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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 10-Q**

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

for the quarterly period ended September 30, 2016

OR

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

**COMMISSION FILE NUMBER: 001-37590**

**Cerecor Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State of incorporation)

**400 E. Pratt Street, Suite 606  
Baltimore, Maryland 21202**

(Address of principal executive offices)

**45-0705648**

(I.R.S. Employer Identification No.)

**(410) 522-8707**

(Registrant's telephone number,  
including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a  
smaller reporting company)

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 1, 2016, the registrant had 9,264,141 shares of common stock outstanding.

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**FORM 10-Q**  
**For the Quarter Ended September 30, 2016**  
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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

## CERECOR INC.

## Balance Sheets

	September 30, 2016 (unaudited)	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,815,177	\$ 21,161,967
Grants receivable	379,256	—
Prepaid expenses and other current assets	210,023	401,550
Restricted cash, current portion	87,882	58,832
Total current assets	9,492,338	21,622,349
Property and equipment, net	40,393	35,216
Restricted cash, net of current portion	50,001	—
Total assets	<u>\$ 9,582,732</u>	<u>\$ 21,657,565</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Current portion of long term debt, net of discount	\$ 3,189,793	\$ 3,208,074
Accounts payable	809,151	678,109
Accrued expenses and other current liabilities	3,361,189	1,885,458
Warrant liability	44,992	27,606
Unit purchase option liability	90,780	50,571
Total current liabilities	7,495,905	5,849,818
Long term debt, net of current portion and discount	—	2,353,482
Other long term liabilities	1,500,000	370,538
Total liabilities	8,995,905	8,573,838
Stockholders' equity:		
Preferred stock—\$0.001 par value; 5,000,000 shares authorized at September 30, 2016 and December 31, 2015; zero shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock—\$0.001 par value; 200,000,000 shares authorized at September 30, 2016 and December 31, 2015; 9,075,143 and 8,650,143 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	9,075	8,650
Additional paid-in capital	68,974,131	66,638,557
Accumulated deficit	(68,396,379)	(53,563,480)
Total stockholders' equity	586,827	13,083,727
Total liabilities and stockholders' equity	<u>\$ 9,582,732</u>	<u>\$ 21,657,565</u>

See accompanying notes to unaudited financial statements.

**CERECOR INC.****Statements of Operations (Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Grant revenue	\$ 321,497	\$ —	\$ 971,985	\$ —
Operating expenses:				
Research and development	4,581,605	1,237,375	9,376,633	4,835,981
General and administrative	1,703,188	721,658	5,989,053	2,498,475
Loss from operations	(5,963,296)	(1,959,033)	(14,393,701)	(7,334,456)
Other income (expense):				
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(101,246)	1,465,422	(57,595)	1,127,683
Interest expense, net	(104,183)	(197,470)	(381,603)	(634,772)
Total other income (expense)	(205,429)	1,267,952	(439,198)	492,911
Net loss	<u>\$(6,168,725)</u>	<u>\$ (691,081)</u>	<u>\$(14,832,899)</u>	<u>\$(6,841,545)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (1.06)</u>	<u>\$ (1.71)</u>	<u>\$ (10.53)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>8,756,393</u>	<u>649,721</u>	<u>8,685,818</u>	<u>649,721</u>

See accompanying notes to unaudited financial statements.

**CERECOR INC.****Statements of Cash Flows (Unaudited)**

	<b>Nine Months Ended September</b>	
	<b>30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating activities</b>		
Net loss	\$ (14,832,899)	\$ (6,841,545)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	20,468	17,360
Stock-based compensation expense	1,439,194	321,228
Non-cash interest expense	134,096	204,759
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	57,595	(1,127,683)
Changes in assets and liabilities:		
Grants receivable	(379,256)	—
Prepaid expenses and other assets	191,527	255,248
Restricted cash	(79,051)	58,333
Accounts payable	109,908	318,218
Accrued expenses and other liabilities	2,478,234	178,982
Net cash used in operating activities	<u>(10,860,184)</u>	<u>(6,615,100)</u>
<b>Investing activities</b>		
Purchase of property and equipment	(25,646)	(19,984)
Net cash used in investing activities	<u>(25,646)</u>	<u>(19,984)</u>
<b>Financing activities</b>		
Proceeds from sale of shares under common stock purchase agreement	1,000,000	—
Principal payments on term debt	(2,459,493)	(1,023,798)
Payment of deferred financing costs	(1,467)	(775,475)
Net cash used in financing activities	<u>(1,460,960)</u>	<u>(1,799,273)</u>
Decrease in cash and cash equivalents	(12,346,790)	(8,434,357)
Cash and cash equivalents at beginning of period	21,161,967	11,742,349
Cash and cash equivalents at end of period	<u>\$ 8,815,177</u>	<u>\$ 3,307,992</u>
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	<u>\$ 287,841</u>	<u>\$ 434,971</u>
<b>Supplemental disclosures of noncash financing activities</b>		
Accrued deferred financing costs	<u>\$ 101,728</u>	<u>\$ 1,104,316</u>

See accompanying notes to unaudited financial statements.

## CERECOR INC.

### Notes to Unaudited Financial Statements

#### 1. Business

Cerecor Inc. (the “Company” or “Cerecor”) is a clinical-stage biopharmaceutical company developing innovative drug candidates to make a difference in the lives of patients with neurological and psychiatric disorders. The Company’s operations since inception have been limited to organizing and staffing the Company, acquiring rights to and developing certain product candidates, business planning and raising capital.

##### *Liquidity*

The Company's financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue to fund its operations. The Company has not generated any product revenues and has not yet achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and if achieved, could be sustained on a continuing basis.

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2016, the Company incurred a net loss of \$14.8 million and generated negative cash flows from operations of \$10.9 million. As of September 30, 2016, the Company had an accumulated deficit of \$68.4 million. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to the clinical development of its product candidates, its preclinical programs, business development and its organizational infrastructure. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy. The Company plans to meet its capital requirements primarily through a combination of equity and debt financings, collaborations, strategic alliances, federal and private grants, marketing, distribution or licensing arrangements and in the longer term, revenue from product sales to the extent its product candidates receive marketing approval and are commercialized. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations and develop its product candidates or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable positive cash flow. The Company currently anticipates that current cash and cash equivalents will be sufficient to meet its anticipated cash requirements through the end of 2016. These factors raise significant doubt about the Company’s ability to continue as a going concern. The Company has the potential to raise additional cash through a common stock purchase agreement with Aspire Capital Fund, LLC (“Aspire Capital”) as described in Note 8.

#### 2. Significant Accounting Policies

##### *Basis of Presentation*

The Company’s unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). In the opinion of management, the accompanying unaudited financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company’s financial position, results of operations and cash flows. The balance sheet at December 31, 2015 has been derived from audited financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the United States Securities and Exchange Commission (“SEC”). The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited financial statements are read in conjunction with the December 31, 2015 audited financial statements.

### ***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, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals, the warrant liability and the unit purchase option liability. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

### ***Net Loss Per Share, Basic and Diluted***

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects, if any, of preferred stock, the investor rights obligation, warrants on preferred stock and common stock, stock options and unvested restricted stock. Diluted net loss per share of common stock is computed by dividing the net loss attributable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of preferred stock, the investor rights obligation, warrants on preferred stock and common stock, stock options and unvested restricted stock outstanding during the period calculated in accordance with the treasury stock method, although these shares and options are excluded if their effect is anti-dilutive. In addition, the Company analyzes the potential dilutive effect of any outstanding preferred stock, the investor rights obligation, and warrants on preferred stock and common stock under the "if-converted" method when calculating diluted earnings per share, in which it is assumed that the outstanding security converts into common stock at the beginning of the period. Because the impact of these items is generally anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2016 and 2015.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The carrying amounts reported in the balance sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

### ***Restricted Cash***

During 2013, the Company entered into a lease for new office space for its principal offices in Baltimore, Maryland. The Company initially provided the landlord with a letter of credit in the amount of \$175,000 as security by the Company of the Company's obligations under the lease. The letter of credit is supported by funds that are invested in a certificate of deposit. Provided there has been no event of default by the Company, the Company may request that the amount of the letter of credit be reduced by one-third (approximately \$58,000) at the end of each of the first three years of the lease term. At the expiration of the third year of the lease term, which will occur in the fourth quarter of 2016, the Company is required to deposit with the landlord the sum of \$13,000 as a security deposit.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains a portion of its cash and cash equivalent balances in the form of a money market account with a financial institution that management believes to be creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

### ***Debt Issuance Costs***

The Company may record debt and equity discounts in connection with raising funds through the issuance of convertible notes or equity instruments. These discounts may arise from (i) the receipt of proceeds less than the face value of the convertible notes or equity instruments, (ii) allocation of proceeds to beneficial conversion features and/or

(iii) recording derivative liabilities related to embedded features. These costs are amortized over the life of the debt to interest expense utilizing the effective interest method.

### ***Property and Equipment***

Property and equipment consists of computers, office equipment, and furniture and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company uses a life of four years for computers and software, and five years for equipment and furniture. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

### ***Grant Revenue Recognition***

The Company recognizes grant revenue when there is (i) reasonable assurance of compliance with the conditions of the grant and (ii) reasonable assurance that the grant will be received. In April 2016, the Company received a research and development grant from the National Institute on Drug Abuse at the National Institutes of Health to provide additional resources for the period from May 2016 through April 2017 for the Company's ongoing Phase 2 clinical trial for CERC-501, "*A Randomized, Double-Blind, Placebo-Controlled, Crossover Design Study of CERC-501 in a Human Laboratory Model of Smoking Behavior.*" The amount of the award was \$1.0 million. The Company recognizes revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred. As such, the Company has recognized revenue in the amounts of \$321,497 and \$971,985 for the three and nine months ended September 30, 2016, respectively. As of September 30, 2016, the Company had received \$592,729 of the revenue earned during the nine months ended September 30, 2016.

### ***Research and Development***

Research and development costs are expensed as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation of research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; other supplies; facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities and insurance; and costs associated with preclinical activities and regulatory operations.

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 information provided to the Company by its vendors, such as clinical research organizations, with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

### ***Comprehensive Loss***

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss was equal to net loss for all periods presented.

### ***Income Taxes***

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The deferred tax asset primarily includes net operating loss and tax credit carryforwards, accrued expenses not currently

deductible and the cumulative temporary differences related to certain research and patent costs, which have been charged to expense in the accompanying statements of operations but have been recorded as assets for income tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. A full valuation allowance has been established against all of the deferred tax assets as it is more likely than not that these assets will not be realized given the Company's history of operating losses. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position.

The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of September 30, 2016, the Company does not believe any material uncertain tax positions are present.

#### ***Stock-Based Compensation***

The Company applies the provisions of ASC 718, *Compensation—Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including employee stock options, in the statements of operations.

For stock options issued to employees and members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For stock options issued to non-employees, the Company initially measures the options at their grant date fair values and revalues as the underlying equity instruments vest and are recognized as expense over the earlier of the period ending with the performance commitment date or the date the services are completed in accordance with the provisions of ASC 718 and ASC 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50").

#### ***Clinical Trial Expense Accruals***

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period.

### **Segment Information**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief executive officer view the Company's operations and manage its business as one operating segment. All long-lived assets of the Company reside in the United States.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue From Contracts With Customers* ("ASU 2014-09"). Pursuant to this update, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue From Contracts With Customers (Topic 606)*, which delays the effective date of ASU 2014-09 by one year. As a result, ASU 2014-09 will be effective for annual reporting periods beginning after December 15, 2017 with early adoption permitted for annual reporting periods beginning after December 15, 2016. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* ("ASU 2016-08") and ASU No. 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"), and in May 2016 the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606), Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), each of which clarify the guidance in ASU 2014-09 and have the same effective date as the original standard. The Company has not yet determined the impact of adoption of ASU 2014-09, ASU 2016-08, ASU 2016-10, or ASU 2016-12 on the financial statements, although, the impact, if any, is not expected to be significant given the Company has not historically recognized significant amounts of revenue.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern within one year after the date the financial statements are issued, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. This guidance revises existing practice related to accounting for leases under ASC 840, *Leases* ("ASC 840") for both lessees and lessors. The new guidance in ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability for nearly all leases (other than leases that meet the definition of a short-term lease). The lease liability will be equal to the present value of lease payments and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or capital leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while capital leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*. The guidance is intended to simplify several areas of accounting for share-based compensation, including income tax impacts, classification on the statement of cash flows and forfeitures. The new standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

### 3. Net Loss Per Share of Common Stock, Basic and Diluted

The following table sets forth the computation of basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss per share, basic and diluted calculation:				
Net loss	<u>\$(6,168,725)</u>	<u>\$(691,081)</u>	<u>\$(14,832,899)</u>	<u>\$(6,841,545)</u>
Weighted-average common shares outstanding	<u>8,756,393</u>	<u>649,721</u>	<u>8,685,818</u>	<u>649,721</u>
Net loss per share, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (1.06)</u>	<u>\$ (1.71)</u>	<u>\$ (10.53)</u>

The following outstanding securities at September 30, 2016 and 2015 have been excluded from the computation of diluted weighted-average shares outstanding, as they would have been anti-dilutive:

	September 30, 2016	September 30, 2015
Series A convertible preferred stock	—	31,116,391
Series A-1 convertible preferred stock	—	9,074,511
Series B convertible preferred stock	—	58,948,735
Stock options	1,828,441	510,884
Warrants on common stock	7,400,934	681,858
Warrants on preferred stock	—	625,208
Investor rights obligation	—	53,351,117
Underwriters' unit purchase option	40,000	—

### 4. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures* (“ASC 820”), defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

At September 30, 2016 and December 31, 2015, the Company’s financial instruments included cash and cash equivalents, restricted cash, accounts payable, accrued expenses and other current liabilities, long term debt, the term loan warrant liability and the underwriters’ unit purchase option liability. The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, restricted cash, accounts payable, and accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The estimated fair value of the Company’s debt of \$3.2 million as of September 30, 2016 was based on current interest rates for similar types of borrowings and is in Level 2 of the fair value hierarchy.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis:

	September 30, 2016		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>			
Investments in money market funds*	\$ 8,661,483	\$ —	\$ —
<b>Liabilities</b>			
Warrant liability	\$ —	\$ —	\$ 44,992
Unit purchase option liability	\$ —	\$ —	\$ 90,780

	December 31, 2015		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>			
Investments in money market funds*	\$ 21,122,553	\$ —	\$ —
<b>Liabilities</b>			
Warrant liability	\$ —	\$ —	\$ 27,606
Unit purchase option liability	\$ —	\$ —	\$ 50,571

\* Investments in money market funds are reflected in cash and cash equivalents on the accompanying Balance Sheets.

### Level 3 Valuation

The warrant liability (which relates to warrants to purchase shares of common stock as part of the term loan agreement) is marked-to-market each reporting period with the change in fair value recorded to other income (expense) in the accompanying statements of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified to stockholders' equity. The fair value of the warrant liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option pricing model for valuing the warrant liability as of September 30, 2016, include (i) volatility of 85%, (ii) risk free interest rate of 1.02%, (iii) strike price (\$8.40), (iv) fair value of common stock (\$4.23), and (v) expected life of 4.1 years.

The underwriters' unit purchase option (the "UPO") was issued to the underwriters of the Company's initial public offering ("IPO") and provides the underwriters the option to purchase up to a total of 40,000 units. The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants). The Underwriters' Warrants are warrants to purchase shares of common stock. The Company classifies the UPO as a liability as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders' equity. The UPO liability is marked-to-market each reporting period with the change in fair value recorded to other income (expense) in the accompanying statements of operations until the UPO is exercised, expire or other facts and circumstances lead the UPO to be reclassified to stockholders' equity. The fair value of the UPO liability is estimated using a Black-Scholes option-pricing model within a Monte Carlo simulation model framework. The significant assumptions used in preparing the simulation model for valuing the UPO as of September 30, 2016, include (i) volatility range of 65% to 95%, (ii) risk free interest rate range of 0.12% to 1.03%, (iii) unit strike price (\$7.48), (iv) underwriters' Class A warrant strike price (\$5.23), (v) underwriters' Class B warrant strike price (\$4.49), (vi) fair value of underlying equity (\$4.23), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurs on April 20, 2017. The increase in the fair value of underlying equity was the primary driver of the increase in fair value of the UPO liability from \$50,571 as of December 31, 2015 to \$90,780 as of September 30,

2016. This \$40,209 gain on the change in fair value of the UPO liability was recorded to other income in the accompanying statement of operations for the nine months ended September 30, 2016.

The table presented below is a summary of changes of the Company's Level 3 warrant liability and unit purchase option liability for the nine months ended September 30, 2016:

	<b>Warrant liability</b>	<b>Unit purchase option liability</b>	<b>Total</b>
Balance at December 31, 2015	\$ 27,606	\$ 50,571	\$ 78,177
Change in fair value	17,386	40,209	57,595
Balance at September 30, 2016	<u>\$ 44,992</u>	<u>\$ 90,780</u>	<u>\$ 135,772</u>

No other changes in valuation techniques or inputs occurred during the nine months ended September 30, 2016 and no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2016.

## 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Compensation and benefits	\$ 849,859	\$1,128,073
Research and development expenses	2,166,342	464,719
General and administrative	156,021	253,132
Accrued interest	188,967	39,534
Total accrued expenses and other current liabilities	<u>\$3,361,189</u>	<u>\$1,885,458</u>

## 6. License Agreements

### *Lilly CERC-611 License*

On September 22, 2016, the Company entered into an exclusive license agreement with Eli Lilly and Company ("Lilly") pursuant to which the Company received exclusive, global rights to develop and commercialize CERC-611, previously referred to as LY3130481, a potent and selective Transmembrane AMPA Receptor Regulatory Proteins ("TARP")  $\gamma$ -8-dependent  $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid ("AMPA") receptor antagonist. The terms of the license agreement provide for an upfront payment of \$2.0 million, of which \$750,000 is due within 30 days of the effective date of the license agreement, and the remaining balance of \$1.25 million is due after the first subject is dosed with CERC-611 in a multiple ascending dose study. The Company recorded the \$2.0 upfront amount as a research and development expense in the accompanying statement of operations for the three and nine months ended September 30, 2016. Additional payments may be due upon achievement of development and commercialization milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Lilly milestone payments and a royalty on net sales.

