing of such Joint Patents, and Ovid shall consult with, and consider in good faith the requests and suggestions of, Licensee with respect to filing, prosecuting, and defending of the Joint Patents in the Licensee Territory.

(ii) In the event that Ovid desires to abandon or cease prosecution or maintenance of any Joint Patent in any country in the Licensee Territory, Ovid shall provide reasonable prior written notice to Licensee of such intention to abandon (which notice shall, to the extent possible, be given no later than sixty (60) days prior to the next deadline for any action that must be taken with respect to any such Joint Patent in the relevant patent office). In such case, at Licensee's sole discretion, upon written notice from Licensee to Ovid, Licensee may elect to continue prosecution or maintenance of any such Joint Patent at its own expense, and Ovid shall execute such documents and perform such acts, at Licensee's expense, as may be reasonably necessary to allow Licensee to continue the prosecution and maintenance of such Joint Patent in such country in the Licensee Territory. Any such assignment shall be completed in a timely manner to allow Licensee to continue prosecution and maintenance of any such Joint Patent and any such Patent so assigned shall cease to be either a Joint Patent or a Licensee Patent and shall no longer be subject to the licenses and other rights granted by Licensee to Ovid under this Agreement

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, maintenance, and defense, if any, of Patents under Section 10.2 and in the obtaining and maintenance of any patent term extensions and supplementary protection certificates and their equivalents, at its own cost (except as expressly set forth otherwise in this Section 10). Such cooperation includes (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 10.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent application and the obtaining of any patent term extensions or supplementary protection certificates or their equivalents.

10.3 Patent Enforcement.

(a) Notice. Each Party shall notify the other within [***] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Ovid Patents (including Joint Patents) in the Licensee Territory, which infringement adversely affects or is reasonably expected to adversely affect any Product, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement of any of the Ovid Patents (collectively, "**Product Infringement**").

(b) Enforcement Right. Ovid shall have the first right to use Ovid Commercially Reasonable Efforts to bring and control any legal action in connection with such

Product Infringement at its own expense as it reasonably determines appropriate. If Ovid (i) decides not to bring such legal action against a Product Infringement (the decision of which Ovid shall inform Licensee promptly) or (ii) Ovid otherwise fails to bring such legal action against a Product Infringement within [***] after first becoming aware of such Product Infringement, subject to the terms of the Lundbeck License Agreement, Licensee shall have the right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate after [***] Ovid.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including to be named in such action if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Expense and Recovery.

(i) Except as set forth in Section 10.3(d)(ii), the enforcing Party shall be solely responsible for any cost and expenses incurred by such Party as a result of such enforcement action. If such Party recovers monetary damages in such enforcement action, such recovery shall be allocated [***].

(ii) Notwithstanding the foregoing, if [***] to bring such action. If [***], then [***].

(e) Other Infringement. Except for Product Infringement as set forth above, each Party shall have the exclusive right to enforce its own Patents against any infringement anywhere in the world. For clarity, as between the Parties, Ovid shall have the exclusive right to enforce (i) the Ovid Patents against any infringement in the Licensee Territory that is not a Product Infringement, and (ii) the Ovid Patents and Joint Patents against any infringement in the Ovid Territory, in each case at its own expense as it reasonably determines appropriate, and subject to the terms of the Lundbeck License Agreement. The Parties shall discuss global enforcement strategy for the Ovid Patents and Licensee Patents, including the defense of validity and enforceability challenges arising from any enforcement action.

10.4 Infringement of Third Party Rights. If any Product used or sold by Licensee, its Affiliates, or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any intellectual property rights in a jurisdiction within the Licensee Territory, Licensee shall promptly notify Ovid and the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Absent any agreement to the contrary, and subject to claims for indemnification under Article 12, each Party may defend itself from any such Third Party claim at its own cost and expense, provided that [***]. If [***].

10.5 Trademarks.

(a) Product Trademarks. Ovid shall develop and adopt trademarks, including trade names, trade dresses, branding, and logos, to be used for the Products (the "**Product Marks**"). Ovid shall own all Product Marks throughout the world and all goodwill in the Product Marks shall accrue to Ovid. The Parties shall collaborate to have a global, worldwide trademark to be used on the Product. In the event Ovid is unable to obtain or maintain the Product Marks for the Product in the Licensee Territory or in some countries in the Licensee Territory, the Parties shall collaborate to select such other Product Marks as may be available for registration and marketing of the Product in those countries. Ovid shall be responsible for the registration, maintenance, defense and enforcement of the Product Marks using counsel of its own choice in the Ovid Territory and counsel mutually agreed to by the Parties in the Licensee Territory. Ovid shall keep Licensee informed of material progress with regard to the registration, prosecution, maintenance and defense, if any, of the Product Trademarks in the Licensee Territory, including content, timing, and jurisdiction of the filing of such Product Trademarks in the Licensee Territory, sufficiently in advance for Licensee to be able to review any material documents, and Ovid shall consult with, and consider in good faith the requests and suggestions of, Licensee with respect to strategies for filing, prosecuting and defending the Product Trademarks in the Licensee Territory.

(b) Trademark License. Licensee shall use the Product Marks to Commercialize the Product in the Licensee Territory. In addition, unless prohibited by Applicable Laws, Licensee shall use Commercially Reasonable Efforts to include Ovid's corporate trademark on the packaging and product information of the Products sold in the Licensee Territory to indicate that the Product is licensed from Ovid. Ovid hereby grants to Licensee a limited, royalty-free license to use Ovid's corporate trademark and Product Marks solely in connection with the Commercialization of the Product in the Licensee Territory under this Agreement. All use of the Product Marks and Ovid's corporate trademark shall comply with Applicable Laws and shall be subject to Ovid's review and approval. For clarity, Licensee shall also include its (or its Affiliate's or Sublicensee's, as applicable) corporate logo in the Product sold in the Licensee Territory.

(c) Product Domain Names. In the Licensee Territory, Licensee shall have the exclusive right to register Product Marks as domain names, including all internet domain names under all existing top level domains. This includes as example top level domains such as .com, .net., .info and country code top level domains such as .dk, .uk and .it.

11. Representations and Warranties

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction

over it, (d) it has the right to grant the licenses granted by it under this Agreement; (e) the execution and delivery of this Agreement and the performance of such Party's obligations under this Agreement do not and will not result in the breach of, constitute a default, cause the acceleration of performance, require any consent under, or result in the creation of any lien, charge or encumbrance upon any of its property or assets pursuant to any material instrument or agreement to which it is a party, or by which it or its properties may be bound or affected, as of the Effective Date; and (f) it is not a party to any agreement, arrangement or understanding with any Third Party which in any significant way prevents it from fulfilling any its material obligations under the terms of this Agreement.

11.2 Covenants.

(a) Employees, Consultants, and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign (or, in the case of contractor, grant a license under) Inventions, in each case in a manner consistent with the provisions of this Agreement.

(b) Debarment. Each Party represents, warrants, and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to the Compound or any Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Sublicensees, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) Compliance. Licensee covenants as follows:

(i) In the performance of its obligations under this Agreement, Licensee shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws.

(ii) Licensee and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including, Licensee (and Licensee represents and warrants that as of the Effective Date, Licensee, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered, or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of Licensee's obligations under this Agreement, and Licensee covenants that it and

its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(iii) Licensee and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, (1) shall not violate or cause the violation of the FCPA, Export Control Laws, or any other Applicable Laws, or otherwise cause any reputational harm to Ovid, and (2) shall immediately notify Ovid if Licensee has any information or suspicion that there may be a violation of any of the foregoing in connection with activities under this Agreement.