### *Merck CERC-301 License*

In 2013, the Company entered into an exclusive license agreement with Merck & Co., Inc. ("Merck") pursuant to which Merck granted the Company rights relating to certain small molecule compounds. In consideration of the license, the Company may be required to make initial payments totaling \$1.5 million upon the achievement of certain milestones. Pursuant to the license agreement the Company paid an initial payment of \$750,000, which was recorded as a research and development expense in the Company's statement of operations for the year ended December 31, 2013, and upon achievement of acceptance by the United States Food and Drug Administration, or FDA, of Merck pre-clinical data and FDA approval of a Phase 3 clinical trial the Company will pay an additional \$750,000. Additional payments may be due upon achievement of development and regulatory milestones, including the first commercial sale. Upon

commercialization, the Company is obligated to pay Merck milestone payments and royalties on net sales.

#### ***Lilly CERC-501 License***

In 2015, the Company acquired rights to CERC-501 through an exclusive, worldwide license from Lilly. Pursuant to the license agreement, the Company paid \$750,000 to Lilly within 30 days of the execution of the license agreement, which was recorded as research and development expense in the accompanying statement of operations for the nine months ended September 30, 2015. Upon the Company undertaking a nine-month toxicology study of CERC-501 in non-human primates and delivering a final study report, the Company will be required to pay Lilly an additional \$250,000. Additional payments may be due upon achievement of development and regulatory milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Lilly milestone payments and royalties on net sales.

#### ***Merck COMTi License***

In 2013, the Company entered into a separate exclusive license agreement with Merck pursuant to which Merck granted the Company certain rights in small molecule compounds which are known to inhibit the activity of COMT. In consideration of the license, the Company made a \$200,000 upfront payment to Merck, which was recorded as research and development expense in the Company's statement of operations for the year ended December 31, 2013. Additional payments may be due upon the achievement of development and regulatory milestones. Upon commercialization of a COMT product, the Company is required to pay Merck royalties on net sales.

### **7. Term Loan**

In August 2014, the Company entered into a \$7.5 million secured term loan from a finance company. The loan is secured by a lien on all of the Company's assets, excluding intellectual property, which was subject to a negative pledge. The loan contains certain additional nonfinancial covenants. In connection with the loan agreement, the Company's cash and investment accounts are subject to account control agreements with the finance company that give the finance company the right to assume control of the accounts in the event of a loan default. Loan defaults are defined in the loan agreement and include, among others, the finance company's determination that there is a material adverse change in the Company's operations. Interest on the loan is at a rate of the greater of 7.95%, or 7.95% plus the prime rate as reported in *The Wall Street Journal* minus 3.25%. The interest rate effective from loan inception to December 16, 2015 was 7.95%. Effective December 17, 2015, the prime rate as reported by *The Wall Street Journal* increased 0.25% resulting in an increase to the current interest rate, which was 8.20% as of September 30, 2016. The loan was interest-only through May 2015, and is repayable in equal monthly payments of principal and interest of approximately \$305,000 over 27 months, which began in June 2015. The loan matures in August 2017. Debt consisted of the following as of September 30, 2016 and December 31, 2015:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Term loan	\$ 3,228,763	\$ 5,688,256
Less: debt discount	(38,970)	(126,700)
Term Loan, net of debt discount	3,189,793	5,561,556
Less: current portion, net of debt discount	(3,189,793)	(3,208,074)
Long term debt, net of current portion and debt discount	\$ —	\$ 2,353,482

Interest expense, which includes amortization of a discount and the accrual of a termination fee, was approximately \$404,000 for the nine months ended September 30, 2016, in the accompanying statement of operations.

In connection with the term loan, the Company issued warrants to purchase 625,208 shares of Series B convertible preferred stock at an exercise price of \$0.2999 per share that is exercisable for a period ending in October 2020, which is five years following the closing of the Company's IPO. Upon the closing of the Company's IPO, these warrants became warrants to purchase 22,328 shares of common stock at an exercise price of \$8.40 per share, in accordance with their terms. The Company's warrant to purchase shares of Series B convertible preferred stock

represented a freestanding financial instrument that was indexed to an obligation of the Company to repurchase its Series B convertible preferred stock by transferring assets and, therefore, met the criteria to be classified as a liability under FASB ASC 480, *Distinguishing Liabilities from Equity*. The Company records the warrant liability at its fair value using the Black-Scholes option pricing model and revalues the warrant at each reporting date (see Note 4).

## **8. Capital Structure**

### ***Initial Public Offering***

On October 20, 2015, the Company closed an IPO of its units. Each unit consisted of one share of common stock, one Class A warrant to purchase one share of common stock at an exercise price of \$4.55 per share and one Class B warrant to purchase one-half share of common stock at an exercise price of \$3.90 per full share (the “units”). The Class A warrants expire on October 20, 2018 and the Class B warrants expire on April 20, 2017. The closing of the IPO resulted in the sale of 4,000,000 units at an initial public offering price of \$6.50 per unit for gross proceeds of \$26.0 million. The net proceeds of the IPO, after underwriting discounts, commissions and expenses, and before offering expenses, to the Company were approximately \$23.6 million. On November 13, 2015, the units separated into common stock, Class A warrants and Class B warrants and began trading separately on the NASDAQ Capital Market.

On November 23, 2015, the underwriter of the IPO exercised its over-allotment option for 20,000 shares of common stock, 551,900 Class A warrants to purchase one share of common stock and 551,900 Class B warrants to purchase one-half share of common stock for additional gross proceeds of \$135,319.

The common stock and accompanying Class A warrants and Class B warrants have been classified to stockholders’ equity in the Company’s balance sheet.

#### *Underwriter’s Unit Purchase Option*

The underwriter of the IPO received, for \$100 in the aggregate, a unit purchase option (the “UPO”) to purchase up to a total of 40,000 units (or 1% of the units sold in the IPO) exercisable at \$7.48 per unit (or 115% of the public offering price per unit in the IPO). The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters’ Class A warrants and underwriters’ Class B warrants (such warrants together referred to as the “Underwriters’ Warrants”) such that, upon exercise, the holder of a UPO will not receive actual units but will instead receive the shares of common stock and Underwriters’ Warrants, to the extent that any portion of the Underwriters’ Warrants underlying such units have not otherwise expired. The exercise prices of the underwriters’ Class A warrants and underwriter’s Class B warrants underlying the UPO are \$5.23 and \$4.49, respectively. The UPO may be exercised for cash or on a cashless basis, at the holder’s option, and expires on October 14, 2020; provided, that, following the expiration of underwriters’ Class B warrants on April 20, 2017, the UPO will be exercisable only for shares of common stock and underwriters’ Class A warrants at an exercise price of \$7.475 per unit; provided further, that, following the expiration of underwriters’ Class A warrants on October 20, 2018, the UPO will be exercisable only for shares of common stock at an exercise price of \$7.47. The Company classified the UPO as a liability as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders’ equity. The fair value of the UPO is re-measured each reporting period and the change in fair value is recognized in the statement of operations (see Note 4).

#### ***The Aspire Capital Transaction***

On September 8, 2016, the Company entered into a common stock purchase agreement (the “Purchase Agreement”) with Aspire Capital, pursuant to which Aspire Capital committed to purchase up to an aggregate of \$15.0 million of shares of the Company’s common stock over the 30-month term of the Purchase Agreement. Under the Purchase Agreement, on any trading day selected by the Company on which the closing price of the Company’s common stock exceeds \$0.50, the Company may, in its sole discretion, present a purchase notice directing Aspire Capital to purchase up to 50,000 shares of common stock per day, up to \$15.0 million of the Company’s common stock in the aggregate at a per share price calculated by references to the prevailing market price of the Company’s common stock. Upon execution of the Purchase Agreement, the Company issued and sold to Aspire Capital 250,000 shares of common

stock at a price per share of \$4.00, for gross proceeds of \$1.0 million, and concurrently entered into a registration rights agreement with Aspire Capital registering the shares of the Company’s common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. Additionally, as consideration for Aspire Capital entering into the Purchase Agreement, the Company issued 175,000 shares of common stock as a commitment fee. The net proceeds of the Aspire Capital transaction, after offering expenses, to the Company were approximately \$900,000 for the three and nine months ended September 30, 2016. As of September 30, 2016, the Company had sold 250,000 shares of common stock to Aspire Capital under the Purchase Agreement. Subsequent to September 30, 2016, the Company sold an additional 188,998 shares of common stock to Aspire Capital under the terms of the Purchase Agreement for gross proceeds of approximately \$700,000. As of the date of this filing, the Company may issue to Aspire Capital under the Purchase Agreement 1,115,165 shares of common stock.

**Common Stock Warrants**

At September 30, 2016, the following common stock purchase warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
109,976	\$ 28.00	February 2017
29,260	\$ 14.00	February 2017
90,529	\$ 28.00	March 2017
29,557	\$ 14.00	March 2017
130,233	\$ 28.00	April 2017
2,275,950	\$ 3.90	April 2017
20,000*	\$ 4.49	April 2017
14,284	\$ 28.00	July 2017
80,966	\$ 28.00	August 2018
4,551,900	\$ 4.55	October 2018
40,000*	\$ 5.23	October 2018
3,571	\$ 28.00	December 2018
22,328*	\$ 8.40	October 2020
2,380	\$ 8.68	May 2022
<b>7,400,934</b>		

\* Accounted for as a liability instrument (see Note 4)

**9. Stock-Based Compensation**

**2016 Equity Incentive Plan**

On April 5, 2016, the Company’s board of directors adopted the 2016 Equity Incentive Plan (the “2016 Plan”) as the successor to the 2015 Omnibus Plan (the “2015 Plan”). The 2016 Plan was approved by the Company’s stockholders and became effective on May 18, 2016 (the “2016 Plan Effective Date”).

As of the 2016 Plan Effective Date, no additional grants will be made under the 2015 Plan or the 2011 Stock Incentive Plan (the “2011 Plan”), which was previously succeeded by the 2015 Plan effective October 13, 2015. Outstanding grants under the 2015 Plan and 2011 Plan will continue in effect according to their terms as in effect under the applicable plan.

Upon the 2016 Plan Effective Date, the 2016 Plan reserved and authorized up to 600,000 additional shares of common stock for issuance, as well as 464,476 unallocated shares remaining available for grant of new awards under the 2015 Plan. During the term of the 2016 Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, beginning in 2017, by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. As of September 30, 2016, there were 691,987 shares available for future issuance under the 2016 Plan.

The estimated grant date fair market value of the Company’s stock-based awards is amortized ratably over the employees’ service periods, which is the period in which the awards vest. Stock-based compensation expense recognized for the three and nine months ended September 30, 2016 and 2015 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 43,861	\$ 13,986	\$ 95,013	\$ 57,353
General and administrative	243,913	15,029	1,344,181	263,875
Total stock-based compensation	\$ 287,774	\$ 29,015	\$ 1,439,194	\$ 321,228

During the first quarter of 2016, the Company modified stock options of its former chief executive officer by extending the life of the awards, which were set to expire in March 2016, to coincide with their original life. This modification resulted in the recording of \$781,266 of compensation expense, which is included in general and administrative expenses for the nine months ended September 30, 2016 in the accompanying statement of operations.

A summary of option activity for the nine months ended September 30, 2016 is as follows:

	Options Outstanding			Weighted average remaining contractual term (in years)
	Number of shares	Weighted-average exercise price	Fair value of options granted	
Balance, December 31, 2015	959,188	\$ 7.68		
Granted	869,253	\$ 3.48	\$2,124,922	
Balance, September 30, 2016	1,828,441	\$ 5.68		8.54
Vested or expected to vest at September 30, 2016	1,828,441	\$ 5.68		8.54
Exercisable at September 30, 2016	657,099	\$ 8.19		7.10

**Employee Stock Purchase Plan**

On April 5, 2016, the Company’s board of directors approved the 2016 Employee Stock Purchase Plan (the “ESPP”). The ESPP was approved by the Company’s stockholders and became effective on May 18, 2016 (the “ESPP Effective Date”).

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company’s board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company’s common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period. The Company’s board of directors may establish a maximum number of shares of the Company’s common stock that may be purchased by any participant, or all participants in the aggregate, during each offering or offering period. Under the ESPP, a participant may not accrue rights to purchase more than \$25,000 of the fair market value of the Company’s common stock for each calendar year in which such right is outstanding.

Upon the ESPP Effective Date, the ESPP reserved and authorized up to 500,000 shares of common stock for issuance. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increase by a number equal to the lesser of (i) 1% of the total number of shares of the Company’s capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company’s common stock, or (iii) a number of shares of the Company’s common stock as determined by the Company’s board of directors or compensation committee. As of September 30, 2016, 500,000 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Share Purchase Plans* (“ASC 718-50”), the ability to purchase shares of the Company’s common stock at the lower of the offering date price or the purchase date price

represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of \$36,690 and \$43,213 for the three and nine months ended September 30, 2016, respectively.

## 10. Commitments and Contingencies

### *Office Lease*

The Company's corporate office space, which is leased under an operating lease, is located in Baltimore, Maryland. The lease provided for three months of rent abatement and includes escalating rent payments. Rent expense is recognized on a straight-line basis over the term of the lease. Rent expense for the office lease amounted to approximately \$106,000 for the nine months ended September 30, 2016 and 2015. Pursuant to the terms of such lease, the Company's future lease obligation is as follows:

Year ending December 31,	
2016*	\$ 38,471
2017	154,845
2018	<u>158,716</u>
	<u>\$ 352,032</u>

\* Three months remaining in 2016

### *Obligations to Contract Research Organizations and External Service Providers*

The Company has entered into agreements with contract research organizations and other external service providers for services, primarily in connection with the clinical trials and development of the Company's product candidates. The Company was contractually obligated for up to approximately \$1.7 million of future services under these agreements as of September 30, 2016. The Company's actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

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

*This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "may," "will," "plans," "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or other similar words (including their use in the negative), or by discussions of future matters such as the development of product candidates or products, technology enhancements, possible changes in legislation, and other statements that are not historical. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item 1A, "Risk Factors," as well as in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 23, 2016 and in our other filings with the SEC. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.*

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2015 appearing in our Annual Report on Form 10-K filed with the SEC on March 23, 2016.

### Overview

We are a clinical-stage biopharmaceutical company developing innovative drug candidates to make a difference in the lives of patients with neurological and psychiatric disorders. We have a portfolio of clinical and preclinical compounds that we believe are best-in-class due to their unique mechanism of action. We are currently pursuing the development of two clinical Phase 2-stage product candidates, CERC-301 and CERC-501, as well as two earlier stage programs.

CERC-301 is currently in a Phase 2 clinical trial as an oral, adjunctive treatment for patients with severe major depressive disorder, or MDD, who are failing to achieve an adequate response to their current antidepressant treatment, with a rapid onset of effect. We expect top-line data from this trial in November 2016. We received fast track designation by the FDA in 2013 for CERC-301 for the treatment of MDD. CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the N-methyl-D-aspartate, or NMDA, receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. We believe CERC-301 has the potential to be a first-in-class medication providing a significant reduction in depressive symptoms in a matter of days, as compared to weeks or months with conventional therapies, because it specifically blocks the NMDA receptor subunit 2B, or NR2B, a mechanism of action we believe may provide rapid and significant antidepressant activity without the adverse side effect profile of non-selective NMDA receptor antagonists.

We are also currently developing CERC-501, which is in a Phase 2 clinical trial for smoking cessation. We expect top-line data from this trial in December 2016. We intend to develop CERC-501 for treatment of substance use disorders, such as nicotine, alcohol, and/or cocaine addiction, and as an adjunctive treatment of MDD. If we receive approval for CERC-501 for treatment of substance use disorders and for adjunctive treatment of MDD, we plan to further develop CERC-501 for the concurrent treatment of MDD and substance use disorders, or co-occurring disorders. CERC-501 is a potent and selective kappa opioid receptor, or KOR, antagonist. KORs are believed to play key roles in modulating stress, mood and addictive behaviors, which form the basis of co-occurring disorders. We are planning to conduct a Phase 2 clinical trial in inadequately treated subjects with MDD currently on antidepressants. Thereafter we intend to pursue additional studies focused on the adjunctive treatment of MDD and substance use disorders for

registration and commercialization. We also intend to pursue studies of the treatment of the co-occurrence of MDD and substance use disorders.

On September 22, 2016, we acquired exclusive, worldwide rights to CERC-611 from Eli Lilly and Company, or Lilly. CERC-611 is a potent and selective Transmembrane AMPA Receptor Regulatory Proteins, or TARP,  $\gamma$ -8-dependent  $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid, or AMPA, receptor antagonist in development as an adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy. TARPs are a fairly recently discovered family of proteins that have been found to associate with and modulate the activity of AMPA receptors. TARP  $\gamma$ -8-dependent AMPA receptors are localized primarily in the hippocampus, a region of importance in complex partial seizures and particularly relevant to seizure origination and/or propagation. Research suggests that selectively targeting individual TARPs may enable selective modulation of specific brain circuits without globally affecting synaptic transmission, which may lead to an attractive efficacy, safety and tolerability profile. We expect to file an investigational new drug application, or IND, with the FDA and, if clearance is received, commence Phase 1 development of CERC-611 in 2017.

CERC-406 is our lead preclinical candidate from our proprietary platform of compounds that inhibit catechol-O-methyltransferase, or COMT, within the brain, which we refer to as our COMTi platform. We are anticipating developing CERC-406 for the treatment of residual cognitive impairment symptoms in patients with MDD.

Development of CERC-301 and CERC-501 beyond the two currently ongoing Phase 2 clinical trials, as well as the development of our other product candidates, will not be possible unless we secure additional funding. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential collaborations and federal grants. However, we may be unable to raise additional funds or enter into such other agreements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

We were incorporated in Delaware in 2011 and commenced operations in the second quarter of 2011. Since inception, our operations have included organizing and staffing our company, business planning, raising capital and developing our product candidates. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. We have incurred losses in each period since our inception. As of September 30, 2016, we had an accumulated deficit of \$68.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek marketing approval for, our product candidates. Our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and our ability to continue as a going concern will require us to obtain additional financing to fund our operations.

We have financed our operations primarily through a public offering and private placements of our common stock and convertible preferred stock. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate any product revenue unless, and until, we obtain marketing approval for, and commercialize, any of our product candidates. There can be no assurance as to whether or when we will achieve profitability.

## **Recent Developments**

### ***The Aspire Capital Transaction***

On September 8, 2016, we entered into a \$15 million common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital committed to purchase up to an aggregate of \$15 million of shares of our common stock over the 30-month term of the Purchase Agreement. Under the Purchase Agreement, on any trading day that we select on which the closing price of our common stock exceeds \$0.50, we may, in our discretion, present a purchase notice directing Aspire Capital to purchase up to 50,000

shares of common stock per day, up to \$15 million of our common stock in the aggregate at a per share price calculated by reference to the prevailing market price of our common stock. Upon execution of the Purchase Agreement, we issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of \$4.00, for gross proceeds of \$1 million, and concurrently entered into a registration rights agreement with Aspire Capital registering the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. Additionally, as consideration for Aspire Capital entering into the Purchase Agreement, we issued 175,000 shares of common stock as a commitment fee. The net proceeds of the initial purchase of common stock by Aspire Capital, after offering expenses, were approximately \$900,000. As of September 30, 2016, we had sold 250,000 shares of common stock to Aspire Capital under the Purchase Agreement. Subsequent to September 30, 2016, we sold an additional 188,998 shares of common stock to Aspire Capital under the terms of the Purchase Agreement for gross proceeds of approximately \$700,000. As of the date of this filing, we may issue to Aspire Capital under the Purchase Agreement 1,115,165 shares of common stock.

### ***License of CERC-611***

On September 22, 2016, we entered into an exclusive license, development and commercialization agreement, or the Exclusive License Agreement, with Lilly pursuant to which we received exclusive, global rights to develop and commercialize LY3130481, now designated as CERC-611. Our rights under the Exclusive License Agreement are exclusive, even as to Lilly, for the term of the Exclusive License Agreement, with the right to grant sublicenses through multiple tiers. Lilly retains rights for internal, non-clinical research purposes. We are obligated under the Exclusive License Agreement to use commercially reasonable efforts to develop and commercialize CERC-611 at our expense. If Lilly obtains a license for any future patent rights or know-how necessary for the development, commercialization or manufacture under the Exclusive License Agreement, we have the right, but not the obligation, to consent to include such patent rights or know-how, as well as the right to terminate any such license in our discretion.

Pursuant to the Exclusive License Agreement, we paid an initial upfront payment of \$750,000, and the remaining upfront payment of \$1.25 million is due after the first subject is dosed with CERC-611 in a multiple ascending dose study. We recorded the upfront amount of \$2.0 million as a research and development expense for the three and nine months ended September 30, 2016 in the accompanying statement of operations. The terms of the Exclusive License Agreement also require additional one-time payments be made upon achievement of development and commercialization milestones, including the first commercial sale, of up to \$67.5 million. Upon commercialization, we are obligated to pay Lilly milestone payments and a royalty in the mid-single digits to low double digits based on net sales. Unless terminated earlier, the Exclusive License Agreement will remain in effect, on a country-by-country basis and product-by-product basis, until the parties' royalty obligations end.

### **Components of Operating Results**

#### ***Revenue***

To date, we have derived all of our revenue from research grants from the National Institutes of Health. We have not generated any revenue from commercial product sales to date. We will not generate any commercial revenue, if ever, until one of our product candidates receives marketing approval and we successfully commercialize such product candidates.

#### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs incurred developing, testing and seeking marketing approval for our product candidates. These costs include both external costs, which are study-specific costs, and internal research and development costs, which are not directly allocated to our product candidates.

External costs include:

- expenses incurred under agreements with third-party contract research organizations and investigative sites that conduct our clinical trials, preclinical studies and regulatory activities;

- payments made to contract manufacturers for drug substance and acquiring, developing and manufacturing clinical trial materials; and
- payments related to acquisitions of our product candidates and preclinical platform, milestone payments, and fees associated with the prosecution and maintenance of patents.

Internal costs include:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- consulting costs related to our internal research and development programs;
- allocated facilities, depreciation and other expenses, which include rent and utilities, as well as other supplies; and
- product liability insurance.

Research and development costs are expensed as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our vendors.

We track external costs by development program, and subsequently by product candidate once a product candidate has been selected for development. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials. As we advance our product candidates through clinical development, we expect that the amount of our research and development spending allocated to external spending relative to internal spending will continue to grow for the foreseeable future, while our internal research and development spending should grow at a slower and more controlled pace.

As of September 30, 2016, we had eight full-time employees who were primarily engaged in research and development. We anticipate that our research and development costs, including the need to hire additional research and development employees, may increase in the future.

#### ***General and Administrative Expenses***

General and administrative expenses consist primarily of professional fees, investor and public relations expenses and salaries, benefits and related costs for executive and other personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, communication expenses and professional fees for legal, consulting, and tax and accounting services, insurance, depreciation and general corporate expenses.

We anticipate that our general and administrative expenses will increase in the future with continued research, development and potential commercialization of our existing and future product candidates and expanded compliance obligations of operating as a public company. These increases will likely include greater costs for insurance, costs related to the hiring of additional personnel, payments to outside consultants and investor relations providers, and costs for legal and accounting professionals, among other expenses. Additionally, if and when we believe a marketing approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

#### ***Change in Fair Value of Warrant Liability, Unit Purchase Option Liability and Investor Rights Obligation***

In connection with the issuance of our term debt facility in August 2014, we issued warrants to purchase 625,208 shares of Series B convertible preferred stock. Upon the closing of our initial public offering, or IPO, in October

2015, these warrants became warrants to purchase 22,328 shares of common stock, in accordance with their terms. These warrants represent a freestanding financial instrument that is indexed to an obligation, which we refer to as the Warrant Liability. These warrants are classified as a liability at fair value. This liability is remeasured at each balance sheet date and the change in fair value is recorded within our statement of operations.

As part of our IPO, the underwriter of our IPO received a unit purchase option, or UPO, to purchase up to 40,000 units, with a unit consisting of one share of our common stock, one Class A warrant to purchase one share of our common stock and one Class B warrant to purchase one-half share of our common stock. The UPO is classified as a liability at its fair value. This liability is remeasured at each balance sheet date and the change in fair value is recorded within our statement of operations.

Our obligation to issue additional shares of our Series B preferred stock as part of the Series B preferred stock offering was accounted for as a freestanding financial instrument, which we referred to as the Investor Rights Obligation. The Investor Rights Obligation expired upon the closing of our IPO in accordance with its terms, and the related liability was reduced to zero at that time.

### ***Interest Expense, Net***

Net interest expense is primarily related to interest payments pursuant to the terms of our term debt facility entered into in August 2014, as well as the amortization of the debt discounts and premiums and deferred financing fees in connection with such term debt facility.

### **Critical Accounting Policies and Significant Judgments and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. On an ongoing basis, we evaluate our estimates and assumptions, including those related to clinical and preclinical trial expenses and stock-based compensation. Actual results may differ from these estimates under different assumptions or conditions. During the nine months ended September 30, 2016, there were no material changes to our critical accounting policies and use of estimates from those disclosed in Item 7 of our Annual Report on Form 10-K filed with the SEC on March 23, 2016, except with respect to our grant revenue recognition policy, which we adopted in connection with our receipt of the grant awarded in April 2016 from the National Institute on Drug Abuse at the National Institutes of Health, which provided additional resources for our ongoing Phase 2 clinical trial of CERC-501, or the NIDA Grant.

### ***Grant Revenue Recognition***

We recognize grant revenue when there is (i) reasonable assurance of compliance with the conditions of the grant and (ii) reasonable assurance that the grant will be received. We recognize revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred.

### **Results of Operations**

#### ***Comparison of the Three Months Ended September 30, 2016 and 2015***

##### ***Grant Revenue***

The following table summarizes our grant revenue for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,	
	2016	2015
(in thousands)		
Grant revenue	\$ 321	\$ —

Grant revenue was \$321,000 for the three months ended September 30, 2016. The revenue recognized during the quarter was from the NIDA Grant, which provided additional resources for the ongoing Phase 2 clinical trial of CERC-501. We did not have grant revenue in the 2015 quarter.

*Research and Development Expenses*

The following table summarizes our research and development expenses for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,	
	2016	2015
(in thousands)		
CERC-301	\$ 1,142	\$ 650
CERC-501	896	94
CERC-611	2,019	—
COMTi	17	42
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	400	350
Stock-based compensation expense	44	14
Other	64	87
	<u>\$ 4,582</u>	<u>\$ 1,237</u>

Research and development expenses were \$4.6 million for the three months ended September 30, 2016, an increase of approximately \$3.3 million compared to the three months ended September 30, 2015. This increase was largely due to the \$2.0 million total upfront payments recorded in connection with the license of CERC-611 in September 2016. Additionally, costs for CERC-501 increased by \$802,000, primarily due to the significant enrollment activity experienced during the third quarter for our ongoing Phase 2 clinical trial for smoking cessation. Only limited expenses were incurred for CERC-501 in the 2015 period as enrollment for our ongoing Phase 2 clinical trial with CERC-501 did not begin until the first quarter of 2016. Finally, costs for CERC-301 increased by \$492,000, primarily due to the significant enrollment activity experienced during the third quarter for our ongoing Phase 2 clinical trial of CERC-301.

*General and Administrative Expenses*

	Three Months Ended September 30,	
	2016	2015
(in thousands)		
Salaries, benefits and related costs	\$ 556	\$ 403
Legal, consulting and other professional expenses	725	194
Stock-based compensation expense	244	15
Other general and administrative expenses	178	110
	<u>\$ 1,703</u>	<u>\$ 722</u>

General and administrative expenses were \$1.7 million for the three months ended September 30, 2016, an increase of \$981,000 compared to the three months ended September 30, 2015. Legal, consulting and other professional expenses increased by \$531,000, attributable primarily to audit, legal, and other costs resulting from becoming a public company in October 2015, as well as certain financing expenses. Stock-based compensation expense increased by \$229,000 due to a significant increase in the number of options outstanding from September 30, 2015 to September 30,

2016. Salaries, benefits and related costs increased by \$153,000, attributable primarily to salary increases effected at the close of our IPO, as well as an increase in our headcount.

*Change in Fair Value of Warrant Liability, Unit Purchase Option Liability and Investor Rights Obligation*

We recognized a loss on the change in fair value of our warrant liability, UPO liability and investor rights obligation of \$101,000 during the three months ended September 30, 2016 compared to a gain of \$1.5 million during the three months ended September 30, 2015. The loss on the change in fair value during the three months ended September 30, 2016 was due to the increase in fair value of our warrant liability and UPO liability, both attributable to the increase in our common stock price at September 30, 2016 compared to the previous quarter-end.

The \$1.5 million gain on the change in fair value during the 2015 quarter was primarily due to the decrease in fair value of the investor rights obligation from \$1.4 million as of June 30, 2015 to \$0 as of September 30, 2015. The fair value of the investor rights obligation decreased to \$0 as of September 30, 2015 due to our pending IPO. The investor rights obligation expired in October 2015 upon the closing of our IPO and does not affect any reporting periods thereafter.

*Interest Expense, Net*

Net interest expense decreased by \$93,000 for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. The decrease was primarily due to a decrease in interest associated with a reduction in the principal balance of our secured term loan facility.

***Comparison of the Nine Months Ended September 30, 2016 and 2015***

*Grant Revenue*

The following table summarizes our grant revenue for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Grant revenue	\$ 972	\$ —

Grant revenue was \$972,000 for the nine months ended September 30, 2016. The revenue recognized during the period was from the NIDA Grant. We did not have grant revenue in the 2015 period.

*Research and Development Expenses*

The following table summarizes our research and development expenses for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
CERC-301	\$ 2,534	\$ 2,202
CERC-501	3,145	1,197
CERC-611	2,019	—
COMTi	121	200
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,285	978
Stock-based compensation expense	95	57
Other	178	202
	<u>\$ 9,377</u>	<u>\$ 4,836</u>

Research and development expenses were \$9.4 million for the nine months ended September 30, 2016, an increase of \$4.5 million compared to the nine months ended September 30, 2015. This increase was largely due to the \$2.0 million total upfront payment recorded in connection with the license of CERC-611 in September 2016. Additionally, costs for CERC-501 increased by \$1.9 million, driven by the significant enrollment activity experienced in the second and third quarters for our ongoing Phase 2 clinical trial for smoking cessation, offset by the \$1.0 million of costs incurred in the 2015 period related to the in-licensing of CERC-501. Further, we experienced an increase in costs for CERC-301 of \$332,000, driven by the significant enrollment activity experienced in the second and third quarters for our ongoing Phase 2 clinical trial. We also experienced an increase of \$307,000 in salaries, benefits and related costs, driven primarily by salary increases effected at the close of our IPO and an increase in our headcount.

*General and Administrative Expenses*

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Salaries, benefits and related costs	\$ 1,808	\$ 1,264
Legal, consulting and other professional expenses	2,186	665
Stock-based compensation expense	1,344	264
Other	651	305
	<u>\$ 5,989</u>	<u>\$ 2,498</u>

General and administrative expenses were \$6.0 million for the nine months ended September 30, 2016, an increase of \$3.5 million compared to the nine months ended September 30, 2015. Legal, consulting and other professional expenses increased by \$1.5 million, attributable primarily to audit, legal, and other costs resulting from becoming a public company in October 2015, as well as certain financing expenses. Stock-based compensation expense increased by \$1.1 million, driven by the modification of grants made to our former chief executive officer in the first quarter of 2016 in which the exercise term was extended, as well as the significant increase in the number of options outstanding from September 30, 2015 to September 30, 2016. Salaries, benefits and related costs increased by \$544,000,

attributable primarily to salary increases effected at the close of our IPO, as well as an increase in our headcount. Further, other general and administrative expenses increased by \$346,000 due to business development expenses and other costs.

*Change in Fair Value of Warrant Liability, Unit Purchase Option Liability and Investor Rights Obligation*

We recognized a loss on the change in fair value of our warrant liability, UPO liability and investor rights obligation of \$58,000 during the nine months ended September 30, 2016 compared to a gain of \$1.1 million during the nine months ended September 30, 2015. The \$58,000 loss on the change in fair value during the nine months ended September 30, 2016 was due to the increase in fair value of our warrant liability and UPO liability, both attributable to the increase in our common stock price at September 30, 2016 compared to December 31, 2015.

The \$1.1 million gain on the change in fair value during the 2015 period was primarily due to the decrease in fair value of the investor rights obligation from \$1.1 million as of December 31, 2014 to \$0 as of September 30, 2015. The fair value of the investor rights obligation decreased to \$0 as of September 30, 2015 due to our pending IPO. The investor rights obligation expired in October 2015 upon the closing of our IPO and does not affect any reporting periods thereafter.

*Interest Expense, Net*

Net interest expense decreased by \$253,000 for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The decrease was primarily due to a decrease in interest associated with a reduction in the principal balance of our secured term loan facility.

**Liquidity and Capital Resources**

We have devoted most of our cash resources to research and development and general and administrative activities. Since our inception, we have incurred net losses and negative cash flows from our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek marketing approval for, our product candidates. We incurred net losses of \$14.8 million and \$6.8 million for the nine months ended September 30, 2016 and 2015, respectively. At September 30, 2016, we had an accumulated deficit of \$68.4 million, net working capital of \$2.0 million and cash and cash equivalents of \$8.8 million. To date, we have not generated any revenues from the sale of products and we do not anticipate generating any revenues from the sale of our product candidates for the foreseeable future. Historically, we have financed our operations principally through private placements of common and convertible preferred stock, convertible and nonconvertible debt, as well as our IPO in October 2015.

We will require substantial additional financing to fund our operations and to continue to execute our strategy. Development of CERC-301 and CERC-501 beyond the two ongoing Phase 2 clinical trials, as well as the development of our other product candidates, will not be possible unless we secure additional funding. We anticipate funding our operations over the next several years from further offerings of equity or debt securities, as well as non-dilutive financing arrangements such as federal grants or collaboration agreements. Based on our current research and development plans we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the end of 2016. These factors raise significant doubt about our ability to continue as a going concern. We have the potential to raise additional cash through the Purchase Agreement with Aspire Capital.

**Term Loan**

In August 2014, we entered into a \$7.5 million secured term loan from a finance company. The loan is secured by a lien on all of our assets, excluding intellectual property, which is subject to a negative pledge. The loan contains certain additional nonfinancial covenants. In connection with the loan agreement, our cash and investment accounts are subject to account control agreements with the finance company that give the finance company the right to assume control of the accounts in the event of a loan default. Loan defaults are defined in the loan agreement and include, among others, the finance company's determination that there is a material adverse change in our operations. Interest on the loan

is at a rate of the greater of 7.95%, or 7.95% plus the prime rate as reported in *The Wall Street Journal* minus 3.25%. The interest rate effective from loan inception to December 16, 2015 was 7.95%. Effective December 17, 2015, the prime rate as reported by *The Wall Street Journal* increased 0.25% resulting in an increase to the current interest rate, which was 8.20% as of September 30, 2016. The loan was interest-only through May 2015, and is repayable in equal monthly payments of principal and interest of approximately \$305,000 over 27 months, which began in June 2015. The loan matures in the third quarter of 2017 and had an outstanding balance as of September 30, 2016 of \$3.2 million.

### **Cash Flows**

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash used in:		
Operating activities	\$ (10,860)	\$ (6,615)
Investing activities	(26)	(20)
Financing activities	(1,461)	(1,799)
Net decrease in cash and cash equivalents	<u>\$ (12,347)</u>	<u>\$ (8,434)</u>

#### *Net cash used in operating activities*

Net cash used in operating activities was \$10.9 million for the nine months ended September 30, 2016 and consisted primarily of a net loss of \$14.8 million and an increase in grants receivable of \$379,000, offset by non-cash stock-based compensation expense of \$1.4 million and an increase in accrued expenses and other liabilities of \$2.5 million.

Net cash used in operating activities was \$6.6 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of \$6.8 million and a \$1.1 million non-cash gain on the change in fair value of our warrant liability and investor rights obligation. These were offset by non-cash stock-based compensation expense of \$321,000, non-cash interest expense of \$205,000, an increase in accounts payable and accrued expenses and other liabilities of \$497,000, and a decrease in prepaid expenses and other assets of \$255,000.

#### *Net cash used in investing activities*

Net cash used in investing activities is limited to purchases of property and equipment consisting of computers and software and furniture and equipment. Our net cash used in investing activities was \$26,000 for the nine months ended September 30, 2016 and \$20,000 for the prior year period.

#### *Net cash used in financing activities*

Net cash used in financing activities was \$1.5 million for the nine months ended September 30, 2016, which consisted of principal payments on our term loan of \$2.5 million offset by gross proceeds from the sale of common stock to Aspire Capital under the Purchase Agreement.

Net cash used in financing activities was \$1.8 million for the nine months ended September 30, 2015, which consisted of principal payments on our term loan of \$1.0 million and the payment of offering costs related to our IPO of \$775,000.