(iv) In connection with the performance of its obligations under this Agreement, Licensee shall comply and shall cause its and its Affiliates' employees and contractors to comply with Licensee's own anti-corruption and anti-bribery policy, a copy of which has been provided to Ovid prior to the Effective Date.

(v) Ovid will have the right, upon reasonable prior written notice and during Licensee's regular business hours, to conduct at its own cost and expenses inspections of and to audit Licensee's books and records in the event of a suspected violation or to ensure compliance with the representations, warranties, and covenants of this Section 11.2(c); provided, however, that in the absence of good cause for such inspections and audits, Ovid may exercise this right no more than annually.

(vi) In the event that Licensee has violated or been suspected of violating any of the representations, warranties, or covenants in this Section 11.2(c), Licensee will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that Licensee will provide on anti-corruption law compliance.

(vii) Licensee will, at Ovid's request, annually certify to Ovid in writing Licensee's compliance, in connection with the performance of Licensee's obligations under this Agreement, with the representations, warranties, or covenants in Section 11.2(c), which certification shall be issued by Licensee's global commercial head for the Product.

(viii) Ovid shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that Licensee, its Affiliates, or its Sublicensees, in connection with performance of Licensee's obligations under this Agreement, has engaged in chronic or material violations of the FCPA.

11.3 Additional Ovid Representations and Warranties. Ovid represents, warrants, and covenants, on behalf of itself and its Affiliates, as applicable, to Licensee that, as of the Effective Date:

(a) to the extent applicable to the performance of its obligations under this Agreement, Ovid shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws;

(b) **Exhibit B** lists all of the Ovid Patents as of the Effective Date that are necessary or useful for the Development, registration, use or Commercialization of the Product in the Licensee Territory;

(c) to Ovid's knowledge, Ovid has the right to grant all rights and licenses it purports to grant to Licensee with respect to the Ovid Technology under this Agreement;

(d) as set forth above, Ovid is not a party to any agreement, arrangement or understanding with any Third Party which in any manner prevents it from fulfilling or affects its ability to perform any of its obligations under the terms of this Agreement to a material extent;

(e) Ovid and its Affiliates have not granted any liens or security interests on the Ovid Technology;

(f) Ovid and its Affiliates have not received any written notice from a Third Party that the Development of any Product conducted by Ovid prior to the Effective Date has infringed any Patents of any Third Party;

(g) Ovid and its Affiliates have not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the Ovid Technology that would conflict with or derogate the licenses or other rights granted to Licensee hereunder;

(h) no claim or action has been brought or, to Ovid's knowledge, threatened in writing, by any Third Party alleging that the Ovid Patents are invalid or unenforceable, and no Ovid Patent is the subject of any interference, opposition, cancellation, or other protest proceeding;

(i) to Ovid's knowledge, no Third Party is infringing or misappropriating or has materially infringed or misappropriated the Ovid Technology in the Licensee Territory;

(j) to Ovid's knowledge, all research and Development of the Product conducted by or on behalf of Ovid prior to the Effective Date has been conducted in compliance with all Applicable Laws;

(k) to Ovid's knowledge, it has disclosed to Licensee the clinical and non-clinical data in Ovid's Control that is material to the evaluation of the safety, efficacy, and manufacturing process of the Product;

(l) to Ovid's knowledge, there are no issues or information, which to Ovid's knowledge and reasonable opinion, are reasonably likely to have a material impact on the Development of the Product that have not been fully disclosed to Licensee in the course of Licensee's due diligence;

(m) to Ovid's knowledge, the Ovid Technology includes all intellectual property rights which are reasonably necessary for the Development, registration, manufacture, use and Commercialization of the Product in the Licensee Territory as contemplated by the terms of this Agreement;

(n) no litigation has been brought against Ovid or any of its Affiliate, or threatened in writing, which would adversely affect the rights granted to Licensee under the Ovid Technology;

(o) neither Ovid nor any of its Affiliates has granted to any Third Party any right (including any license or option or other right to obtain a license) to develop or commercialize Product in the Field in the Licensee Territory that would conflict with the rights granted to Licensee under this Agreement;

(p) as set forth above, Ovid has not granted any Third Party any license, option or other right under or with respect to the Ovid Technology that would conflict with or derogate from the licenses, options and other rights granted to Licensee hereunder;

(q) Ovid has the right to grant the License under Ovid Know-How specified herein free and clear of any liens or encumbrances which would have prevent or impair the grant of such rights;

(r) as set forth above, to Ovid's knowledge, it has the right to grant the License specified in Section 2.1 free and clear of any liens or encumbrances which would prevent or impair the grant of such rights;

(s) as set forth above, to its knowledge, Ovid has not and will not enter into any agreement that is or would be inconsistent with the obligations, rights and licenses granted to Licensee in this Agreement.

(t) it will use Ovid Commercially Reasonable Efforts in the conduct of the Development and Commercialization of the Compound and/or Product under this Agreement and in compliance with Applicable Law; and

(u) as set forth above, it has to not and will not enter into any agreement that is or would be inconsistent with the obligations, rights and licenses granted to Licensee under this Agreement.

(v) Ovid: (i) has provided or made available to Licensee all material relevant documents and written communications and materials in its and its Affiliates' possession or Control from and to any Regulatory Authority in the Licensee Territory related to the Product; (ii) as of the Effective Date, Ovid and its Affiliates have not received any oral or written communication (including any notice of inspection, deficiency letter, warning letter or similar notice) from any Regulatory Authority alleging that the Development of Product by or on behalf of Ovid and its Affiliates is not currently materially in compliance with any and all applicable laws or regulations implemented by any Regulatory Authority; and (iii) to Ovid's knowledge, Ovid and its Affiliates have not made, with respect to the Product, any untrue statement of material fact to any Regulatory Authority, or failed to disclose a material fact required to be disclosed to such Regulatory Authority.

11.4 Ovid Covenants Regarding the Lundbeck License Agreement. Ovid shall make any and all payments that become due under the Lundbeck License Agreement as a result of any

activity under this Agreement, whether by or on behalf of Ovid or by Licensee or its Affiliate or Sublicensee, in each case in accordance with the terms of the Upstream License Agreement.

(a) Ovid is in compliance in all material respects with the Lundbeck License Agreement, and, to Licensor's knowledge, the other party to the Lundbeck License Agreement is not in breach or default in any respect of the Lundbeck License Agreement pertaining to the Product.

(b) In the event that Ovid receives a notice or other communication alleging it is in breach (including a notice or other communication threatening termination) of the Lundbeck License Agreement, Ovid shall promptly provide Licensee with a copy of such notice.

(c) Ovid shall not agree to any amendment or other modification (including termination) to the Lundbeck License Agreement in a manner that materially adversely affects the rights sublicensed to Licensee under this Agreement without Licensee's prior written consent, such consent not to be unreasonably withheld or delayed.