### **Operating and Capital Expenditure Requirements**

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to increase in the near term as we fund the development of our programs. Following the closing of our IPO in October 2015, we expect to continue to incur significant legal, accounting

and other expenses that we were not previously required to incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the SEC and the NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that were previously inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We may also acquire or in-license new product candidates. Based on our research and development plans, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the end of 2016, which raises substantial doubt about our ability to continue as a going concern. We will require substantial additional financing to fund our operations and to continue to execute our strategy. Development of CERC-301 and CERC-501 beyond the two currently ongoing Phase 2 clinical trials, as well as the development of our other product candidates, will not be possible unless we secure additional funding.

Each of our product candidates are still in the early stages of clinical and preclinical development and the outcome of these efforts is uncertain. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may generate revenue. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings, grant funding and exploring the possibility of entering into collaboration agreements.

We will need to raise substantial additional capital in the future to fund our operations and to continue to execute our strategy. We plan to meet our capital requirements primarily through a combination of equity and debt financings, collaborations, strategic alliances, federal grants and marketing distribution or licensing arrangements. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we raise additional funds through collaboration and licensing agreements with third parties, it may be necessary to relinquish valuable rights to our product candidates, technologies or future revenue streams or to grant licenses on terms that may not be favorable to us. Our future capital requirements will depend on many forward-looking factors, including:

- the progress and results of the Phase 2 clinical program for CERC-301 and changes to our development plan with respect to CERC-301, if any;
- the progress and results of the clinical trials being conducted, or contemplated being conducted, for CERC-501 and changes to our development plan with respect to CERC-501, if any;
- our plan and ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- the number and development requirements of any other product candidates that we may pursue;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;
- the costs and timing of any product candidate acquisition or in-licensing opportunities;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined by applicable SEC rules and regulations.

#### **Recent Accounting Pronouncements**

See Item 1 of Part I, “Notes to Unaudited Financial Statements,” Note 2, of this Quarterly Report on Form 10-Q.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

#### **Interest Rate Risk**

We maintain a short-term investment portfolio consisting mainly of highly liquid short-term money market funds, which we consider to be cash equivalents. These investments earn interest at variable rates and, as a result, decreases in market interest rates would generally result in decreased interest income. We do not believe that a 10% increase or decrease in interest rates would have a material effect on the fair value of our investment portfolio due to the short-term nature of these instruments, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Further, in 2014 we entered into our term debt facility, which carries a variable interest rate that is the greater of 7.95%, or 7.95% plus the prime rate as reported in *The Wall Street Journal* minus 3.25%. As a result, increases in market interest rates would generally result in increased interest expense. Given the stable nature of prime rates, the Company does not expect our operating results or cash flows to be materially affected by changes in market interest rates through the date of the maturity of our term debt facility in August 2017. The interest rate effective as of September 30, 2016 was 8.20%.

#### **Item 4. Controls and Procedures**

##### **Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

##### **Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal controls over financial reporting during the quarter ended September 30, 2016 that materially affected, or are reasonably likely to materially affect, our internal control over

financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

### Item 1A. Risk Factors

In addition to the risk factors stated below and the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 23, 2016, which could materially affect our business, financial condition or future results. Except as set forth below, our risk factors as of the date of this Quarterly Report on Form 10-Q have not changed materially from those described in our Annual Report on Form 10-K. However, the risks described below and in our Annual Report on Form 10-K are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results of operations and the trading price of our common stock.

***Our recurring operating losses and negative cash flows from operations have raised substantial doubt regarding our ability to continue as a going concern.***

Our recurring operating losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. We have no current source of revenues to sustain our present activities, and we do not expect to generate revenues until, and unless, the FDA or other regulatory agencies approve our product candidates and we successfully commercialize any such product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

***If we are unable to enroll appropriate subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all.***

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates as well as completion of required follow-up periods. If subjects are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industry or for other reasons, including competitive clinical trials for similar subject populations, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed. For example, we have experienced delays in enrolling patients in our CERC-301 Phase 2 clinical trial, due in part we believe to the highly competitive environment for recruiting patients to clinical trials studying depression. In addition, we believe the decision by the National Institutes of Health to discontinue a Phase 2 trial for CERC-501 was due in part to difficulties experienced in enrolling patients into the trial.

Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

- ⌚ the size and nature of the subject population;
- ⌚ the number and location of clinical sites we enroll;

- ⌚ the proximity of subjects to clinical sites;
- ⌚ perceived risks and benefits of the product candidate under trial;
- ⌚ competition with other companies for clinical sites or subjects;
- ⌚ competing clinical trials;
- ⌚ the eligibility and exclusion criteria for the trial;
- ⌚ the design of the clinical trial;
- ⌚ effectiveness of publicity for the clinical trials;
- ⌚ inability to obtain and maintain subject consents;
- ⌚ risk that enrolled subjects will drop out or be withdrawn before completion; and
- ⌚ clinicians' and subjects' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

There is significant competition for recruiting subjects in clinical trials for product candidates for the treatment of depression, substance use disorders and impaired executive function, and we or our partners may be unable to enroll the subjects we need to complete clinical trials on a timely basis or at all. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or may not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

***The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.***

We have registered for sale the 175,000 commitment shares and the 250,000 initial purchase shares that we have issued, and 3,461,010 additional shares that we may sell, to Aspire Capital from time to time under the Purchase Agreement. Approximately \$14 million, or up to 3,461,010 shares, remains available to be issued to Aspire Capital under the Purchase Agreement as of September 30, 2016. Depending on a variety of factors, including market liquidity of our common stock, the sale of shares under the Purchase Agreement may cause the trading price of our common stock to decline.

Aspire Capital may ultimately purchase all, some or none of the common stock that can be sold under the Purchase Agreement. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in such offering, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. However, we have the right under the Purchase Agreement to control the timing and

amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

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

### **Unregistered Sales of Equity Securities**

On September 8, 2016, we issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of \$4.00, for gross proceeds of \$1 million and issued to Aspire Capital 175,000 shares of common stock as a commitment fee as consideration for entering into the Purchase Agreement, both in transactions exempt from registration under the Securities Act, in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D thereunder. Aspire Capital represented that it was an “accredited investor,” as defined in Regulation D, and was acquiring the Securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. On September 16, 2016, we filed a Registration Statement on Form S-1 (File No. 333-213676) that registered the aggregate of 425,000 shares of our common stock sold to Aspire on September 8, 2016. This Registration Statement on Form S-1 was declared effective by the SEC on September 28, 2016.

### **Use of Proceeds from Registered Securities**

#### ***Initial Public Offering***

Pursuant to the Registration Statement on Form S-1 (File No. 333-204905), as amended, that was declared effective by the SEC on October 14, 2015, we registered the units to be sold in our IPO (including 600,000 units with respect to an over-allotment option granted by us to the underwriters in the offering). Each unit consisted of one share of common stock, one Class A warrant to purchase one share of common stock at an exercise price of \$4.55 per share and one Class B warrant to purchase one-half share of common stock at an exercise price of \$3.90 per full share (the “units”). Maxim Group LLC acted as the sole book-running manager, and Laidlaw & Company (UK) acted as the lead manager.

On October 20, 2015, we sold a total of 4,000,000 units in the IPO at an initial public offering price of \$6.50 per unit for gross proceeds of \$26.0 million. The net proceeds of the IPO, after underwriting discounts, commissions and expenses, and before offering expenses, were approximately \$23.6 million.

On November 23, 2015, the underwriter of the IPO exercised its over-allotment option for 20,000 shares of common stock, 551,900 Class A warrants to purchase one share of common stock and 551,900 Class B warrants to purchase one-half share of common stock for additional gross proceeds of \$135,319.

There have been no material changes in the planned use of proceeds from our IPO, as described in our final prospectus filed with the SEC on October 15, 2015 pursuant to Rule 424(b)(4) under the Securities Act related to the IPO.

**Item 6. Exhibits**

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
3.1	Amended and Restated Certificate of Incorporation of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 20, 2015).
3.2	Amended and Restated Bylaws of Cerecor Inc. (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the Current Report on Form 8-K filed on October 20, 2015).
4.1	Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014 (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.2	Form of Warrant to Purchase Shares of Common Stock issued in connection with the sale of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.3	Form of Warrant to Purchase Shares of Common Stock issued in connection with the sale of Series A-1 Convertible Preferred Stock, as amended by the Amendment to Common Stock Warrants, dated as of July 11, 2014 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.4	Form of Warrant to Purchase Shares of Common Stock, issued to CIFCO International Group and its affiliate (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.5	Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible promissory notes from April 2014 through June 2014 (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.6	Warrant Agreement, dated as of August 19, 2014, issued to Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.7	Form of Unit Purchase Option (incorporated by reference to Annex IV of Exhibit 1.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.9	Form of Class A Warrant Agreement (incorporated by reference to Exhibit 4.9 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.10	Specimen Class A Warrant Certificate (incorporated by reference to Exhibit 4.10 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.11	Form of Class B Warrant Agreement (incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.12	Specimen Class B Warrant Certificate (incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.13	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 filed on October 13, 2015).

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4.14	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed on May 20, 2016).
10.1 †	Exclusive License Agreement, dated as of September 22, 2016, by and between Cerecor Inc. and Eli Lilly and Company.
10.1.1	Addendum to Exclusive License Agreement, dated as of October 13, 2016, by and between Cerecor Inc. and Eli Lilly and Company.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 *	Certification of Chief Executive Officer and Chief Financial Officer 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.

\* These certifications are being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

**SIGNATURES**

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

**Cerecor Inc.**

/s/ Uli Hacksell

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**Uli Hacksell**  
President, Chief Executive Officer and Chairman of the  
Board  
*(on behalf of the registrant and as the registrant's  
Principal Executive Officer)*

Date: November 8, 2016

/s/ Mariam E. Morris

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**Mariam E. Morris**  
Chief Financial Officer  
*(Principal Financial Officer)*

Date: November 8, 2016

**CONFIDENTIAL TREATMENT REQUESTED**

**LICENSE AGREEMENT**  
**by and between**  
**Eli Lilly and Company and**  
**CERECOR INC.**

Effective Date of September 08, 2016

\*\*\*\* CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION.  
CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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## LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this “**Agreement**”), effective as of this 8th day of September, 2016 (the “**Effective Date**”), is by and between Eli Lilly and Company (“**Lilly**”), and Cerecor Inc. (“**Cerecor**”), a corporation organized and existing under the laws of Delaware (hereinafter referred to as “**Licensee**”). Lilly and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, Lilly and its Affiliates have discovered and developed the Transmembrane AMPA Receptor Regulatory Protein (TARP) gamma-8-dependent AMPA receptor antagonist designated as LY3130481;

WHEREAS, Licensee desires to develop and commercialize LY3130481; and

WHEREAS, Licensee and Lilly desire to enter into a license arrangement whereby Licensee will develop and commercialize LY3130481.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, Licensee and Lilly hereby agree as follows:

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### ARTICLE I - DEFINITIONS

As used in this Agreement, the following capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth below:

**1.01 “Affiliate”** shall mean any individual or entity directly or indirectly controlling, controlled by or under common control with a Party to this Agreement. For purposes of this Agreement, the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of an entity, or the right to receive fifty percent (50%) or more of the profits or earnings of an entity, shall be deemed to constitute control. Such other relationship as in fact results in actual control over the management, business and affairs of an entity shall also be deemed to constitute control.

**1.02 “Calendar Quarter”** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect.

**1.03 “Calendar Year”** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31, for so long as this Agreement is in effect.

**1.04 “Change of Control”** shall mean with respect to a Party: (a) the sale to a Third Party of all or substantially all of such Party’s assets and business; (b) a merger, reorganization or consolidation involving such Party and a Third Party in which the voting securities of such Party outstanding immediately prior thereto ceases to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party. Notwithstanding the foregoing, a Change of Control shall not be deemed to occur (i) on account of the acquisition of securities of a Party by any institutional investor, or affiliate thereof, or similar investor, that acquires the Party’s securities in a transaction or series of related transactions that are primarily a private financing transaction of the Party or (ii) a sale of assets, merger, or other transaction effected exclusively for the purpose of

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changing domicile of the Party. For clarity, any public offering of a Party's equity securities shall not be deemed to be a Change of Control.

**1.05 "Clinical Trial"** shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III clinical Trial, Phase IIIb Clinical Trial and/or post-approval clinical trial.

**1.06 "Commercialization" or "Commercialize"** shall mean, with respect to Licensed Product, any and all activities directed to the marketing, promotion, distribution, offering for sale and selling of such product, importing and exporting such product for sale, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall also include Commercialization Studies. "Commercialize" has a correlative meaning.

**1.07 "Commercialization Studies"** shall mean a study or data collection effort for the Licensed Product that is initiated in the Territory after receipt of Marketing Authorization for the Licensed Product and is principally intended to support the Commercialization of the Licensed Product in the Territory; provided, that such study or data collection effort is not principally to support or maintain a Marketing Authorization or obtain a label change or maintain a label.

**1.08 "Commercially Reasonable Efforts"** shall mean, with respect to the performance of obligations or tasks of a Party, the level of efforts and resources, normally used by a similarly situated biopharmaceutical company in the exercise of its reasonable discretion relating to the Development or commercialization of a product, in each case owned by it or to which it has exclusive rights, having similar technical and regulatory factors and similar market potential, profit potential and strategic value, and that is at a similar stage in its Development or product life cycle as the Licensed Product, taking into account issues of patent coverage, safety and efficacy, product profile, competitiveness of the marketplace, proprietary position, and profitability (including pricing and reimbursement).

**1.09 "Compliance"** shall mean the adherence by the Parties in all material respects to all applicable laws and Party Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.

**1.10 "Development" or "Develop"** shall mean all preclinical research and development activities and all clinical drug development activities, including, among other things: drug discovery, toxicology, formulation, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining and maintaining Marketing Authorization (including without limitation, post-marketing studies), and regulatory affairs related to all of the foregoing. Development shall include all clinical studies (including Phase III-B) that are primarily intended to support or maintain a Marketing Authorization, maintain a label or obtain any label change, but shall exclude Commercialization Studies.

**1.11 "Field"** shall mean the prevention, diagnosis and/or treatment of all disease in humans.

**1.12 "First Commercial Sale"** shall mean, with respect to a particular Licensed Product in a particular country in the Territory, the first commercial sale of such Licensed Product to a Third Party for end use or consumption in such country in an arm's length transaction by Licensee, its Affiliates or sublicensee in the Field after the receipt of Marketing Authorization in such country. Sales for test marketing, sampling and promotional uses, Clinical Trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

**1.13 "Generic Product"** means, with respect to a particular Licensed Product in a country, a generic or biosimilar pharmaceutical product, that is not produced, licensed or owned by Licensee or any of

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its Affiliates, that: (a) contains the same, or a bioequivalent of the, active ingredient as a Licensed Product; and (b) is approved for use in such country by a regulatory authority through a regulatory pathway by referencing clinical data first submitted for obtaining regulatory approval for such Licensed Product. Generic Product includes any pharmaceutical products obtained via a bioequivalence or bioavailability showing such as those covered by section 505(b)(2) or under 505(j) of the U.S. Federal Food, Drug, and Cosmetic Act or an equivalent outside the United States.

**1.14 “Good Clinical Practices”** shall mean the then current Good Clinical Practices as such term is defined from time to time by the United States Food and Drug Administration (“FDA”), or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or sale of Licensed Product in a particular jurisdiction of the Territory, if and to the extent the Development, Manufacture or sale of Licensed Product takes place in such jurisdiction.

**1.15 “Good Laboratory Practices”** shall mean the then current good laboratory practice regulations of the FDA as described in the United States Code of Federal Regulations (“CFR”) or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or sale of Licensed Product in a particular jurisdiction of the Territory, if and to the extent the Development, Manufacture or sale of Licensed Product takes place in such jurisdiction.

**1.16 “Good Manufacturing Practices”** shall mean the then current Good Manufacturing Practices as such term is defined from time to time by the FDA or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or sale of Licensed Compound or Licensed Product in a particular jurisdiction of the Territory, if and to the extent the Development, Manufacture or sale of Licensed Compound or Licensed Product takes place in such jurisdiction.

**1.17 “Government Official”** shall mean (i) an officer, or employee of: (a) a government, or any department or agency thereof; (b) a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university; or (c) a public international organization (such as the United Nations, the International Monetary Fund, the International Committee of the Red Cross, and the World Health Organization), or any department or agency thereof; (ii) any political party or party official or candidate for public or political party office; and (iii) any person acting in an official capacity on behalf of any of the foregoing.

**1.18 “IND”** shall mean an investigational new drug application with respect to the Licensed Product filed with the FDA for beginning Clinical Trials in humans, or any comparable application filed with the Regulatory Authorities of a country other than the United States prior to beginning Clinical Trials in humans in that country, as well as all supplements or amendments filed with respect to such filings.

**1.19 “Internal Compliance Codes”** shall mean a Party’s internal policies and procedures intended to ensure that a Party complies with applicable laws, Party Specific Regulations, and such Party’s internal ethical, medical and similar standards.

**1.20 “Transmembrane AMPA Receptor Regulatory Protein (TARP) gamma-8-dependent AMPA Receptor Antagonist”** shall mean an AMPA ( $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor antagonist or inverse agonist which selectively targets transmembrane AMPA receptor regulatory protein (TARP) gamma-8-dependent AMPA .

**1.21 “Know-How”** shall mean scientific and technical information, trade secrets and data used or generated and owned or controlled, by a Party or on behalf of a Party, which are based on, derived

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from, or are directed to the Lilly Patent Rights with respect to Lilly Know-How, Licensee Patent Rights with respect to Licensee Know-How, Licensed Compounds or Licensed Products, or the manufacture or use of the foregoing, that are not in the public domain, including but not limited to (a) unpatented ideas, discoveries, inventions, or improvements, (b) information related to methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies useful in the development, testing, or analysis of the Licensed Compounds or Licensed Products, (c) medicinal chemistry, medical, pre-clinical, toxicological biological, chemical, pharmacological, safety, manufacturing and quality control data or other scientific data and information related thereto, and (iv) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information.

**1.22 “Licensee”** shall have the meaning given to such term in the preamble of this Agreement.

**1.23 “Licensee Know-How”** shall mean Know-How developed by Licensee and/or any of its Affiliates or sublicensees after the Effective Date pursuant to this Agreement that is necessary for the Development, Commercialization or Manufacture of Licensed Compound or Licensed Product.