(d) Ovid and Licensee have negotiated with Lundbeck a technology transfer agreement (the "**Technology Transfer Agreement**") for the transfer from Lundbeck to Licensee of Know-How, information, and data owned or controlled by Lundbeck that is necessary or reasonably useful for the manufacture of the Compound and Drug Product in or for the Licensee Territory and according to the technology transfer plan (the "**Technology Transfer Plan**") as attached to the Technology Transfer Agreement. Such Technology Transfer Agreement shall provide such transfer to be finalized over a period of [***] starting from the Effective Date, provided that such time period shall be extended to the extent of any delay caused by Licensee or any other factor outside Ovid's reasonable control, including delays caused by any force majeure event as described in Section 16.8 of the Agreement.

11.5 Additional Licensee Representations, Warranties, and Covenants. Licensee represents, warrants, and covenants to Ovid that, as of the Effective Date, Licensee has not granted, and will not grant during the Term, any right to any Third Party under the Licensee Technology that would conflict with the rights granted to Ovid hereunder. Licensee further represents, warrants, and covenants to Ovid that, as of the Effective Date, Licensee does not own or control any Licensee Patents. Licensee further represents, warrants, and covenants to Ovid that Licensee has the personnel, expertise, capacity, resources, equipment, and facilities necessary to implement the Technology Transfer Plan in accordance with the timelines specified therein so that such plan can be completed over a period of [***] following the date such technology transfer is commenced.

11.6 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or warrants that any data obtained from conducting Clinical

Trials in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.

12. INDEMNIFICATION

12.1 Indemnification by Ovid. Ovid hereby agrees to defend, indemnify, and hold harmless Licensee and its Affiliates and their respective directors, officers, employees, and agents (each, a "**Licensee Indemnitee**") from and against any and all liabilities, expenses, and losses including any product liability, personal injury, property damage, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**") to which any Licensee Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of or result from: (a) the Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Ovid or its Affiliates or licensees or the contractors of any of them (excluding any activities by or on behalf of Licensee or its Affiliates or Sublicensees), (b) the negligence or willful misconduct of any Ovid Indemnitee, or (c) the breach by Ovid of any warranty, representation, covenant, or agreement made by Ovid in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities for which Licensee is obligated to indemnify any Ovid Indemnitee(s) under Section 12.2.

12.2 Indemnification by Licensee. Licensee hereby agrees to defend, indemnify, and hold harmless Ovid, its Affiliates, and licensees and their respective directors, officers, employees, and agents (each, a "**Ovid Indemnitee**") from and against any and all Losses to which any Ovid Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Licensee or its Affiliates or Sublicensees or the contractor of any of them, (b) the negligence or willful misconduct of any Licensee Indemnitee, or (c) the breach by Licensee of any warranty, representation, covenant, or agreement made by Licensee in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities for which Ovid is obligated to indemnify any Licensee Indemnitee(s) under Section 12.1.

12.3 Procedure. A party that intends to claim indemnification under this Article 12 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party claim, demand, action, or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own choice. The indemnity arrangement in this Article 12 shall not apply to amounts paid in settlement of any action with respect to a Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 12 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal

representatives in the investigation of any action with respect to a Claim covered by this indemnification.

12.4 Insurance. Each Party, at its own expense, hereby agrees and undertakes to maintain insurance policies with respect to the activities to be made by and obligations assumed by each of the Party in accordance to the provisions of this Agreement. In this respect the Parties agree to carry out at their sole expense and with a commercially reasonable insurance company, the following liability policies, in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term:

(a) Clinical Trial liability policies reasonable for each specific phase and country in which a Party is conducting activities under this Agreement, with limits and warranties no less than those required by Applicable Law; and

(b) product liability policies with limits at a minimum equivalent to [***] per each occurrence and per year.

The Public and Product liability policies above shall start from the Effective Date and last for a period of [***] after the expiration or the earlier termination of the Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverages to the other Party upon request. It is understood that such policies shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations hereunder. In the event of use by either Party of subcontractors, sublicensees, or any Third Party in the performance of such Party's obligations under the Agreement, such Party shall ensure that its subcontractor, sublicensee, or Third Party has a proper and adequate general liability or professional liability insurance to cover its risks with respect to the other Party for damages mentioned above.

12.5 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED, HOWEVER, THAT THIS SECTION 12.5 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12 OR DAMAGES AVAILABLE AS A RESULT OF A BREACH OF A PARTY'S EXCLUSIVITY OBLIGATIONS UNDER SECTION 2.8 OR CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 13.

13. CONFIDENTIALITY

13.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [***] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to the remainder of this Article 13, shall not publish or otherwise disclose

the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

13.2 Exceptions. The obligations of confidentiality and restriction on use under Section 13.1 will not apply to any information that the receiving Party can prove by competent written evidence: (a) is at the time of disclosure, or thereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public; (b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is disclosed to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto; or (d) is independently discovered or developed by the receiving Party without the use of or reference to the Confidential Information belonging to the disclosing Party.

13.3 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing, prosecuting, and maintaining Patents as permitted by this Agreement;

(b) submitting and maintaining Regulatory Filings for Products that such Party has a license or right to Develop or Commercialize under this Agreement in a given country or jurisdiction;

(c) prosecuting and defending litigation as permitted by this Agreement;

(d) complying with applicable court orders or governmental regulations, including regulations promulgated by securities exchanges; and

(e) disclosure to its and its Affiliates' employees, consultants, contractors, agents, licensees, and sublicensees, in each case on a need-to-know basis in connection with the Development, manufacture, or Commercialization of the Compound and Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein;

(f) disclosure to actual and bona fide potential investors, acquirors, licensees, and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, collaboration, or other business relationship, in each case under written obligations of confidentiality and non-use at least as

stringent as those herein, provided that the disclosing Party redacts the financial terms and other provisions of this Agreement that are not reasonably required to be disclosed in connection with such potential investment, acquisition, collaboration, or business transaction which redaction shall be prepared in consultation with the other Party; and

(g) disclosure to Third Party licensors of intellectual property that is related to the Compound or any Product (e.g., the Third Party that is party to the Lundbeck License Agreement) for the purpose of meeting reporting obligations under such Third Party agreement.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 13.3(c) or 13.3(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure, and to the extent possible, at least [***] notice, and use the same diligent efforts to secure confidential treatment of such Confidential Information as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 13.3 shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Section 13.

13.4 Publications.

(a) Ovid shall have the right to review and comment on any material proposed for disclosure or publication by Licensee regarding results of and other information regarding Licensee's Development activities during the Term with respect to the Compound and Product, whether by oral presentation, manuscript, or abstract. Before any such material is submitted for publication, or presentation of any such material is made, Licensee shall deliver a complete copy of the material proposed for disclosure to Ovid at least [***] prior to submitting the material to a publisher or initiating any other disclosure, or as close to these time frames as reasonably possible. Ovid shall review any such material and give its comments to Licensee within [***] of the receipt of such material. With respect to oral presentation materials and abstracts, Ovid shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to Licensee with comments, if any. Subject to Section 13.4(b), following the expiration of the applicable time period for review, Licensee shall be free to submit such proposed manuscript for publication or presentation materials for public disclosure, and does not need to follow this process for subsequent publications or presentations of the same data.

(b) If Ovid notifies Licensee within the applicable time period set forth in Section 13.4(a) that such publication or presentation, in Ovid's reasonable judgment:

(i) contains an invention for which Ovid desires to obtain patent protection, Licensee shall delay such publication or presentation for a period of up to [***] (or such other time period agreed by the Parties in writing) to permit the preparation and filing of a patent application for such invention, or

(ii) contains any Confidential Information of Ovid, or could be expected to have an adverse effect on the commercial value of any Confidential Information disclosed by

Ovid to Licensee, the Parties shall attempt to agree on revisions to the applicable disclosure so as to preserve both the commercial value of such Confidential Information and the scientific merit of such disclosure, provided that if and to the extent the Parties are unable to agree, Licensee shall delete such Confidential Information from the proposed publication or presentation.

13.5 Publicity; Public Disclosures and Public Announcements. Save as permitted in this Section 13.5, neither Party shall make any public announcement or statement to the public containing Confidential Information of the other Party without the prior consent of such other Party. On or promptly after the Effective Date, the Parties shall issue a joint public announcement, or either Party may issue its own public announcement, regarding the execution of this Agreement with information substantially consistent with the information contained in the form of press release attached hereto as **Exhibit D**. It is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases prior to the issuance thereof, to the extent practicable, and in the case of any press release Licensee wishes to issue, Licensee shall first obtain Ovid's written approval of such release. Notwithstanding the foregoing, neither Party may unreasonably withhold, condition, or delay consent to such releases by more than [***], and either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, is reasonably necessary to comply with Applicable Laws or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable, and to the extent possible, at least [***] prior to such disclosure. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following the initial joint press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party, and those terms of the Agreement which have already been publicly disclosed in accordance with.

13.6 Prior Confidentiality Agreement. As of the Effective Date, the terms of this Article 13 shall supersede any prior non-disclosure, secrecy, or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information under this Agreement.

13.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 13. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 13.

14. TERM AND TERMINATION

14.1 Term. This Agreement shall commence on the Effective Date and shall continue until terminated as provided in this Article 14 (the "**Term**"). Notwithstanding anything herein, on

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

a Product-by-Product and country-by-country basis, upon the expiration of the Royalty Term the licenses granted to Licensee in Section 2.1 shall become perpetual and fully paid-up with respect to such Product in such country, subject to Licensee's payment obligations under Article 8 during the Extended Commercialization Term, but thereafter shall be on a non-exclusive basis.

14.2 Termination for Cause.

(a) Material Breach. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the other Party within [***] after notice of such breach from the non-breaching Party. In the event of any dispute, the Agreement shall remain in place during the pendency of any such dispute.

(b) Insolvency Event.

(i) Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files a petition for relief in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes the involuntary subject of any proceeding or action of the type described above and such proceeding or action remains un-dismissed or un-stayed for a period of more than [***].

(ii) All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any other jurisdiction outside of the Territory (collectively, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall perform all of the obligations in this Agreement intended to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the non-bankrupt Party copies of all Patents and Information necessary for the non-bankrupt Party to [***] enjoy its rights under the terms of this Agreement. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. [***].

(c) Patent Challenge. Ovid shall have the right to terminate this Agreement immediately in its entirety upon written notice to Licensee if Licensee or any of its

Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Ovid Patent.

14.3 Termination without Cause.

(a) Prior to the First Commercial Sale. Prior to the First Commercial Sale of the Product in the Licensee Territory, Licensee shall have the right to terminate this Agreement in its entirety without cause [***].

(b) After the First Commercial Sale. Following the First Commercial Sale of the Product in the Licensee Territory, Licensee shall have the right to terminate this Agreement in its entirety without cause [***].

14.4 Effects of Termination. Upon any termination of this Agreement by either Party, the following Sections 14.4(a) through 14.4(g) will apply. For clarity, during the pendency of any termination notice period, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(a) Licenses. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason, the licenses granted by Licensee to Ovid shall survive such termination and shall automatically become worldwide. All of the licenses granted by Ovid to Licensee shall be automatically terminated.

(b) Regulatory Materials; Data. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason (where Licensee elects to continue the Development and Commercialization of the Product), within [***] after the effective date of such termination, Licensee shall transfer and assign to Ovid, at no cost to Ovid, all Regulatory Filings and Regulatory Approvals for the Products, Data from all pre-clinical, non-clinical, and clinical studies of the Product conducted by or on behalf of Licensee, its Affiliates, or Sublicensees, and all pharmacovigilance data (including all adverse event data) on the Products. In addition, at Ovid's request, Licensee shall provide Ovid with reasonable assistance with any inquiries and correspondence with Regulatory Authorities regarding the Product in the Licensee Territory, such assistance shall be limited to a period of [***] after such termination.

(c) Development Wind-Down. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason (where Licensee elects to continue the Development and Commercialization of the Product), Licensee shall either, as directed by Ovid, (i) wind-down any ongoing Development activities (including any Clinical Trials) of Licensee or its Affiliates and Sublicensees with respect to any Product in the Licensee Territory in an orderly fashion or (ii) promptly transfer such

Development activities to Ovid or its designee, in each case in compliance with all Applicable Laws.

(d) Cost of Ongoing Trials. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason, if there is any ongoing Clinical Trial of the Product under the Development Plan for which the Parties are sharing costs, then Licensee shall continue to share the cost of such Clinical Trial until the effective date of termination.

(e) Commercial Wind-Down. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason (where Licensee elects to continue the Development and Commercialization of the Product), Licensee shall, as directed by Ovid, (A) continue certain ongoing Commercial activities of Licensee and its Affiliates and Sublicensees with respect to any Product in the Licensee Territory for a period of up to [***] after the effective date of termination, as determined by Ovid, and (B) handoff such Commercial activities to Ovid or its designee, on a timetable to be set by Ovid, not to exceed [***] after the effective date of termination, and in compliance with all Applicable Laws. During such commercial wind-down period, Licensee shall continue to book sales and pay royalties to Ovid in accordance with Section 8.5. Except as necessary to conduct the foregoing activities as directed by Ovid, Licensee shall immediately discontinue its (and shall ensure that its Affiliates and Sublicensees immediately discontinue their) promotion, marketing, offering for sale, and servicing of the Product and its use of all Product Marks. In addition, Licensee shall immediately deliver to Ovid (at Licensee's expense) all samples, demonstration equipment, sales materials, catalogs, and literature of Ovid in Licensee's possession or control.

(f) Transition Assistance. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason (where Licensee elects to continue the Development and Commercialization of the Product), Licensee shall, at no cost to Ovid, provide reasonable consultation and assistance for a period of no more than [***] after the effective date of termination for the purpose of transferring or transitioning to Ovid all Licensee Know-How not already in Ovid's possession and, at Ovid's request, all then-existing commercial arrangements, customer lists, and similar information relating to the Products that Licensee is able, using Commercially Reasonable Efforts, to transfer or transition to Ovid or its designee, in each case, to the extent reasonably necessary for Ovid to continue the Development or Commercialization of the Compound and Products in the Licensee Territory. If any such contract between Licensee and a Third Party is not assignable to Ovid or its designee (whether by such contract's terms or because such contract does not relate specifically to the Products) but is otherwise reasonably necessary for Ovid to continue the Development or Commercialization of the Compound and Products in the Licensee Territory, or if Licensee is performing such work for the Compound and Product itself (and thus there is no contract to assign), then Licensee shall reasonably cooperate with Ovid to negotiate for the continuation of such services for Ovid from such entity, or Licensee shall continue to perform such work for Ovid, as applicable, for a reasonable period (not to exceed [***]) after the effective date of termination at Ovid's cost until Ovid establishes an alternate, validated source of such services.