**1.24 “Licensee Patent Rights”** shall mean those patents and patent applications including all (a) continuations, continuations-in-part, divisionals and substitute applications with respect to any such patent applications; (b) patents issued based on or claiming priority to any such patent applications; (c) any reissue, reexamination, renewal, extension (including any supplemental protection certificate) or restoration of any such patents; (d) any confirmation patent or registration patent or patent of addition based on any such patents; (e) foreign counterparts and (f) any other patents and patent applications that dominate the foregoing patents, that (x) are owned by Licensee as of the effective date of termination of this Agreement, and (y) claim the Licensed Compound or Licensed Product or their use, composition, formulation, preparation or manufacture.

**1.25 “Licensed Compound”** shall mean those compounds listed in Schedule 1.25, including salts, esters, metabolites, prodrugs, acid forms, base forms, stereoisomers, racemates, tautomers, polymorphs, solvates, hydrates, crystalline forms, isotopic or radiolabeled equivalents, clathrates, hemihydrates, anhydrides, chelates, conformers, congeners, amorphous solids, isomers, enantiomers, conjugates, and complexes thereof.

**1.26 “Licensed Product”** shall mean:

- (a) any product containing a Licensed Compound which is covered in whole or in part by any Valid Patent Claim of the Lilly Patent Rights;
- (b) any product containing a Licensed Compound, the manufacture or use of which is covered in whole or in part by any Valid Patent Claim of the Lilly Patent Rights; and
- (c) any pharmaceutical product containing a Licensed Compound, including all dosage forms, formulations and line extensions thereof, including, without limitation, a Combination Product, except in the context of the calculation of Net Sales which is specifically addressed in Section 1.32. For avoidance of any doubt and notwithstanding anything to the contrary in this Agreement, the license granted under Section 2.01 of this Agreement with respect to Combination Product is limited to only the License Compound contained in such Combination Product and does not grant or convey any rights with respect to any other compound or ingredient that may be included in such Combination Product.

**1.27 “Lilly”** shall have the meaning given to such term in the preamble to this Agreement.

**1.28 “Lilly Know-How”** shall mean the Know-How (a) owned or controlled by Lilly and/or any of its Affiliates as of the Effective Date, and/or (b) controlled by Lilly pursuant to a written agreement

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between Lilly and a Third Party executed during the Term for which Licensee has elected to pay Third Party License Expenses in accordance with Section 2.06, in each of (a) and (b) that was (i) used or generated by or on behalf of Lilly or its Affiliates prior to the Effective Date in the Development or Manufacture of Licensed Compound or Licensed Product or (ii) that is reasonably necessary for the Development, Commercialization or Manufacture of Licensed Compound or Licensed Product. Lilly Know-How shall include without limitation the Know-How that is listed on Schedule 1.28 or is otherwise provided to Licensee by Lilly under this Agreement.

**1.29 “Lilly Patent Rights”** shall mean solely (a) those patents and patent applications listed in Schedule 1.29, and/or (b) those patent and patent applications controlled by Lilly pursuant to a written agreement between Lilly and a Third Party executed during the Term for which Licensee has elected to pay Third Party License Expenses in accordance with Section 2.06, and in the case of (b) all of Lilly’s rights together with all inventions disclosed or claimed therein or covered thereby but only to the extent such rights or inventions are reasonably necessary for the Development, Commercialization or Manufacture of Licensed Compound or Licensed Product including all (i) continuations, continuations-in-part, divisionals and substitute applications with respect to any such patent applications; (ii) patents issued based on or claiming priority to any such patent applications; (iii) any reissue, reexamination, renewal, extension (including any supplemental protection certificate) or restoration of any such patents; (iv) any confirmation patent or registration patent or patent of addition based on any such patents; (v) foreign counterparts and (vi) any other patents and patent applications that dominate the foregoing patents.

**1.30 “Major European Country”** shall mean each of France, Germany, Italy, Spain or the United Kingdom.

**1.31 “Manufacture”** shall mean all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including but not limited to test method development and stability testing, formulation, process development, manufacturing for use in non-clinical or clinical studies, manufacturing scale-up, manufacturing Licensed Compound or Licensed Product quality assurance/quality control development, quality control testing (including in-process release and stability testing), packaging, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, distribution and regulatory activities related to all of the foregoing.

**1.32 “Marketing Authorization”** shall mean, with respect to each country in the Territory, the receipt of all approvals from the relevant Regulatory Authority necessary to market and sell a Licensed Product in any country (including without limitation all applicable Price Approvals even if not legally required to sell Licensed Product in a country).

**1.33 “Multiple Ascending Dose (MAD) Study”** shall mean a study to investigate the pharmacokinetics, pharmacodynamics, safety and tolerability of multiple doses of Licensed Product

**1.34 “NDA”** shall mean a New Drug Application, Marketing Application Authorization, filing pursuant to Section 510(k) of the of the Food, Drug and Cosmetic Act, or similar application or submission for Marketing Authorization of a Licensed Product filed with a Regulatory Authority to obtain Marketing Authorization for a pharmaceutical or diagnostic product in that country or in that group of countries.

**1.35 “Net Sales”** shall mean with respect to a Licensed Product, the gross amount invoiced by *Licensee* (including a *Licensee* Affiliate) or any sublicensee thereof to unrelated Third Parties, excluding any sublicensee, for the Licensed Product in the Territory, less the following items consistent with U.S. Generally Accepted Accounting Principles consistently applied:

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- a) Trade, quantity, and cash discounts allowed;
- b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price;
- c) Licensed Product returns, rejections, damaged goods and allowances;
- d) Allowance for distribution expenses \* \* \* \*;
- e) The annual fee imposed on the pharmaceutical manufacturers by the U.S. government;
- f) A reasonable allowance for uncollectible or bad debts; and
- g) Tariffs, duties, excise, sales, value-added and other similar taxes (other than taxes based on income), customs duties or other government charges, in each case imposed on the sale of Licensed product to the extent included in the price and separately itemized on the invoice, including VAT, but only to the extent that such VAT are not reimbursable or refundable.

Disposition of Licensed Product for, or use of the Licensed Product in, clinical trials or other scientific testing, as free samples, or under compassionate use, patient assistance, or test marketing programs or other similar programs or studies where a Licensed Product is supplied without any charge shall not result in any Net Sales.

Such amounts shall be determined from the books and records of *Licensee*, affiliates of Licensee or any sublicensee maintained in accordance with U. S. Generally Accepted Accounting Principles consistently applied. *Licensee* further agrees in determining such amounts, it will use *Licensee*'s then current standard procedures and methodology, including *Licensee*'s then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars.

In the event that the Licensed Product is sold as part of a Combination Product (where “**Combination Product**” means any pharmaceutical product which comprises the Licensed Product and other pharmaceutically active compound(s) and/or ingredients), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product (as defined in the standard Net Sales definition) by the fraction,  $A / (A+B)$  where A is the weighted average sale price of the Licensed Product when sold separately in finished form, and B is the weighted average sale price of the other product(s) sold separately in finished form.

In the event that the weighted average sale price of the Licensed Product can be determined but the weighted average sale price of the other product(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction  $A / C$  where A is the weighted average sale price of the Licensed Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of the other product(s) can be determined but the weighted average sale price of the Licensed Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: one (1) minus  $(B / C)$  where B is the weighted average sale price of the other product(s) when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of both the Licensed Product and the other product(s) in the Combination Product cannot be determined, the Parties shall negotiate in good faith and agree on another, commercially reasonable means of calculating Net Sales with respect to such Combination Product that fairly reflects the relative contribution, to the total market value of such Combination Product, of the Licensed Product in the Combination Product.

The weighted average sale price for a Licensed Product, other product(s), or \_Combination Product

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shall be calculated once each Calendar Year and such price shall be used during all applicable royalty reporting periods for the entire following Calendar Year. When determining the weighted average sale price of a Licensed Product, other product(s), or Combination Product, the weighted average sale price shall be calculated by dividing the sales dollars (translated into U.S. dollars) by the units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial calendar year) of the preceding Calendar Year for the respective Licensed Product, other product(s), or Combination Product. In the initial Calendar Year, a forecasted weighted average sale price will be used for the Licensed Product, other product(s), or Combination Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the following Calendar Year.

**1.36 “Party” or “Parties”** shall have the meaning given to such term in the preamble to this Agreement.

**1.37 “Party Specific Regulations”** shall mean all judgments, decrees, orders or similar decisions issued by any Government Official specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Government Official, in each case as the same may be in effect from time to time and applicable to a Party’s activities contemplated by this Agreement.

**1.38 “Phase I Clinical Trial”** shall mean a clinical trial of a Licensed Product in human patients at single and multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamic properties of such Licensed Product, and which is consistent with 21 U.S. CFR § 312.21(a). For the avoidance of doubt, a Phase I Clinical Trial may include studies of the Licensed Compounds with chemotherapy agents to determine combination doses thereof.

**1.39 “Phase II Clinical Trial”** shall mean a clinical trial of a Licensed Product in human patients, the principal purposes of which are to make a preliminary determination that the Licensed Product is safe for its intended use, to determine its optimal dose, and to obtain sufficient information about such Licensed Product’s efficacy to permit the design of Phase III Trials, and which is consistent with 21 U.S. CFR § 312.21(b).

**1.40 “Phase III Clinical Trial”** shall mean a clinical trial of a Licensed Product in human patients, which trial is designed (a) to establish that the Licensed Product is safe and efficacious for its intended use, (b) to define warnings, precautions and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed, (c) to be, either by itself or together with one or more other Clinical Trials having a comparable design and size, the final human Clinical Trial in support of Marketing Authorization of such Licensed Product, and (d) consistent with 21 U.S. CFR § 312.21(c). “Phase III Trial” shall not include a Phase IIIb Trial.

**1.41 “Phase IIIb Clinical Trial”** shall mean a clinical trial of a Licensed Product in human patients, which provides for product support (i.e., a clinical trial which is not required for receipt of initial Marketing Authorization but which may be useful in providing additional drug profile data or in seeking a label expansion) commenced before receipt of Marketing Authorization for the indication for which such trial is being conducted.

**1.42 “Price Approval”** shall mean the approval or determination by a Regulatory Authority for the pricing or pricing reimbursement for a pharmaceutical product.

**1.43 “Proprietary Information”** shall mean, as applicable, unpublished patent applications, Know-How and all other scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, verbally or electronically, that is provided by one Party to the

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other Party in connection with this Agreement . All Know-How and other information disclosed by or on behalf of either Party pursuant to the Mutual Confidential Disclosure Agreement between Lilly and Licensee dated September 25, 2014 (the “**Confidentiality Agreement**”) shall be deemed to be Party’s Proprietary Information disclosed hereunder. The Parties agree that, effective as of the Effective Date, the Confidentiality Agreement shall be terminated, and superseded by this Agreement in its entirety.

**1.44 “Regulatory Authority”** shall mean any United States federal, state, or local government, or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body with responsibility for granting licenses or approvals, including Marketing Authorizations, necessary for the marketing and sale of the Licensed Product in any country.

**1.45 “Related Party”** shall mean each of Licensee, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.

**1.46 “Territory”** shall mean the entire world.

**1.47 “Third Party”** shall mean an entity other than Lilly and its Affiliates and Licensee and its Related Parties.

**1.48 “Valid Patent Claim”** shall mean a claim of an issued and unexpired patent included within the Lilly Patent Rights, that has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer.

## ARTICLE II - LICENSE

**2.01 License Grant.** Subject to the terms and conditions of this Agreement, Lilly hereby grants to Licensee and its Affiliates an exclusive, even as to Lilly and its Affiliates, transferrable as provided herein, royalty bearing license in the Territory in the Field, with the right to grant sublicenses (through multiple tiers) as provided herein, under the Lilly Patent Rights and the Lilly Know-How to research, develop, make, have made, use, import, offer for sale and sell the Licensed Compounds and Licensed Products in the Field in the Territory during the Term. Notwithstanding anything to the contrary in this Agreement, Lilly retains rights under Lilly Patent Rights and Lilly Know-How for internal, non-clinical research purposes.

**2.02 No Non-Permitted Use.** Licensee hereby covenants that it shall not, nor shall it cause or authorize, provide material support to or encourage any Affiliate or sublicensee to knowingly use or practice, directly or indirectly, any Lilly Know-How or Lilly Patent Rights for any purposes other than those expressly permitted by this Agreement.

**2.03 No Other Licenses.** Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

**2.04 Sublicenses.** Beginning after the \* \* \* \* of the Effective Date, Licensee may sublicense its rights under Section 2.01 to one or more Third Parties, to the extent necessary or useful to enable such Third Parties to research, develop, make, have made, use, import, offer for sale or sell Licensed Compound(s)

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or Licensed Product(s) in the Field in the Territory, and subject to the conditions of this Section 2.04. Any such sublicenses granted hereunder shall survive termination of this Agreement as further described in this Section 2.04.

- (a) Licensee shall remain responsible for its sublicensees' performance under this Agreement.
- (b) Licensee shall provide, in the Development Report required pursuant to Section 3.03, a list of any sublicensees granted a sublicense during the preceding twelve (12) months. At Lilly's request, Licensee shall provide to Lilly a copy of any sublicense agreement.
- (c) Each and every sublicense granted by Licensee to a sublicensee must be in a written agreement, in English, executed by the sublicensee and giving its place of business. In addition, each and every such sublicense must be consistent with those terms of this Agreement which are applicable to that portion of the Field and/or Territory to which the sublicensee has been granted rights, including, without limitation, must require the sublicensee to abide by confidentiality and non-use obligations at least as stringent as those contained in Article IX of this Agreement.
- (d) In the event that that this Agreement is terminated in its entirety by Licensee pursuant to Section 12.02 or Lilly for any reason as permitted under the Agreement, each sublicense granted by Licensee will survive such termination (as a direct license from Lilly) on the terms and conditions of this Agreement (but with the scope and limitations of any sublicense granted by Licensee, such as territory, field and other limitations).

**2.05 Exclusivity.** For a period of \* \* \* \* following the Effective Date, Lilly shall not, and shall ensure that none of its Affiliates will, either by itself or through collaboration with a Third Party, conduct human clinical studies, manufacture or commercialize anywhere in the Territory any product containing or comprising a selective Transmembrane AMPA Receptor Regulatory Protein (TARP) gamma-8-dependent AMPA Receptor Antagonist (such product, a "**Competing Product**"). In the event that Lilly acquires, is acquired by or merges with a Third Party that is engaged in active development or commercialization of a Competing Product at the closing of such acquisition or merger, then Lilly shall not be deemed to be in breach of this Section 2.05 with respect to any such Competing Product, and the terms of this Section 2.05 will not apply in any way to limit or restrict, by or on behalf of a Party or its Affiliates, the development, use, manufacture, marketing, sale, promotion or commercialization of any such Competing Product that as of the date immediately prior to the closing of such acquisition or merger was controlled by such Third Party.

**2.06 Third Party Licenses.** During the Term, if Lilly obtains a license for any Patent rights or Know-how from a Third Party that would be necessary for the Development, Commercialization or Manufacture of License Compound or License Product for which payments would be due to such Third Party on account of such license, then Lilly, provided it has the legal right to do so, shall notify Licensee, identifying the relevant patent rights or Know-how. If Licensee provides Lilly with written notice in which (a) Licensee consents to including such patent rights or Know-how as Lilly Patent Rights or Lilly Know-How under this Agreement and (b) Licensee agrees to be responsible for (i) all royalty payments due on account of a Licensed Product and all other current and future payments specific to one or more License Products, and (ii) its pro rata share of current and future payments which are reasonably applicable to both Licensed Products and other products or services offered by Lilly or its licensees of such patents rights and/or Know-How, in each of (i) and (ii) due to such Third Party on account of the use of such patent rights or Know-how in connection with the use, sale, offer for sale, importation, and development, manufacture or commercialization of any Licensed Compound or Licensed Product in the Field ("**Third Party License Expenses**"), then, if legally permissible, such patent rights or Know-how, as applicable, will be deemed Lilly Patent Rights or Lilly Know-How

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hereunder, as applicable. Licensee shall have the discretion to terminate its license under the Third Party License at any time and upon thirty (30) days' written notice to Lilly provided that Licensee shall be responsible for all Third Party License Expenses due and owing prior to the effective date of such termination and shall be responsible for a proportional share of any subsequent liability to the extent directly resulting from such termination. For purposes of clarity, upon the effective date of such termination, such patent rights and know-how shall not be Lilly Patent Rights or Lilly Know-How.

**2.07 Section 365(n) of the Bankruptcy Code.** All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or equivalent legislation in any other jurisdiction. Upon the bankruptcy of either Party, the other Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to such other Party, unless the Party in bankruptcy elects to continue, and continues, to perform all of its obligations under this Agreement.

### ARTICLE III – DEVELOPMENT AND COMMERCIALIZATION

**3.01 Overview.** As of the Effective Date, Licensee shall be solely responsible for the Development and Commercialization, including all costs thereof, of the Licensed Product in the Field in the Territory. Licensee shall perform all of its Development activities consistent with the IND for the Licensed Product and in shall perform all of its Development and Commercialization activities accordance with all applicable laws, rules and regulations.

#### **3.02 Development and Commercialization Plans.**

- (a) **Initial Development Plan.** An initial Development plan for the Licensed Product in the Field in the Territory is attached hereto as Attachment 3.02(a) (as may be amended in accordance with this Agreement, the "**Development Plan**").
- (b) **Annual Development Plan.** Not later than sixty (60) days after December 31 of each Calendar Year, Licensee shall submit to Lilly an updated Development Plan for the pending Calendar Year. Such update shall take into account the anticipated Development activities, for the applicable development period, of Licensee or a Related Party for the Development of Licensed Product in the Field. Lilly shall have the right to comment on such annual plan, provided, however, that Licensee shall not be obligated to incorporate such Lilly comments and Licensee retains final decision making authority with respect to all such plans.
- (c) **Performance.** Licensee shall perform, and shall ensure that its Affiliates, sublicensees, and Third Party contractors perform, the activities described in the Development Plan in a professional manner and in compliance with, to the extent applicable, Good Laboratory Practices, Good Clinical Practices and/or Good Manufacturing Practices and in compliance with all other applicable laws, rules, and regulations.

**3.03 Development Reports.** Licensee shall submit to Lilly, every twelve (12) months after the Effective Date until the First Commercial Sale, a written report in reasonably sufficient detail describing the research, development and manufacturing progress of Licensee or a Related Party for Licensed Compounds and/or Licensed Products during the previous twelve (12) month period, as well as a list of any sublicensees granted during the preceding twelve (12) months. All such reports shall be considered Proprietary Information of Licensee.

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**3.04 Commercialization.** Licensee shall provide Lilly with the anticipated commercial launch of each Licensed Product in a country for which NDA (or foreign equivalent) and Marketing Authorization has been obtained.