(g) Remaining Inventories. Except in the event of (i) termination by Licensee for an uncured material breach by Ovid, or (ii) termination by Licensee in the circumstances set forth in Section 14.2(b)(i) with respect to Ovid, or (iii) Ovid's termination for Safety Reason (where Licensee elects to continue the Development and Commercialization of the Product), Ovid shall have the right, at its discretion, to obtain from Licensee any or all of the inventory of the Products held by Licensee as of the date of termination, free of charge. Ovid shall notify Licensee within [***] after the effective date of termination whether Ovid elects to exercise such right.

14.5 Licensee Continuation. If (a) Licensee has the right to terminate this Agreement in its entirety for an uncured material breach by Ovid, but elects to continue this Agreement in its entirety as modified by this Section 14.5, or (b) Licensee has the right to terminate in the circumstances set forth in Section 14.2(b)(i), but elects to continue this Agreement as modified by this Section 14.5, or (c) Ovid elects to terminate this Agreement in its entirety for Safety Reason, but Licensee elects to continue this Agreement as modified by this Section 14.5, then, except as provided below, effective as of the date Licensee delivers notice of such election to Ovid, the following shall apply:

i. Licensee shall have the right to terminate the Supply Agreement, and if Licensee terminates the Supply Agreement, Ovid shall cooperate with Licensee for smooth technology transfer of the manufacturing process if termination occurs prior to the Technology Transfer Completion Date.

ii. Notwithstanding anything contained in this Agreement to the contrary, Ovid shall cease any and all Development/Regulatory activities with respect to the Product in the Field in the Licensee Territory (other than the Ovid Ongoing Trials if still ongoing);

iii. All Licensee payment obligations provided in this Agreement shall continue, including those that are accrued and unpaid as of the date of such election by Licensee, [***];

iv. After the effective date of such election by Licensee, the licenses granted by Ovid to Licensee in Section 2.1 under the Product Marks, Ovid Know-How and Ovid Patents for the research, the Development, the use, and the Commercialization of the Product in the Field in the Licensee Territory shall continue and the Licensee shall have such rights to Develop, Manufacture and Commercialize any Product in the Field in the Licensee Territory at Licensee's sole discretion;

v. The CGB shall coordinate the wind-down of Ovid's efforts under this Agreement, and Ovid, as soon as reasonably practical after the effective date of such election, shall provide to Licensee, as applicable and to the extent permitted under any applicable Third Party contract, (1) any information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ovid for a Product in the Field in the Licensee Territory; and (2) other documents to the extent relating to the Products that are necessary for the continued Development, Commercialization and Manufacture of the Product (including material documents and agreements relating to the sourcing and Manufacture of a Product for sale, promotion, distribution, or use of a Product) in the Field throughout the Licensee Territory. Ovid will cooperate with Licensee to

provide a transfer of such material information and documents. At Licensee's request, Ovid shall use reasonable efforts to assign to Licensee any and all agreements to which Ovid, or its Affiliate, and a Third Party are parties, and that solely cover or govern the Development, Commercialization and Manufacturing activities conducted in connection with a Product in the Field in the Territory prior to such election by Licensee, or if such assignment is not permitted under the relevant agreement, (A) grant to Licensee other reasonable rights to provide to Licensee the benefit of such non-assignable agreement, at Licensee's expense, to the extent permitted under the terms of such non-assignable agreement; or (B) to the extent not permitted under the terms of such non-assignable agreement, the Parties shall discuss in good faith an alternative solution to enable Licensee to receive, at Licensee's expense, the benefit of the terms of such non-assignable agreement. Ovid shall take such other reasonable actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights to such Product(s) as described in this Section 14.5(v) hereunder to Licensee;

vi. Ovid shall transfer to Licensee any and all Regulatory Materials directly and solely related to the Product in the Field in the Licensee Territory, and, upon Licensee's request, shall make available to Licensee any other relevant information reasonably requested by Licensee related to such Regulatory Materials;

vii. As long as Licensee is not in breach of this Agreement or the Lundbeck License Agreement at the effective date of such election, Licensee shall have the rights of a non-breaching sublicensee set forth in the Lundbeck License Agreement (as amended by the Lundbeck Sublicense Amendment) from and after such election;

viii. Licensee shall have no further obligation to use Angelini Commercially Reasonable Efforts with respect to its obligations hereunder;

ix. Ovid shall be obliged to bear the costs of the Ovid Ongoing Trials, if still ongoing; and

x. In lieu of Section 12.1 and Section 12.2, the following shall apply: Licensee hereby agrees to defend, indemnify, and hold harmless the Ovid Indemnitees from and against any and all Losses to which any Ovid Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (A) Licensee's decision to continue the Development, Manufacture and Commercialization of Product following Ovid's cessation of such activities for Safety Reason, (B) any Development, use, handling, storage, manufacture, Commercialization, or other disposition of any Compound or Product by Licensee or its Affiliates or Sublicensees or the contractor of any of them, (C) the negligence or willful misconduct of any Licensee Indemnitee or Licensee's Affiliates or Sublicensees, or (D) the breach by Licensee of any warranty, representation, covenant, or agreement made by Licensee in this Agreement.

14.6 Confidential Information. Upon expiration or termination of this Agreement in its entirety, except to the extent that a Party obtains or retains the right to use the other Party's Confidential Information, each Party shall promptly return to the other Party, or delete or destroy,

all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations. All Licensee Data and Regulatory Filings assigned to Ovid upon termination of this Agreement will be deemed Ovid's Confidential Information and no longer Licensee's Confidential Information.

14.7 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement.

14.8 Exercise of Right to Terminate. All rights and obligations of a Party accrued prior to the effective date of a termination (including the rights to receive reimbursement for costs incurred prior to the effective date of such termination and payments accrued or due prior to the effective date of such termination) shall survive such termination.

15. Dispute Resolution

15.1 General. Except as provided in Sections 3.4 and 9.4, any dispute between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**") shall be resolved pursuant to this Section 15.

15.2 Executive Officers. Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties.

15.3 Intellectual Property Disputes. If the Executive Officers are not able to agree on the resolution of a Dispute within thirty (30) days (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them and such Dispute is with respect to the validity, scope, enforceability, inventorship, or ownership of any Patent, trademark, or other intellectual property right ("**IP Dispute**"), then, if a Party wishes to pursue further resolution of such IP Dispute, an action, claim, or proceeding to resolve such IP Dispute shall be brought in any court of competent jurisdiction in any country or jurisdiction in which such intellectual property rights apply.