**3.05 Commercialization Reports.** Licensee shall submit to Lilly, every twelve (12) months after First Commercial Sale of a Licensed Product, a written report in reasonably sufficient detail describing the general commercialization progress of Licensee or a Related Party for Licensed Compounds and/or Licensed Products during the previous twelve (12) month period, including a list all ongoing Commercialization Studies and the status of such studies in the United States, the Major European Countries and Japan.

**3.06 \* \* \* \***

**3.07 Subcontracting.** Consistent with the provisions of this Agreement and subject to compliance with Section 9.01(d), Licensee may perform any activities in support of its development and commercialization of Licensed Compounds and Licensed Products through subcontracting to its Affiliates or Third Parties, including Third Party subcontractors, contract service organizations, and academic or government collaborators.

#### **ARTICLE IV – TRANSFER OF LILLY KNOW-HOW & EXISTING STUDIES**

##### **4.01 Materials and Regulatory Filings Transfer.**

- (a) Promptly following the Effective Date, but in any event, within \* \* \* \* thereof: (i) Lilly will provide Licensee with the Licensed Compounds listed in Schedule 1.25 and Lilly Know-How listed in Schedule 1.28; and (ii) Lilly shall transfer to Licensee, in a mutually agreed manner, the quantities of available physical inventory of Licensed Compounds solely as listed in Schedule 1.25 and shall inform Licensee in writing as to the lot numbers and quantities of such physical inventory that were made and stored in compliance with Good Manufacturing Practices; provided that the quantities listed are general guidance estimates only of the amounts currently anticipated to be available. Licensee shall not use such inventory for clinical or commercial purposes, except to the extent that the inventory was made and stored in compliance with Good Manufacturing Practices and is recertified and/or re-purified and certified as compliant prior to such clinical or commercial use. Lilly shall have no responsibility to recertify or re-test any physical inventory to be provided under the Agreement, including if it is beyond its dating period (i.e., the material may require additional stability data and/or analytical testing and/or re-purified prior to use. Lilly shall provide the reports and data as described in Schedule 1.28 in a single copy in electronic format if available otherwise in paper. Lilly shall be responsible for the costs associated with transfer of Lilly Know-How subject to Section 4.02 below.
- (b) Promptly following the Effective Date, Lilly shall transfer to Licensee one (1) copy of the material documents and records that have been generated by or on behalf of Lilly with respect to any planned INDs and other drug approval applications covering the Licensed Product in the Territory, as well as any material correspondence between Lilly and Regulatory Authorities related to Licensed Product in electronic format if available.

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- (c) In the event that any Regulatory Authority (a) threatens or initiates any action to remove a Licensed Product from the market in any country in the Field in the Territory or (b) requires Licensee, its Affiliates, or its sublicensees to distribute a “Dear Doctor” letter or its equivalent regarding use of Licensed Product in the Field, Licensee shall notify Lilly of such event within three (3) business day after Licensee becomes aware of the action, threat, or requirement (as applicable). Licensee shall keep Lilly reasonably informed with respect to any recall or withdrawal of Licensed Product in the U.S., Japan, or a Major European Country; provided, however, that the final decision as to whether to recall or withdraw a Licensed Product in the Territory shall be made by Licensee in its sole discretion. Licensee shall be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action. Lilly shall, at the request and reasonable expense of Licensee, cooperate with Licensee (including providing assistance and support) on any recall or withdrawal of Licensed Product to the extent necessary to comply with applicable laws, rules and regulations or any requirements by the Regulatory Authority.

**4.02 Transfer of Know-How.** Lilly shall, pursuant to Section 4.01(a), transfer to Licensee, or a Third Party manufacturer designated by Licensee, all Lilly Know-How that is reasonably necessary or useful to enable Licensee or its Third Party manufacturer to Manufacture the Licensed Compound or Licensed Product. In addition, as reasonably requested by \* \* \* \*.

## ARTICLE V - DILIGENCE

**5.01 Generally.** Licensee shall use Commercially Reasonable Efforts to Develop and Commercialize (following Regulatory Approval) at least one Licensed Compound or Licensed Product in the Field in the United States, a Major European Country or Japan, whether alone or with or through one (1) or more Related Party.

- (a) Licensee shall be responsible for overseeing, monitoring and coordinating all regulatory actions, communications and filings with, and submissions to, the FDA and other Regulatory Authorities in the Territory with respect to Licensed Product.
- (b) Licensee shall be solely responsible for interfacing, corresponding and meeting with the FDA and other regulatory authorities throughout the Territory with respect to Licensed Product.

### Pharmacovigilance and Product Complaints.

- (a) Licensee shall be solely responsible for the collection, review, assessment, tracking and filing of information related to adverse events (“AEs”) associated with Licensed Product, in accordance with 21 CFR 312.32, 314.80 and comparable regulations, guidance, directives and the like governing AEs associated with Licensed Product that are applicable outside of the United States.
- (b) Licensee shall assume responsibility for maintaining a global safety database for Licensed Product consistent with industry practices.
- (c) Licensee will be responsible to notify Lilly of any product complaints (non-AEs) associated with material supplied by Lilly. Lilly will be responsible to support the investigation of the product complaints as it relates to the activities conducted by Lilly and share the results of the investigation with Licensee.

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**5.02 Understanding Regarding Diligence.** It is understood and agreed that the obligation of Licensee to use Commercially Reasonable Efforts with respect to the development of any specific Licensed Compound or Licensed Product under Section 5.01 of this Agreement is expressly subject to the continuing absence of any materially adverse condition or event relating to the safety or efficacy of the Licensed Compound or Licensed Product, and the specific tasks that Licensee shall undertake to develop or market any such Licensed Compound or Licensed Product, in compliance with such Commercially Reasonable Efforts obligation, shall be modified or delayed as may be required in Licensee's reasonable opinion in order to address any such materially adverse condition or event so long as any such condition or event exists.

## ARTICLE VI – MANUFACTURING

**6.01 Manufacturing Responsibility.** After the Effective Date, Licensee will be responsible for the manufacturing and any ongoing or future stability studies related to the Licensed Compound and Licensed Product for use by Licensee, its Affiliates and its sublicensees in the Field in the Territory.

## ARTICLE VII - PAYMENTS; ROYALTIES AND REPORTS

**7.01 Consideration for License.** In consideration for the license granted hereunder, Licensee shall pay to Lilly a non-refundable, non-creditable, upfront payment of two million U.S. dollars (\$2,000,000), of which seven hundred fifty thousand U.S. dollars (\$750,000) shall be due within thirty (30) days of the Effective Date of this Agreement, and the remaining balance of one million two hundred fifty thousand U.S. dollars (\$1,250,000) payable within thirty (30) days after the first subject dosed with a Licensed Product in a Multiple Ascending Dose (MAD) study.

### 7.02 Milestone Payments.

(a) **Development and Commercialization Milestone Payments.** Subject to the terms and conditions of this Agreement and in further consideration for the license granted herein, Licensee shall make each of the following one-time, non-refundable, non-creditable milestone payments to Lilly for the first Licensed Product to achieve such milestone:

Milestone Event	Amount Due
The first subject dosed in a Phase 2 Clinical Trial.	\$* * * *
The first subject dosed in a Phase 3 Clinical Trial.	* * * *
Acceptance for filing of an NDA or equivalent for a Licensed Product in the United States	\$* * * *
NDA approval for a Licensed Product in the United States	\$* * * *

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Milestone Event	Amount Due
NDA approval or equivalent for a Licensed Product by the European Medicines Agency or in any Major European Country	\$* * * *
NDA approval or equivalent for a Licensed Product in Japan	\$* * * *
First Commercial Sale of a Licensed Product in the United States	\$* * * *
First Commercial Sale of a Licensed Product in a Major European Country	\$* * * *
First Commercial Sale of a Licensed Product in Japan	\$* * * *

**(b) Aggregate Net Sales Milestone Payments.** Subject to the terms and conditions of this Agreement and in further consideration for the license granted herein, Licensee shall make each of the following one-time, non-refundable, non-creditable milestone payments to Lilly the first time the aggregate Net Sales of all Licensed Products meets or exceeds the following thresholds:

- \* \* \* \* U.S. dollars (\$\* \* \* \*) at the end of the first calendar year in which aggregate Net Sales for Licensed Products in such calendar year exceeds \$\* \* \* \*; and
- \* \* \* \* U.S. dollars (\$\* \* \* \*) at the end of the first calendar year in which aggregate Net Sales for Licensed Products in such calendar year exceeds \$\* \* \* \*.
- \* \* \* \* U.S. dollars (\$\* \* \* \*) at the end of the first calendar year in which aggregate Net Sales for Licensed Products in such calendar year exceeds \$\* \* \* \*; and
- \* \* \* \* U.S. dollars (\$\* \* \* \*) at the end of the first calendar year in which aggregate Net Sales for Licensed Products in such calendar year exceeds \$\* \* \* \*.

**(c) Notice and Payment.** Licensee shall notify Lilly in writing within ten (10) business days after the achievement of each such milestone event by Licensee, its Affiliates or a sublicensee giving rise to a payment obligation under this Section 7.02 and Licensee shall pay Lilly the indicated amount no later than forty-five (45) days after such notification to Lilly.

### 7.03 Royalties.

**(a) Royalty Rates.** Subject to the terms and conditions of this Agreement, Licensee shall pay to Lilly royalties on Net Sales made by Licensee, its Affiliates or sublicensees of any Licensed Product commencing upon the First Commercial Sale of a Licensed Product in a particular country in the Territory and will continue on a Licensed Product-by-Licensed Product and country-by-country basis until the later of (i) the expiration of the last to expire Valid Patent Claim covering a Licensed Product in such country, or (ii) \* \* \* \* (\* \* \*) years from First Commercial Sale of the Licensed Product in such country, at the tiered rates in U.S. dollars as set forth as follows:

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- For the first \$\* \* \* \* of annual worldwide Net Sales for such Licensed Products: \* \* \* \*; and
- For the portion of annual worldwide Net Sales for such Licensed Products greater than \$\* \* \* \* but less than or equal to \$\* \* \* \*, \* \* \* \*; and
- For the portion of annual worldwide Net Sales for such Licensed Products greater than \$\* \* \* \* but less than or equal to \$\* \* \* \*, \* \* \* \*; and
- For the portion of annual worldwide Net Sales for such Licensed Products greater than \$\* \* \* \*, \* \* \* \*.

- (b) **Third Party Licenses – Royalty Offset.** Should Licensee or any of its Related Parties determine in good faith that it is reasonably necessary to obtain a license for a patent that is necessary to Develop, manufacture and/or Commercialize Licensed Compounds and/or Licensed Products contemplated by this Agreement, Licensee may offset royalty payments due hereunder by \* \* \* \* (\* \* \* \*%) percent of the amounts due under such third party license agreement, provided, that under no circumstance will the royalties due to Lilly be offset by more than \* \* \* \* (\* \* \* \*%) percent of the royalties owed to Lilly.
- (c) **Early Generic Product Entry and/or No Lilly Patent Rights .** For a given Licensed Product, if in a given country within the Territory entry of a Generic Product has occurred and subsequently the sales of the Licensed Product have declined by \* \* \* \* percent (\* \* \* \*%) or more as compared to the two consecutive Calendar Quarters immediately prior to such Generic Product entry (“**Generic Competition Threshold**”), then the royalty payments due to Lilly for such Licensed Product in such country shall be reduced by \* \* \* \* percent (\* \* \* \*%). Such reduction shall be first applied with respect to such country starting with sales in the Calendar Quarter following the entry of such Generic Product.

#### 7.04 Reports; Payment of Royalty; Payment Exchange Rate and Currency Conversions.

- (a) **Royalties Paid Quarterly.** Licensee shall keep (and shall cause its affiliates and requires its sublicensees to keep) complete and accurate books and records that are necessary to ascertain and verify the payments owed hereunder. Within forty-five (45) calendar days following the end of each Calendar Quarter, following the First Commercial Sale of a Licensed Product, Licensee shall furnish to Lilly a written report for the Calendar Quarter showing the Net Sales by country of Licensed Product sold by Licensee and its Related Parties in the Territory during such Calendar Quarter and the royalties payable by country due on such Net Sales under this Agreement for such Calendar Quarter. Licensee shall provide Lilly with a sales forecast for the subsequent 8 quarters. Licensee will mail such reports to the attention of: Eli Lilly and Company, Lilly Royalty Administration in Finance, Drop Code 1064, Lilly Corporate Center, Indianapolis, Indiana, 46285. Simultaneously with the submission of the written report, Licensee shall pay to Lilly the royalty due for such Calendar Quarter calculated in accordance with this Agreement.
- (b) **Method of Payment.** All payments to be made by Licensee to Lilly under this Agreement shall be paid by bank wire transfer in immediately available funds to such bank account as is designated in writing by Lilly from time to time. Royalty payments shall be made in United States dollars using the rate of exchange as defined in 1.31 Net Sales.

#### 7.05 Maintenance of Records; Financial Audits.

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- (a) **Record Keeping by Licensee.** Licensee shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. As a part of Licensee's annual fiscal year-end audit, Licensee will provide to Lilly an Independent Auditor's Report in which the Independent Auditor will audit the royalties paid or to be paid under the Agreement. Commencing upon date of delivery by Licensee to Lilly of any royalty report or record, and continuing for thirty (30) consecutive calendar days thereafter, Lilly shall have the right to (i) identify concerns or discrepancies in royalty payments, and (ii) discuss such concerns or discrepancies with an Independent Auditor. Upon conclusion of this thirty (30) day review period, the royalty report or record submitted by Licensee to Lilly shall be deemed accepted in its entirety.
- (b) **Underpayments/Overpayments.** If such Independent Auditor correctly concludes that additional royalties were owed during such period, Licensee shall pay such additional royalties within thirty (30) days of the date Lilly delivers to Licensee such Independent Auditor's written report so correctly concluding. Any overpayments by Licensee will be credited against the next quarterly royalty obligation or, at Licensee's request, promptly refunded to Licensee.
- (c) **Confidentiality.** Lilly shall treat all financial information subject to review under this Section 7.05, in accordance with the confidentiality provisions of Article IX of this Agreement.
- (d) **Late Payments.** Any amount owed by Licensee to Lilly under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the rate of the one (1) month London Inter-Bank Offering Rate ("**LIBOR**") plus \* \* \* \* percent (\* \* \* %) as set by the British Bankers Association as of the due date, or whatever is the legal limit if lower.

**7.06 Income Tax.** If laws, rules, or regulations require the withholding of income tax or other taxes imposed upon payments set forth in this Article VII, Licensee will notify Lilly in writing of such payment or withholding requirements prior to making the payment and provide such assistance to Lilly, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary to claim an exemption from or reduction of such taxes. In the event Licensee withholds taxes under this section and remits such taxes to the appropriate tax authority, Licensee will furnish Lilly with proof of payment of such taxes promptly following payment thereof. If taxes are paid to a tax authority, Licensee will provide Lilly all such assistance as is reasonably required to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid.

## ARTICLE VIII – PATENTS

**8.01 Ownership of Inventions.** As between the Parties, Licensee shall own the entire right, title and interest in and to any and all Know-How discovered, created, identified or made solely by it and its Related Parties and their respective employees, agents or independent contractors in the course of performing or exercising its rights under this Agreement, and all intellectual property rights in any of the foregoing. Inventorship shall be determined in accordance with U.S. patent laws.

**8.02 Prosecution and Maintenance of Patents.** Licensee shall have the first right, but not the obligation, at its expense, to prepare, file, prosecute and maintain Lilly Patent Rights in the Territory, on its own or through its Affiliate, or through outside counsel or Third Party contractor. Licensee will provide Lilly with copies of any substantive papers filed with or received by a patent office related to the maintenance of such patent filings. Licensee shall provide Lilly with drafts of any material filings in a reasonable amount of time in advance of the anticipated filing date and shall consider Lilly's reasonable comments thereto in good faith. The abandonment of any of the Lilly Patent Rights shall be governed by Section 8.07. Promptly following the Effective Date, Lilly shall transfer the existing,

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complete patent files for all applicable patents and patent applications to Licensee, shall file all documents necessary to transfer correspondence with the U.S. Patent and Trademark Office and other applicable patent authorities to Licensee and shall give Licensee's designated patent counsel power of attorney thereto. Lilly shall cooperate with Licensee in the transfer of all prosecution and maintenance responsibilities relating to the Lilly Patent Rights. For clarity, after such transfer, Lilly will cooperate, but will not be responsible for further maintenance and annuity payments.

**8.03 Patent Term Restoration.** Licensee shall have the first right, but not the obligation, with respect to election to obtain patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Lilly Patent Rights. Lilly agrees to reasonably assist Licensee as needed with the filing and prosecuting of any such application for patent term restoration or supplemental protection certificates or their equivalents. To the extent Licensee has elected to seek such patent term restoration or supplemental protection certificates or equivalents, Licensee (a) shall pay all costs associated with the preparation, filing and prosecuting of any such application for patent term restoration or supplemental protection certificates or their equivalents hereunder, (b) agrees to consult with Lilly as to the preparation, filing, prosecution of such application for patent term restoration or supplemental protection certificates or their equivalents reasonably prior to any deadline of action, and (c) shall provide Lilly with drafts of any material filings in a reasonable amount of time in advance of the anticipated filing date and shall consider in good faith any comments of Lilly.

**8.04 Interference, Derivation, Opposition, Reissue Reexamination and Post Grant Review Proceedings.** Any Party shall, within ten (10) business days of learning of any request for, or filing or declaration of, any interference, derivation, opposition, reexamination, or post grant review (or similar administrative proceedings) relating to Lilly Patent Rights, inform the other Party of such event. Licensee shall have the first right, but not the obligation, to determine a course of action with respect to any such proceeding and to control such proceeding. Lilly shall have the right to review any submission to be made in connection with such proceeding. In connection with any such interference, derivation, opposition, reissue, reexamination, or post grant review proceeding (or similar administrative proceedings) or correction relating to Lilly Patent Rights, Lilly will cooperate fully and will provide Licensee with any information or assistance that Licensee may reasonably request. Licensee shall keep Lilly informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto. To the extent Licensee has elected to control the foregoing, Licensee shall bear the expense of such proceeding or action with respect to the Lilly Patent Rights.

**8.05 Enforcement and Defense.** In the event that either Licensee or Lilly becomes aware of any alleged, threatened or actual commercially material infringement of a Lilly Patent Right in a country in the Territory, or judicial challenge to the validity of a Lilly Patent Right in a country in the Territory, it will notify the other Party in writing to that effect within a reasonable time period.

- (a) **First Right of Licensee; Right of Lilly to Assume.** Licensee shall have the first right, but not the obligation, to bring a suit or otherwise take action against any person or entity directly infringing, contributorily infringing or inducing infringement of the Lilly Patent Rights. If Licensee fails to bring a suit or otherwise take action with respect to infringement of any Lilly Patent Rights within (i) thirty (30) days with respect to potential infringement in the context of a Paragraph IV certification, or (ii) sixty (60) days with respect to potential infringement in some context other than a Paragraph IV certification, following receipt of notice of the alleged infringement, Lilly shall have the right to bring suit or otherwise take action with respect to such infringement at its own expense and by counsel of its own choice, and Licensee shall have the right, at its own expense, to be represented in any such suit by counsel of its own choice.

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- (b) **Expenses and Cooperation.** Each Party shall cooperate with and provide to the Party enforcing any such rights under this Section 8.05 reasonable assistance in such enforcement, at such enforcing Party's request and expense. Lilly further agrees to join, at Licensee's expense, any such action brought by Licensee under this Section 8.05 as a party plaintiff if required by applicable law to pursue such action. The enforcing Party under this Section 8.05 shall keep the other Party regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider the other Party's comments on any such efforts. In the event that Lilly is a party to such a legal action, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the mutual consent of Licensee and Lilly, and such consent shall not be unreasonably withheld. In no event shall Licensee or Lilly settle any such action or proceeding in a manner which restricts the scope, or adversely affects the enforceability, of Lilly Patent Rights or Licensee Patent Rights claiming or covering Licensed Compounds or Licensed Products without the prior written consent of Licensee and Lilly, such consent shall not be unreasonably withheld.
- (c) **Recovery.** Any recovery obtained by either or both of the Parties in connection with or as a result of any action to enforce any Lilly Patent Rights, whether by settlement or otherwise, shall first be applied to reimburse the costs and expenses of the Party that brought and controlled such action and then to reimburse the costs and expenses of the other Party in connection with such action, and any amounts remaining after such reimbursement shall be retained by the Party that brought and controlled such action, except that if Licensee is the Party that brought and controlled such action, any remaining portion of such recovery that is attributable to lost sales with respect to Licensed Products shall be treated as Net Sales and subject to payment of royalties pursuant to Section 7.03.

**8.06 Third Party Infringement Suit.** In the event that a Third Party sues Licensee alleging that Licensee's, its Affiliates' or its sublicensees' making, having made, importing, exporting or using Licensed Compound or distributing, marketing, promoting, offering for sale or selling Licensed Product infringes or will infringe a claim of a Third Party patent that specifically covers the Licensed Compound or its manufacture, then Licensee may elect to defend such suit.

**8.07 Abandonment.** In the event that Licensee determines not to file, maintain or continue prosecution of any patent or patent application within the Lilly Patent Rights, Licensee shall provide Lilly written notice thereof at least thirty (30) days before the applicable deadline. Upon receipt of such notice, Lilly shall have the right, but not the obligation, at its expense, to assume responsibility for filing, prosecuting, and maintaining such patents and patent applications. If Lilly decides to assume such responsibility, in its sole discretion, it shall so notify Licensee in writing.

**8.08 Supplemental Examination.** In the event that Licensee decides to file one or more requests for supplemental examination for any U.S. patent within the Lilly Patent Rights, Lilly will cooperate fully and will provide Licensee with any information or assistance that Licensee may reasonably request, and Licensees' shall bear all expenses associated therewith, including, without limitation, all expenses associated with the supplemental examination and any *ex parte* reexamination ordered as a result of supplemental examination.

## ARTICLE IX - CONFIDENTIALITY AND PUBLICATION

### 9.01 Confidentiality.

- (a) **Nondisclosure Obligation.** Each of Lilly and Licensee shall use any Proprietary Information received by it from the other Party only in accordance with this Agreement and shall not

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disclose to any Third Party any such Proprietary Information without the prior written consent of the other Party. The foregoing obligations shall survive the expiration or termination of this Agreement for a period of \* \* \* \*. These obligations shall not apply to Proprietary Information that:

- (a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's written records;
  - (b) is at the time of disclosure, or thereafter becomes, published or otherwise part of the public domain without breach of the obligations of confidentiality under this Agreement by the receiving Party;
  - (c) is subsequently disclosed to the receiving Party by a Third Party who has the right to make such disclosure, as documented by the receiving Party's written records; or
  - (d) is independently developed by the receiving Party or its Affiliates and without the aid, use or application of any of the disclosing Party's Proprietary Information, and such independent development can be documented by the receiving Party's written records.
- (b) **Authorized Disclosure.** Each Party shall have the right to disclose Proprietary Information received by it from the other Party to the extent required to be disclosed by law, regulation, rule, act or order of any governmental authority or agency to be disclosed, provided that notice is promptly delivered to the other Party (to the extent permitted) in order to provide an opportunity to seek a protective order or other similar order with respect to such Proprietary Information and thereafter the receiving Party discloses to the requesting entity only the minimum information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the other Party.
- (c) **Permitted Disclosures.** Notwithstanding provisions of Section 9.01(a), Licensee, its Affiliates or sublicensees shall have the right to disclose Proprietary Information received by it from Lilly:
- (a) to any institutional review board of any entity conducting Clinical Trials with Licensed Product or to any governmental or other regulatory agencies in order to obtain patents or to gain approval to conduct Clinical Trials or to market Licensed Product, provided that such disclosure may be made only to the extent reasonably necessary to obtain such patents or authorizations; or
  - (b) to any bonafide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner; provided that in connection with such disclosure, Licensee shall require each disclosee to enter into a confidentiality agreement with respect to such Proprietary Information.
- (d) **Disclosure to Agents/Subcontractors.** Notwithstanding the provisions of Section 9.01(a) and subject to the other terms of this Agreement, each of Licensee and Lilly shall have the right to disclose Proprietary Information to their respective sublicensees, agents, subcontractors, consultants, Affiliates or other Third Parties (collectively "**Agents**") in accordance with this Section 9.01(d). Such disclosure shall be limited only to those Agents directly involved in the development, manufacturing, marketing or promotion of Licensed Compound or Licensed Product (or for such Agents to determine their interest in performing such activities) in accordance with this Agreement. Any such Agents must agree in writing to be bound by

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confidentiality and non-use obligations no less restrictive than those contained in this Agreement.

- (e) **Disclosure to Taxing Authorities.** Notwithstanding the provisions of Section 9.01(a), either Party shall be permitted and allowed to provide a copy of this Agreement to the United States Internal Revenue Service or other tax authorities, if requested, without advanced written notice or approval of the other Party.

**9.02 Breach of Confidentiality.** The Parties agree that the disclosure of the Disclosing Party's Proprietary Information in violation of this Agreement may cause the Disclosing Party irreparable harm and that any breach or threatened breach of this Agreement by the Receiving Party entitles disclosing Party to seek injunctive relief, in addition to any other legal or equitable remedies available to it, in any court of competent jurisdiction. For clarity, such disputes shall not be subject to Article XIII.

**9.03 No Publicity.** A Party may not use the name of the other Party in any publicity or advertising and may not issue a press release or otherwise publicize or disclose any information related to the existence of this Agreement or the terms or conditions herein, except (a) on the advice of its counsel as required by law (e.g., any Securities and Exchange Commission filings and disclosures) and provided the Party who will be disclosing such information has consulted with the other Party to the extent feasible prior to such disclosure with respect to the substance of the disclosure; or (b) as consented to in advance by the other Party in writing. Notwithstanding the foregoing, Licensee shall have the right without obtaining Lilly's consent to make public announcements concerning the Development or Commercialization of the Licensed Product in the Field in the Territory under this Agreement, such as announcing the commencement of any clinical trial for the Licensed Product, the publication of data and results, the filing of regulatory filings for the Licensed Product and the achievement of Marketing Authorization of the Licensed Product. The Parties have agreed on a form of initial press release that may be used by either Party on an ongoing basis to describe this Agreement that is attached hereto as Attachment 9.03. Licensee shall provide Lilly with reasonable advance written notice of any press release or other public disclosure of the results of any of its work on Licensed Compound or Licensed Product under this Agreement.

**9.04 Scientific Publications.** Each Party recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 9.01 and Section 9.03 of this Agreement, in the event that a Party wishes to make a publication containing any Lilly Know-How or subject of Lilly Patent Rights, such Party shall deliver to the other Party a copy of the proposed written publication at least thirty (30) days prior to submission for publication. The Parties shall have the right to propose modifications to or delay of the publication for patent reasons or trade secrets. If a reviewing Party requests a delay for patent reasons, the other Party shall delay submission for a period of up to forty-five (45) days to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article VIII of this Agreement. Upon expiration of such delay, the Party seeking to publish shall be free to proceed with the publication. If a Party requests modifications to the publication, the Party seeking to publish shall edit such publication to prevent disclosure of trade secret or Proprietary Information prior to submission of the publication.

**9.05 Terms of Agreement.** Neither Party nor its Affiliates shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as follows: a Party and its Affiliates may disclose the terms or conditions of this Agreement (but not any other Proprietary Information, which may be disclosed only as described elsewhere in this Article IX), (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, provided that such advisors are subject to confidentiality with regard to such information

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under an agreement or ethical obligation; (b) to a Third Party or Related Party in connection with (i) a financing (or proposed financing) or an equity investment (or proposed investment) in such Party or its Affiliates, including to its shareholders and prospective shareholders, (ii) the granting of a sublicense pursuant to Section 2.04 or entry into any agreement with respect to the development, manufacture or commercialization of a Licensed Product, (iii) a merger, consolidation or similar transaction by such Party or its Affiliates, (iv) the sale of all or substantially all of the assets of such Party or its Affiliates to which this Agreement relates, or (v) in connection with a securitization, provided that such Third Party executes a non-use and non-disclosure agreement with confidentiality and non-use obligations similar to those contained in this Agreement; (c) to the United States Securities and Exchange Commission or any other securities exchange or governmental entity, including as required to make an initial or subsequent public offering, or (d) as otherwise required by law or regulation, provided that in the case of (c) and (d) the disclosing Party shall (x) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (y) if requested by such other Party, seek, or cooperate with such Party's efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent available at such other Party's expense, and (z) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or protective order.

## ARTICLE X - REPRESENTATIONS AND WARRANTIES

**10.01 Representations and Warranties of Each Party.** Each of Lilly and Licensee hereby represents, warrants and covenants to the other Party hereto as follows:

- (a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;
- (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;
- (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
- (d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions herein does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its corporate charter or other operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;
- (e) except for the governmental and Marketing Authorizations required to market the Licensed Product in the Territory, the execution, delivery and performance of this Agreement by such Party does not require the consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental or Regulatory Authority and the execution, delivery or performance of this Agreement will not violate any law, rule or regulation applicable to such Party;
- (f) this Agreement has been duly authorized, executed and delivered and constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general

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applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles; and

- (g) it shall comply with all applicable laws and regulations relating to its activities under this Agreement.

**10.02 Lilly's Representations.** Lilly hereby represents, warrants and covenants to Licensee that as of the Effective Date:

- (a) Schedule 1.29 accurately identifies all patents and patent applications owned or controlled by Lilly as of the Effective Date that are necessary for the, and/or in absence of a license, would prevent Licensee to, research, Develop, Manufacture, use and/or Commercialize Licensed Compounds and Licensed Products as contemplated by this Agreement;
- (b) Lilly is the sole owner of the entire right, title and interest in and to all patents, patent applications and other intellectual property rights within the Lilly Patent Rights as set forth on Schedule 1.29 and Lilly Know-How. Lilly has the full and legal rights and authority to license to Licensee the Lilly Patent Rights and Lilly Know-How, and (i) it has not previously transferred, assigned, conveyed or otherwise encumbered its right, title and interest in and to the Licensed Compound or Licensed Product to any Third Party, and (ii) no Third Party has been granted by Lilly any license, option or other rights or interest in or to the Lilly Patent Rights and Lilly Know-How or any part thereof, in each case with respect to any Licensed Compound or Licensed Product. Lilly has not received, nor is it aware of, any claims or allegations that a Third Party has any right or interest in or to any patent or patent application in the Lilly Patent Rights or in or to the Lilly Know-How with respect to any Licensed Compound or Licensed Product, or any claims or allegations by a Third Party that any patents or patent applications within the Lilly Patent Rights are invalid or unenforceable;
- (c) To the best of its knowledge, no intellectual property rights of any Third Party were infringed or misappropriated during the creation of the Lilly Patent Rights or Lilly Know-How;
- (d) All patents and patent applications within the Lilly Patent Rights are in good standing with the applicable patent office. In particular, all required filings have been timely made, and all maintenance fees, renewal fees, annuities and the like have been timely paid. Timely payment includes payment of any fee for which the fee is payable (e.g., within the fee payment window) even if the surcharge date or final deadline for payment of such fee would be in the future.
- (e) To the best of its knowledge and belief, Lilly has provided Licensee with all relevant information reasonably required for Licensee to properly evaluate and conduct due diligence on the Lilly Patent Rights, and all such information is true and accurate.
- (f) All physical inventory of the Licensed Compound designated LY3130481 that is transferred to Licensee pursuant to Section 4.01(a) and that has been recertified prior to the Effective Date by Lilly as in compliance with Good Manufacturing Practices (i) were manufactured, stored and transported in accordance with Good Manufacturing Practices and any applicable federal, state and local laws, rules and regulations and (ii) complies at the time of delivery with the specifications established by Lilly for administration to humans.

**10.03 Licensee's Representations.** Licensee hereby represents and warrants as of the Effective Date, and covenants during the Term, to Lilly that, it will not knowingly use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the United States Food, Drug and Cosmetic Act. Licensee represents and warrants that

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there are no pending or, to Licensee's knowledge, threatened judicial, administrative or arbitral actions, claims, suits or proceedings pending as of the Effective Date hereof against Licensee which, to Licensee's knowledge, either individually or together with any other, would have a material adverse effect on the ability of Licensee to perform its obligations under this Agreement or any agreement or instrument contemplated hereby.

**10.04 No Inconsistent Agreements.** Neither Party has in effect, and after the Effective Date neither Party shall enter into, any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement.

**10.05 Representation by Legal Counsel.** Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting of this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party that drafted such terms and provisions.

**10.06 Disclaimer.** EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE X, THE LICENSED COMPOUND, LICENSED PRODUCT, LILLY PATENT RIGHTS, LILLY KNOW-HOW, LICENSEE PATENT RIGHTS AND LICENSEE KNOW-HOW ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED OR STATUTORY, 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.

## ARTICLE XI - INDEMNIFICATION AND LIMITATION ON LIABILITY

**11.01 Indemnification by Licensee.** Licensee shall indemnify, defend and hold harmless Lilly and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "**Lilly Indemnified Party**") from and against any and all liability, loss, damage, cost, and expense (including reasonable attorneys' fees), (collectively, a "**Liability**") that a Lilly Indemnified Party may incur, suffer or be required to pay resulting from or arising out of a suit or action brought by a Third Party with respect to (i) the Development, Manufacture, Commercialization, promotion, distribution, use, marketing, sale or other disposition of the Licensed Compound or Licensed Product by Licensee, its Affiliates or sublicensees, (ii) any breach by Licensee of any of its representations, warranties and covenants contained in Article X herein or any material breach of its obligations under this Agreement, and (iii) the negligence and/or willful misconduct of Licensee, its Affiliates or sublicensees with respect to its obligations under this Agreement. Notwithstanding the foregoing, Licensee shall have no obligation under this Agreement to indemnify, defend or hold harmless any Lilly Indemnified Party with respect to any Liabilities to the extent that they result from the negligence or willful misconduct of Lilly, Lilly Indemnified Party or any of their respective employees, officers, directors or agents or that result from Lilly's breach of its obligations under this Agreement.

**11.02 Indemnification by Lilly.** Lilly shall indemnify, defend and hold harmless Licensee and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "**Licensee Indemnified Party**") from and against any Liability that a Licensee Indemnified Party may incur, suffer or be required to pay resulting from or arising in connection with a suit or action brought by a Third Party with respect to (i) any breach by Lilly of any of its representations, warranties and covenants contained in Sections 10.01, 10.02 and 10.04 herein or any material breach of its obligations (ii) the negligence and/or willful misconduct of Lilly, and (iii) the Development, Manufacture, use or other disposition of the Licensed Compound or Licensed Product by Lilly or its Affiliates prior to the

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Effective Date, including, with respect to the Existing Studies. Notwithstanding the foregoing, Lilly shall have no obligation under this Agreement to indemnify, defend or hold harmless any Licensee Indemnified Party with respect to any Liabilities to the extent that they result from the negligence or willful misconduct of Licensee, Licensee Indemnified Party or any of their respective employees, officers, directors or agents or that result from Licensee's breach of its obligations under this Agreement.

**11.03 Conditions to Indemnification.** The obligations of the indemnifying Party under Sections 11.01 and 11.02 are conditioned upon the delivery of written notice to the indemnifying Party of any potential Liability promptly after the indemnified Party becomes aware of such potential Liability. The indemnifying Party shall have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing; however, if in the reasonable judgment of the indemnified Party, such suit or claim involves an issue or matter that could have a materially adverse effect on the business operations or assets of the indemnified Party, the indemnified Party may retain control of the defense or settlement thereof by providing written notice of such effect to the indemnifying Party, but in no event shall such action or notice be construed as a waiver of any indemnification rights that the indemnified Party may have at law or in equity. If the indemnifying Party defends the suit or claim, the indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The foregoing notwithstanding, the Parties acknowledge and agree that failure of the indemnified Party to promptly notify the indemnifying Party of a potential Liability shall not constitute a waiver of, or result in the loss of, such Party's right to indemnification under Section 11.01 or 11.02, as appropriate, except to the extent that the indemnifying Party's rights, and/or its ability to defend against such Liability, are materially prejudiced by such failure to notify.

**11.04 Settlements.** Neither Party may settle a claim or action related to a Liability without the consent of the other Party, and such consent shall not be unreasonably withheld, if such settlement would impose any monetary obligation on the other Party or require the other Party to submit to an injunction or otherwise limit the other Party's rights under this Agreement. Any payment made by a Party to settle any such claim or action shall be at its own cost and expense.

**11.05 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, CONSEQUENTIAL OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.05 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.01 OR 11.02, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE IX OR EXCLUSIVITY OBLIGATIONS IN SECTION 2.05.

**11.06 Insurance.** Licensee shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold by or on behalf of Licensee. It is understood that such insurance shall not be construed to create a limit of Licensee's liability with respect to its indemnification obligations under this Article 11. Licensee shall provide Lilly with written evidence of such insurance upon request. Licensee shall provide Lilly with written notice at least thirty (30) days prior to the cancellation, non renewal or material change in such insurance or self-insurance which materially adversely affects the rights of Lilly hereunder.