15.4 Arbitration. If the Executive Officers are not able to agree on the resolution of a Dispute within thirty (30) days (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then, except as otherwise set forth in Section 15.3, if a Party wishes to pursue further resolution of such Dispute, such Dispute shall be finally resolved by binding arbitration in accordance with this Section 15.4. Such Dispute shall be referred to and finally resolved by arbitration under the International Chamber of Commerce ("**ICC**") Rules, as then in effect, by a tribunal of three (3) arbitrators. The seat and legal place of the arbitration shall be [***]. Each Party shall nominate one arbitrator and the third arbitrator shall be nominated by the two Party-nominated arbitrators within [***] after the second arbitrator's appointment. If a Party does not nominate its arbitrator within [***] following the expiry of the allotted period, then such arbitrator shall be appointed by the ICC in accordance with its rules. Any arbitrator appointed by the ICC shall have at least [***] experience in the pharmaceutical

industry. The arbitration shall be conducted, and all documents submitted to the arbitrators shall be, in English. Each Party shall bear its own legal costs for its counsel and other expenses, and the Parties shall equally share the costs of the arbitration; provided that the arbitral tribunal shall have the discretion to provide that the losing party is responsible for all or a portion of such arbitration and legal costs, in such case the arbitral award will so provide. The arbitrators shall have no power to award damages excluded pursuant to Section 12.5. In no event shall the arbitrators assign a value to any issue greater than the greatest value for such issue claimed by either Party or less than the smallest value for such issue for such item claimed by either Party. The award shall be final and binding upon the Parties and the Parties undertake to carry out any award without delay. Judgment on the award may be entered in any court of competent jurisdiction. Except to the extent necessary to confirm, enforce, or challenge an award of the arbitration, to protect or pursue a legal right, or as otherwise required by Applicable Law or regulation or securities exchange, neither Party nor any arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties. Notwithstanding anything to the contrary in the foregoing, in no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy, or claim would be barred by the applicable New York statute of limitations. Any disputes concerning the propriety of the commencement of the arbitration shall be finally settled by the arbitral tribunal.

15.5 Interim Relief. Notwithstanding anything herein to the contrary, nothing in this Article 15 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction, or other interim equitable relief concerning a Dispute in any court of competent jurisdiction before or after the initiation of an arbitration as set forth in Section 15.4, if necessary to protect the interests of such Party. This Section 15.5 shall be specifically enforceable.

16. General Provisions

16.1 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles.

16.2 Entire Agreement; Modification. This Agreement, including the exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

16.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties, including for all tax purposes. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. The Parties (and any successor, assignee, transferee,

or Affiliate of a Party) shall (a) use commercially reasonable efforts to structure the arrangement and activities contemplated by this Agreement to avoid the arrangement contemplated by this Agreement being treated as a partnership that is engaged in a "United States trade or business" for United States tax purposes and (b) not treat or report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes, without the prior written consent of the other Party unless required by a final "determination" as defined in Section 1313 of the United States Internal Revenue Code of 1986, as amended.

16.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

16.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, such consent not to be unreasonably withheld. Any successor or assignee of rights and obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and obligations. Notwithstanding the foregoing, either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the transfer or sale, through whatever means, of all or substantially all of its assets or the business of such Party to which this Agreement relates (whatever by assignment, conveyance, reorganization, merger, assumption, purchase and sale of stock, by contract or by operation of law, provided that the intellectual property rights of the acquiring party to such transaction (if other than one of the Parties) shall not be included in the technology licensed under this Agreement; or

(b) to an Affiliate, provided that if the entity to which this Agreement is assigned ceases to be an Affiliate of the assigning Party, the Agreement shall be automatically assigned back to the assigning Party or its successor.

Any permitted assignment shall be binding on the successors and the permitted assigns of a Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.5 shall be null, void and of no legal effects.

16.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable, or illegal part.

16.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at

its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this Section 16.7. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt, (ii) if air mailed, five (5) days after the date of postmark, (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries, or (iv) if sent by facsimile, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next business day.

If to Licensee, notices must be addressed to:

Angelini Pharma Rare Diseases AG
Consulting GmbH Sumpfstrasse 26 6312
Steinhausen, Zurich
Switzerland
Attention: Chief Executive Officer

With a copy to:
Angelini Pharma S.p.A**.**
Viale Amelia 70, 00181
Roma, Italy
Attention: Enza Maria Cristina Onnis, Global Pharma General Counsel
mail: [***]

If to Ovid, notices must be addressed to:

Ovid Therapeutics
1460 Broadway, Suite 15021
New York, NY 10036
USA
Attention: Chief Executive Officer

And a copy to:

Attention: General Counsel

With a copy to (which shall not constitute notice):

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
USA
Attention: Laura Berezin

16.8 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control including Acts of God, fire, flood, explosion, earthquake, pandemic (including the COVID-19 pandemic), quarantine or similar restrictions, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction

or other casualty, any lack or failure of transportation facilities, any injunction, order, proclamation, demand, or requirement of any Governmental Authority [***], any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur and uses reasonable efforts to overcome such event. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [***] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

16.9 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subjects of the conjunction are, or are intended to be, mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

16.10 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

{SIGNATURE PAGE FOLLOWS}

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

In Witness Whereof, the Parties hereto have caused this **Collaboration and License Agreement** to be executed and entered into by their duly authorized representatives as of the Effective Date.

Ovid Therapeutics Inc.	**Angelini Pharma Rare Diseases AG**
By: /s/ Jeremy Levin	By: /s/ Pierluigi Antonelli
Name: Jeremy Levin	Name: Pierluigi Antonelli
Title: Chief Executive Officer	Title: Chairman of the BoD

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List of Exhibits and Schedules

Exhibit A: Compound

Exhibit B: Ovid Patents

Exhibit C: Development Plan

Exhibit D: Press Release

Exhibit E: Technology Transfer Plan

Exhibit F: Documents to be transferred according to Section 8.1(b)(i)

Exhibit G: Other Documents to be transferred

Exhibit H: Description of Additional Pivotal Trial

Exhibit I: Current Licensee Pipeline Products

Exhibit J: Descriptions of Elara Trial, Neptune Trial, and Rocket Trial

Exhibit K: Supply Agreement

Exhibit L: Finished Product Documentation

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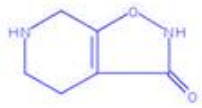
Exhibit A
Compound

DESCRIPTION OF COMPOUND

INN: Gaboxadol

Chemical Name (IUPAC): 4,5,6,7-Tetrahydroisoxazolo[5,4-c]pyridin-3(2H)-one

Structural formula:



CAS Registry Number: 64603-91-4

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit B
Ovid Patents

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit C
Development Plan

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit D
Press Release

Ovid Therapeutics and Angelini Pharma Enter into Exclusive License Agreement to Develop, Manufacture and Commercialize OV101 for the Treatment of Angelman Syndrome in Europe

- Angelini Pharma obtains exclusive development, manufacturing and commercialization rights to OV101 (gaboxadol) for the potential treatment of Angelman syndrome in the European Union and other countries in the European Economic Area, Switzerland, Turkey and the United Kingdom
- Ovid Therapeutics will receive an upfront payment of $20 million and additional payments of up to $212.5 million upon the achievement of development, manufacturing and sales milestones, in addition to double-digit royalties on net sales if successfully commercialized
- Angelini Pharma will execute the agreement through its new affiliate Angelini Pharma Rare Diseases AG

NEW YORK and ROME, July XX, 2020 -- Ovid Therapeutics Inc. (NASDAQ: OVID, hereinafter "Ovid"), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, and Angelini Pharma S.p.A. (hereinafter "Angelini Pharma"), an Italian family-owned pharmaceutical company committed to helping patients with a constant and prevalent focus on Mental Health, Rare Diseases and Consumer Health, announced an agreement in which Angelini Pharma will be responsible to develop, manufacture and commercialize OV101 (gaboxadol) for the potential treatment of Angelman syndrome in the European Union, other countries in the European Economic Area, Switzerland, Turkey and United Kingdom. Angelini Pharma will execute the agreement through its new affiliate Angelini Pharma Rare Diseases AG. OV101 is believed to be the only delta (δ)-selective GABAA receptor agonist in development, and is currently being evaluated in the pivotal Phase 3 NEPTUNE trial in Angelman syndrome, with topline results expected in the fourth quarter of 2020.

Under the terms of the agreement, Ovid will receive an upfront payment of $20 million and is eligible to receive up to an additional $212.5 million in payments upon the achievement of development, manufacturing and sales milestones for the initial indication (Angelman syndrome), as well as double-

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digit royalties on net sales if OV101 is successfully commercialized. Ovid will retain all U.S. and rest-of-world commercial rights to OV101.

“We are excited to enter into a strategic collaboration with Angelini Pharma with the goal of bringing OV101, if approved, to the Angelman community in Europe as quickly as possible. Angelini Pharma is an ideal partner for Europe as they have deep regional knowledge, an established infrastructure with a history of successful product launches, and a commitment to improving the quality of life of the patient communities they serve,” said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. “Finding the right partners to bring OV101 to the Angelman community as rapidly as possible is a core part of our global strategy. We believe this partnership with Angelini will help to maximize the potential commercial value of OV101 and achieve our strategic objectives in this important geography."

“Today is a day that we will remember. Through our collaboration with Ovid Therapeutics, we are laying the foundation to developing innovative health solutions for rare diseases, in line with Angelini Pharma’s new strategy,” said Pierluigi Antonelli, Angelini Pharma CEO. “The new business unit Angelini Pharma Rare Diseases AG will contribute to the development, registration, production and, if approved, commercialization in Europe of OV101, Ovid Therapeutics’ very promising drug being evaluated in a Phase 3 clinical trial for the treatment of Angelman syndrome. As of now, there is no effective treatment for this rare genetic disease, characterized by severe psychomotor disability, which manifests itself from childhood. Delivering on our commitment makes us proud both from a scientific perspective and its social impact”.

"As shareholders and executives of Angelini Holding we continue to invest in the pharma area, which today represents half of our Group's turnover,” commented the executive vice president Thea Paola Angelini and the CEO Sergio Marullo di Condojanni. “Our global development and internationalization strategy focuses on business areas with high growth potential. Particularly, we look closely at all the opportunities that can open up, not only in healthcare, but also in the consumer and machinery sector."

About Angelman Syndrome
Angelman syndrome is a rare genetic condition that is characterized by a variety of signs and symptoms. Characteristic features of this condition include delayed development, intellectual disability, severe speech impairment, problems with movement and balance, seizures, sleep disorders and anxiety. The most common cause of Angelman syndrome is the loss of function of the gene that codes for ubiquitin protein ligase E3A (UBE3A), which plays a critical role in nerve cell communication, resulting in impaired tonic inhibition. Individuals with Angelman syndrome typically have normal lifespans but are unable to live independently. Therefore, they require constant support from a network of specialists and caregivers. Angelman syndrome affects approximately 1 in 12,000 to 1 in 20,000 people globally.

There are no approved therapies by the U.S. Food and Drug Administration (FDA), European Medicines Agency or rest–of-world for Angelman syndrome, and treatment primarily consists of behavioral interventions and pharmacologic management of symptoms.

Angelman syndrome is associated with a reduction in tonic inhibition, a function of the delta (δ)-selective GABAA receptor that allows a human brain to decipher excitatory and inhibitory neurological signals correctly without being overloaded. If tonic inhibition is reduced, the brain becomes inundated with signals and loses the ability to separate background noise from critical information.

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About OV101 (gaboxadol)
OV101 is believed to be the only delta (δ)-selective GABAA receptor agonist in development and the first investigational drug to specifically target the disruption of tonic inhibition, a central physiological process of the brain that is thought to be the underlying cause of certain neurodevelopmental disorders. OV101 has demonstrated in laboratory studies and animal models to selectively activate the δ-subunit of GABAA receptors, which are found in the extrasynaptic space (outside of the synapse), and thereby impact neuronal activity through modulation of tonic inhibition.

Ovid is developing OV101 for the treatment of Angelman syndrome and Fragile X syndrome to potentially restore tonic inhibition and thereby address several core symptoms of these conditions. In both these syndromes, the underlying pathophysiology includes disruption of tonic inhibition modulated through the δ-subunit of GABAA receptors. In preclinical studies, it was observed that OV101 improved symptoms of Angelman syndrome and Fragile X syndrome. This compound has also previously been tested in more than 4,000 patients (more than 1,000 patient-years of exposure) and was observed to have favorable safety and bioavailability profiles. Ovid is conducting a pivotal Phase 3 clinical trial with OV101 in Angelman syndrome (NEPTUNE) and has completed a Phase 2 signal-finding clinical trial with OV101 in Fragile X syndrome (ROCKET).

OV101 has received Rare Pediatric Disease Designation from the FDA for the treatment of Angelman syndrome. The FDA has also granted Orphan Drug and Fast Track designations for OV101 for both the treatment of Angelman syndrome and Fragile X syndrome. In addition, the European Commission (EC) has granted orphan drug designation to OV101 for the treatment of Angelman syndrome. The U.S. Patent and Trademark Office has granted Ovid patents directed to methods of treating Angelman syndrome and Fragile X syndrome using OV101. The issued patents expire in 2035 without regulatory extensions.

About Ovid Therapeutics
Ovid Therapeutics Inc. is a New York-based biopharmaceutical company using its BoldMedicine® approach to develop medicines that transform the lives of patients with rare neurological disorders. Ovid has a broad pipeline of potential first-in-class medicines. The Company's most advanced investigational medicine, OV101 (gaboxadol), is currently in clinical development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid is also developing OV935 (soticlestat) in collaboration with Takeda Pharmaceutical Company Limited for the potential treatment of rare developmental and epileptic encephalopathies (DEE). For more information on Ovid, please visit www.ovidrx.com.

About Angelini Pharma
Angelini Pharma, owned by Angelini Holding, is a pharmaceutical Company committed to helping patients with a constant and prevalent focus on Mental Health, including Pain, Rare Diseases and Consumer Health. Angelini Pharma has an extensive and recognized R&D programs, "World Class" production plants and international commercialization activities of active ingredients and market-leading drugs. For further information, please visit www.angelinipharma.com

About Angelini Holding
Angelini Holding is the parent company of an international group operating in the pharmaceutical and consumer goods sectors. Founded in Italy in 1919, today Angelini group operates in 17 countries with a staff of 5,600 and a turnover of €1,7 billion. In addition to the Pharmaceutical sector, Angelini group operates in Personal and Home Care business area through Fater, a joint venture with Procter & Gamble, in the Machinery field, again in joint venture with P&G, with the group operating in automation

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and robotics for the consumer goods industry Fameccanica, in Perfumery and Skincare and Suncare with Angelini Beauty and in the Wine sector through Bertani Domains. Angelini Holding has recently entered the Baby food market as well through MadreNatura, a joint venture with Hero Group, which offers 100% organic baby food products.

Ovid Therapeutics Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding: advancing development of and commercializing OV101, the potential benefits and value of OV101; the anticipated reporting schedule of clinical data for OV101; and the potential benefits and outcome from this collaboration. You can identify forward-looking statements because they contain words such as "will," "appears," "believes" and "expects." Forward-looking statements are based on Ovid's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include uncertainties in the development and regulatory approval processes, and the fact that initial data from clinical trials may not be indicative, and are not guarantees, of the final results of the clinical trials and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Additional risks that could cause actual results to differ materially from those in the forward-looking statements are set forth in Ovid's filings with the Securities and Exchange Commission under the caption "Risk Factors". Such risks may be amplified by the COVID-19 pandemic and its potential impact on Ovid's business and the global economy. Ovid assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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Exhibit E
Technology Transfer Plan

[***]

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Exhibit F
Documents to be transferred according to Section 8.1(b)(i)

[***]

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Exhibit G

Other Documents to be transferred

[***]

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Exhibit H
Description of Additional Pivotal Trial

[To be completed if and when the Additional Pivotal Trial is required by the EMA or by Licensee at its own discretion.]

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Exhibit I
Current Licensee Pipeline Products

[***]

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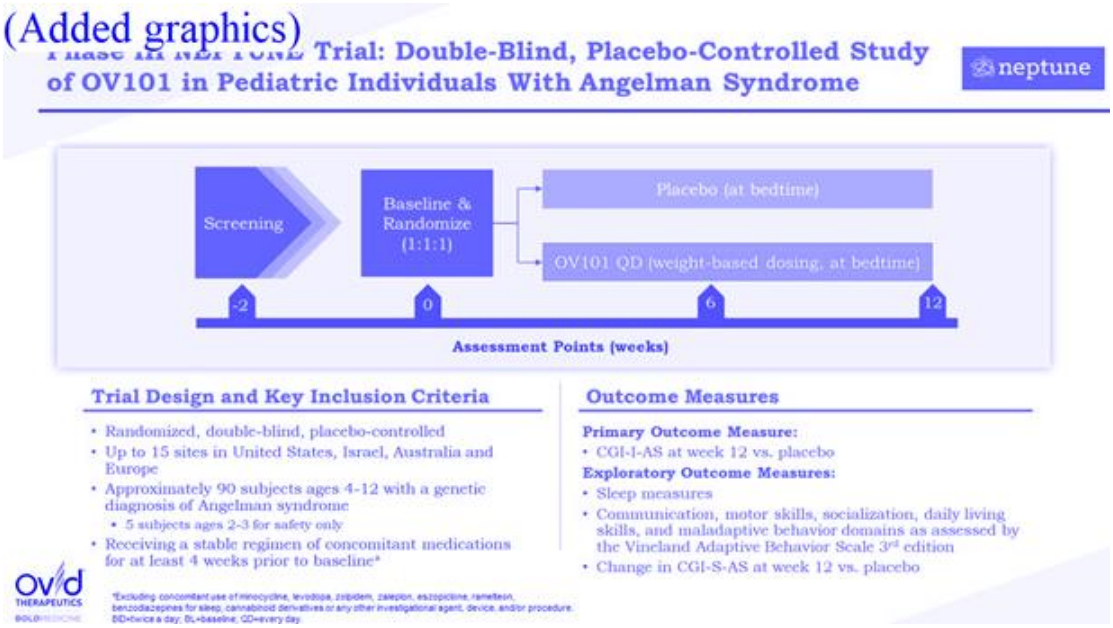
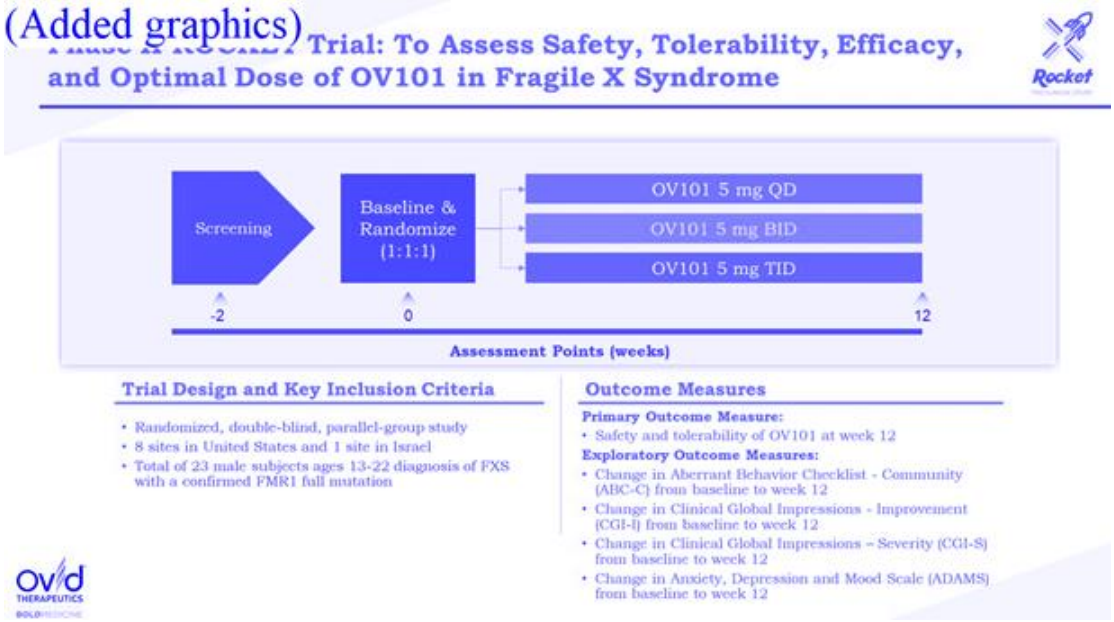
Exhibit J
Descriptions of Elara Trial, Neptune Trial, and Rocket Trial

(Added graphics)



(Added graphics)



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(Added graphics)n-Label Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of OV101 in Individuals with Angelman Syndrome

Trial Design and Key Inclusion Criteria

- Open-label, long-term safety study
- Up to 200 subjects with AS who either have
  - completed previous Ovid studies (OV101-15-001, OV101-16-001, or OV101-19-001) or
  - are siblings (with AS) of subjects with AS who have completed previous Ovid studies of OV101.
- At least 2 years old and has a body weight of at least 9 kg.

Outcome Measures

Primary Objective
- Long-term safety and tolerability of OV101 assessed by the incidence and severity of AEs and SAEs

Secondary Objectives
- Long-term efficacy of OV101 treatment assessed by changes in behavior, motor, communication, and sleep
- Long-term safety and tolerability of OV101 treatment assessed by changes in suicidality assessments, vital sign measurements, laboratory assessments, physical examinations, and seizure frequency

Exploratory Objectives
- Changes in quality of life
- Relationship among study endpoints (e.g., behavior and sleep), where appropriate

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Exhibit K
Supply Agreement

[***]

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LIST OF EXHIBITS

Exhibit A: **The Compound**

Exhibit B: **Mandatory Estimated Forecast**

Exhibit C: **Initial Purchase Order for Allocated Quantity of Compound**

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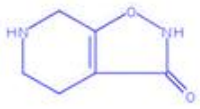
Exhibit A: The Compound

DESCRIPTION OF COMPOUND

INN: Gaboxadol

Chemical Name (IUPAC): 4,5,6,7-Tetrahydroisoxazolo[5,4-c]pyridin-3(2H)-one

Structural formula:



CAS Registry Number: 64603-91-4

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Exhibit B: Mandatory Estimated Forecast

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit C: Initial Purchase Order for Allocated Quantity of Compound

[***]

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Exhibit L

Finished Product Documentation

[***]

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Exhibit 31.1

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

I, Jeremy M. Levin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

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 Quarterly Report on Form 10-Q of Ovid Therapeutics Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

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

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jeremy M. Levin, Chief Executive Officer of Ovid Therapeutics Inc. (the "Company"), and Timothy Daly, Executive 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 September 30, 2020, 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: November 12, 2020

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

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