## ARTICLE XII - TERM AND TERMINATION

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**12.01 Term and Expiration.** This Agreement shall be effective as of the Effective Date and unless terminated earlier by mutual written agreement of the Parties or pursuant to Sections 12.02 or 12.03 below, the term of this Agreement shall continue in effect on a country-by-country and product-by-product basis until the expiration of Licensee's obligation to pay royalties under Article VII herein (the "**Term**"). Upon expiration of this Agreement in its entirety, Licensee's license pursuant to Section 2.01 shall become a fully paid-up, royalty-free, irrevocable, perpetual non-exclusive license.

**12.02 Termination by Licensee.** Notwithstanding anything contained herein to the contrary, Licensee shall have the unilateral right to terminate this Agreement in its entirety without cause at any time by giving ninety (90) days advance written notice to Lilly. In the event of such termination, the rights and obligations hereunder shall terminate; provided, however, that any payment obligations due and owing as of the termination date shall continue.

**12.03 Termination for Cause.**

This Agreement may be terminated, in its entirety by written notice by either Party at any time during the Term of this Agreement:

- (a) upon or after the breach of any material provision of this Agreement if the breaching Party has not cured such breach within (A) sixty (60) days (other than breaches subject to (B)) and (B) one-hundred twenty (120) days with respect to any material breach of Licensee's diligence obligations, in each case following receipt of written notice from the non-breaching Party requesting cure of the breach or, if such breach is not susceptible of cure within such sixty (60) day or one-hundred twenty (120) day period, as applicable, the breaching Party has not taken appropriate steps to commence such cure during such sixty (60)-day period or one-hundred twenty (120) day period, as applicable and continued to diligently pursue such cure in a manner reasonably assuring such cure within a reasonable period of time thereafter (not to exceed one hundred eighty (180) days). The Parties acknowledge and agree that one example of how appropriate steps may be satisfied by Licensee, is by Licensee providing Lilly with a reasonable plan, which Lilly agrees is reasonable, for curing such material breach, and using commercially reasonable efforts to implement such plan in accordance therewith. Any right to terminate under this Section 12.03(a) shall be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article XIII with respect to the alleged breach, which stay and tolling shall last so long as the allegedly breaching Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings. In the event that Lilly exercises its right to terminate this Agreement pursuant to this Section 12.03(a) for Licensee's material breach of its diligence obligation under Article V, then such termination shall be solely with respect to the Licensed Product concerned and the remainder of the Agreement (other than with respect to such terminated Licensed Product) shall continue in full force and effect; or
- (b) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the event a receiver or custodian is appointed for such Party's business, or if a substantial portion of such Party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within one hundred eighty (180) days after the filing thereof.

**12.04 Effect of Termination on License.** In the event this Agreement is terminated in accordance with this Agreement, the rights and license granted to Licensee and its Affiliates under Section 2.01 of

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this Agreement shall terminate and all rights to the Licensed Compound and Licensed Product granted under this Agreement shall revert to Lilly, provided that all sublicenses granted under Section 2.04 shall survive to the extent so provided in Section 2.04 herein.

**12.05 Effect of Termination Generally; Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Article I (Definitions), Article IX (Confidentiality), Article XI (Indemnification and Limitation on Liability), Article XIII (Dispute Resolution), Article XIV (Miscellaneous) and Section 8.01, Section 10.06, Section 10.07, Section 12.01, Section 12.02, Section 12.03(b), Section 12.04, Section 12.05 and Section 12.06, Section 12.07, and Section 12.08 shall survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination, including the obligation to pay royalties for Licensed Product sold prior to such termination.

**12.06 Licensed Product Reversion.** Upon termination of this Agreement in its entirety by Lilly for any reason or by Licensee pursuant to Section 12.02, at Lilly's option and upon Lilly's written request, and at Licensee's expense, the following provisions shall apply:

- (a) Subject to Section 12.06(b), Licensee shall, at its sole expense, transfer to Lilly (or its nominee) all physical inventories of Licensed Compound and Licensed Product, and all INDs, Marketing Authorizations, drug approval applications for Marketing Authorizations, and all supporting documentation for such filings and applications (to the extent assignable and not cancelled) assigned to Licensee by Lilly hereunder to the extent relating to Licensed Product then being Commercialized or in Development.
- (b) For a period of sixty (60) days after the effective date of termination, the Parties shall negotiate in good faith the financial terms (including, without limitation, royalties, milestones and upfronts) and conditions for (i) the transfer of all regulatory filings and documentation, and all physical inventories of Licensed Compound and Licensed Product pursuant to Section 12.06(a) and any other transition assistance required, (ii) the grant of a royalty-bearing license to Lilly under Licensee Know-How and/or Licensee Patent Rights existing as of such effective date of termination with respect to the Licensed Product then being developed as of the date of such termination, and (iii) the transition to Lilly of all clinical trials conducted by Licensee under Licensee's IND for Licensed Product that are ongoing as of the date of termination. Such sixty (60) day period may be extended by mutual written agreement of the Parties for an additional thirty (30) days. In the event that the Parties are unable to mutually agree upon the commercially reasonable compensation and terms with respect to the foregoing within such period, the matter shall be referred to a mutually agreed upon third party expert in the valuation of life sciences assets, each Party shall provide to such third party all information in its control necessary for such third party to resolve such matter, and the costs for such expert shall be borne equally by the Parties.
- (c) Upon the request of Lilly, Licensee shall use reasonable efforts to assign to Lilly any sublicenses previously granted by Licensee related to Licensed Product.

**12.07 Termination in Part.** In the event that this Agreement is terminated in part with respect to an individual Licensed Product, the terms of Sections 12.04 through 12.06 shall apply accordingly to such terminated Licensed Product, as opposed to termination of the Agreement as a whole.

**12.08 Return of Proprietary Information.** Not later than thirty days (30) days after the termination of this Agreement in its entirety, each receiving Party shall, at the disclosing Party's discretion, either

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destroy or return or cause to be returned to the disclosing Party, all Proprietary Information of the disclosing Party in tangible form received from the disclosing Party and any other documents containing the disclosing Party's Proprietary Information, and all copies thereof, including those in the possession of the receiving Party's Agents pursuant to Section 9.01(d), except that the receiving Party may retain one (1) copy of the disclosing Party's Proprietary Information in its confidential files in a secure location solely for the purposes of (i) determining its obligations hereunder, (ii) complying with any applicable regulatory requirements, or (iii) defending against any product liability claim.

### ARTICLE XIII – DISPUTE RESOLUTION

**13.01 Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or the relationship between the Parties with respect to the Licensed Compound or Licensed Product, the Parties shall first try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice appropriate representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said thirty (30) days, either Party may refer the matter by written notice to the other under Section 14.07 to the Vice President of Lilly, or designee, and the Chief Executive Officer of Licensee, or designee, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within sixty (60) days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this Article XIII.

**13.02 Arbitration.** All disputes arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, or relating in any way to the relationship between the Parties with respect to the Licensed Compound or Licensed Product, shall be finally and exclusively settled by arbitration by a panel of three (3) arbitrators, provided such dispute is not an "Excluded Claim". As used in this Section 13.02, the phrase "**Excluded Claim**" shall mean a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright; (b) misappropriation of trade secrets; or (c) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

- (a) The arbitration proceeding shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association ("AAA") with such proceedings to be held in Newark, New Jersey, United States. In all cases, the arbitration proceedings shall be conducted in the English language, and all documents that are submitted in the proceeding shall be in the English language. Judgment upon the award rendered by arbitration may be issued and enforced by any court having competent jurisdiction.
- (b) If a Party intends to begin an arbitration to resolve a dispute, such Party shall provide written notice to the other Party, informing the other Party of such intention and any statement of claim required under the applicable arbitration rules (as determined in accordance with Section 13.02(a)). Within twenty (20) business days after its receipt of such notice, the other Party shall, by written notice to the Party initiating arbitration, add any additional issues to be resolved that would be considered mandatory counterclaims under Delaware law. For clarity, the resolution of any disputes regarding such counterclaims shall be conducted in the same proceedings as the initial claims.
- (c) Within forty-five (45) days following the receipt of the notice of arbitration, the Party referring the matter to arbitration shall appoint an arbitrator and promptly notify the other Party of such appointment. The other Party shall, upon receiving such notice, appoint a second arbitrator within twenty one (21) days, and the two (2) arbitrators shall, within fifteen (15) days of the appointment of the second arbitrator, agree on the appointment of a third arbitrator who will

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act with them and be the chairperson of the arbitration panel. In the event that either Party shall fail to appoint an arbitrator within thirty (30) days after the commencement of the arbitration proceeding, the arbitrator shall be appointed by the AAA. In the event of the failure of the two (2) arbitrators to agree within sixty (60) days after the commencement of the arbitration proceeding to appoint the chairperson, the chairperson shall also be appointed by the AAA.

- (a) All of the arbitrators shall have significant legal or business experience in pharmaceutical licensing matters. The arbitrators shall not be employees, directors or shareholders of either Party or any of their Affiliates.
- (b) Each Party shall have the right to be represented by counsel throughout the arbitration proceedings.
- (c) To the extent possible, the arbitration hearings and award will be maintained in confidence.
- (d) In any arbitration pursuant to this Agreement, the award or decision shall be rendered by a majority of the members of the panel provided for herein, with each member having one (1) vote. The arbitrators shall render a written decision with their resolution of the dispute that shall set forth in reasonable detail the facts of the dispute and the reasons for their decision. The decision of the arbitrators shall be final and non-appealable and binding on the Parties.

**13.03 Injunctive Relief.** By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect.

**13.04 Expenses of Arbitration and Expert Determination.** Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however*, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges and travel expenses). Absent the filing of an application to correct or vacate the arbitration award as permitted by applicable law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days of the service of the award.

#### **ARTICLE XIV - COMPLIANCE WITH ANTI-CORRUPTION LAWS**

**14.01 Compliance.** In connection with this Agreement, Licensee has complied and will comply with all applicable local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development ("OECD") Convention on Combating Bribery of Foreign Officials in International Business Transactions.

**14.02 Prohibited Conduct.** In connection with this Agreement, Licensee has not made, offered, given, promised to give, or authorized, and will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly, to any person or to any Government Official for the purpose of: (i) improperly influencing any act or decision of the person or Government Official; (ii) inducing the person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (iii) securing any improper advantage; or (iv) inducing

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the person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist Licensee or Lilly in obtaining or retaining business.

## ARTICLE XV - MISCELLANEOUS

### 15.01 Assignment/Change of Control.

- (a) Except as provided in this Section 15.01, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; provided, however, that Lilly may, without such consent, assign the Agreement and its rights and obligations hereunder to an Affiliate or in connection with a Change of Control. Licensee may, without Lilly's consent, assign this Agreement and its rights and obligations hereunder to an Affiliate or in connection with a Licensee Change of Control.
- (b) Any permitted assignee shall assume all assigned obligations of its assignor under the Agreement. The terms and conditions of this Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assigns. This Agreement shall be binding upon, and inure to the benefit of, each Party, its Affiliates, and its permitted successors and assigns. Each Party shall be responsible for the compliance by its Affiliates with the terms and conditions of this Agreement.
- (c) The Licensed Patent Rights and Know-How, in the case of Lilly as assignor or transferor, or the Licensee Patent Rights and Licensee Know-How, in the case of Licensee as assignor or transferor, shall exclude any Patent Rights and Know-How controlled by any acquirer (or any Affiliate thereof, excluding the Party hereto that becomes an Affiliate of the acquirer as a result of such transaction) either (i) prior to the Change of Control or (ii) developed outside of any activities under this Agreement. Also, notwithstanding anything to the contrary in this Agreement, the obligations under this Section 15.01 shall exclude patent rights and know-how of Lilly that it acquires (through purchase, license or otherwise) or discovers/develops outside the activity of this Agreement after the Effective Date except for the specific patent rights that fall within the specific definition of Lilly Patent Rights and Lilly Know-How.
- (d) Any attempted assignment not in accordance with Section 15.01 shall be null and void.

**15.02 Governing Law.** This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of Delaware, United States of America without giving effect to its conflict of law principles, and the national patent laws relevant to the patent at issue. Subject to the terms of this Agreement, all disputes under this Agreement shall be governed by binding arbitration pursuant to the mechanism set forth in Article XIII herein, provided, however, that notwithstanding anything to the contrary in this Agreement, nothing herein shall prohibit a Party from bringing a dispute involving an actual or alleged breach of confidentiality or an actual or alleged misappropriation or infringement of its intellectual property rights in a court of competent jurisdiction.

**15.03 Waiver.** Any delay or failure in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

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**15.04 Independent Relationship.** Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

**15.05 Compliance with Internal Compliance Codes.** All Internal Compliance Codes shall apply only to the Party to which they relate. The Parties agree to reasonably cooperate with each other to help insure that each Party is able to comply with the substance of its respective Internal Compliance Codes and, to the extent practicable, to operate in a manner consistent with its usual Compliance related processes.

**15.06 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America that may be imposed upon or related to Lilly or Licensee from time to time by the government of the United States of America. Furthermore, Licensee agrees that it will not export, directly or indirectly, any technical information acquired from Lilly under this Agreement or any Licensed Products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government when required by an applicable statute or regulation.

**15.07 Entire Agreement; Amendment.** This Agreement, including the Schedules hereto and thereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties with regard to the subject matter of this Agreement in the Territory, including the Confidentiality Agreement. There are no other covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, waiver or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**15.08 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or a PDF document sent by electronic mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Licensee, to:       Cerecor Inc.  
                                  400 East Pratt Street  
                                  Baltimore, MD 21202  
                                  Attn : John Kaiser or Uli Hacksell  
                                  jkaiser@cerecor.com or uhacksell@cerecor.com

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With copy to  
(which copy shall  
not constitute  
notice):

Kenneth J. Krisko, Esq.  
Cooley LLP  
One Freedom Square  
Reston Town Center  
11951 Freedom Drive  
Reston, VA 20190-5656  
Ph. 703-456-8581  
kkrisko@cooley.com

if to Lilly, to:

Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, Indiana 46285  
Attention: General Counsel  
Fax: 317-433-3000

Any such notice shall be deemed to have been received on the earlier of the date actually received or the date five (5) days after the same was posted or sent. Either Party may change its address or its facsimile number by giving the other Party written notice, delivered in accordance with this Section 15.08.

**15.09 Force Majeure.** Failure of any Party to perform its obligations under this Agreement (except the obligation to make payments when properly due) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if such failure is due to any cause beyond the reasonable control of such non-performing Party (“**Force Majeure**”), unless conclusive evidence to the contrary is provided. Causes of non-performance constituting Force Majeure shall include, without limitation, acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule materials, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right. The Party affected shall promptly notify the other Party of the condition constituting Force Majeure as defined herein and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed; provided that nothing herein shall obligate a Party to settle on terms unsatisfactory to such Party any strike, lockout or other labor difficulty, any investigation or other proceeding by any public authority or any litigation by any Third Party. If a condition constituting Force Majeure as defined herein exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory resolution to the problem, if practicable. If the Parties cannot in good faith reach a satisfactory resolution to the problem within sixty (60) days of meeting, the matter shall be handled pursuant to the dispute resolution provisions of Article XIII herein.

**15.10 Severability.** If any provision of this Agreement is declared illegal, invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall continue in accordance with its terms except for the part declared invalid or unenforceable by order of such court, provided, however, that in the event that the terms and conditions of this Agreement are materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this Agreement to reasonably substitute such invalid or unenforceable provisions in light of the intent of this Agreement.

**15.11 Extension to Affiliates.** In each case where an Affiliate of Licensee has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement, Licensee shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement. For

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the purposes of this Agreement, the Licensee shall be responsible for the contractual obligations of Affiliates. Licensee shall remain fully liable for any acts or omissions of its Affiliates.

**15.12 Counterpart.** This Agreement shall become binding when any one or more counterparts of it, individually or taken together, shall bear the signatures of each of the Parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be an original as against either Party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.

**15.13 Captions.** The captions of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

**15.14 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.15 Signatures.** For purposes of this Agreement, signatures sent by facsimile or PDF shall also constitute originals.

*[Signature Page Follows.]*

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IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized representatives of the Parties.

**ELI LILLY AND COMPANY**

**CERECOR INC.**

By: /s/ Jan M. Lundberg

By: /s/ Uli Hacksell

Title: Executive Vice President, Science and  
Technology, and President, Lilly  
Research Laboratories

Title: Chief Executive Officer

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**Schedule 1.25**  
**Licensed Compound (LY3130481)**

**Material Transfer**

**API Inventory**

****	Lot#	Inventory	Unit	Project ID	LSN / LY
****	****	****	GM	****	LY3130481

---

Drug product inventory needs to be relabeled before its use in a clinical trial. Cerecor needs to extend the stability study to extend the dating for the drug product.

**DP Inventory**

Project ID	WUXI FP No.	WUXI Batch No.	Description	Inventory	Warehousing Date
****	****	****	****	****	27-Mar-14
	****	****	****	****	27-Mar-14
	****	****	****	****	27-Mar-14
	****	****	****	****	9-Apr-14

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- o \*\*\*\*
- o \*\*\*\*
- o \*\*\*\*
- **List and copies of draft and final manuscripts/publications**
  - o \*\*\*\*
  - o \*\*\*\*
- **Presentations and associated files in PowerPoint**
  - o \*\*\*\*
  - o \*\*\*\*
- **Intellectual Property Materials**
  - o \*\*\*\*
  - o \*\*\*\*
  - o \*\*\*\*
- **Marketing**
  - o \*\*\*\*
- **Material Transfer Agreements**
  - o \*\*\*\*
- **Due Diligence Gaps**

The following are the gaps identified during due diligence review of the data room and is needed as part of tech transfer

  - o CMC Drug Substance Gaps:
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
  - o CMC Drug Product Gaps:
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*
    - \*\*\*\*

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**Schedule 1.29**

**Lilly Patent Rights**

<b>Docket Number</b>	<b>Country</b>	<b>Application Number</b>	<b>Application Date</b>	<b>Patent Number</b>	<b>Grant Date</b>	<b>Status</b>	<b>Sub Status</b>
****	A.R.I.P.O.	****	****			Filed	Filed
****	AAA- Series Summary					Docketed	Mailed
****	Algeria	****	****			Filed	Filed
****	Argentina	****	****			Filed	Published
****	Australia	****	****			Filed	Case Allowed
****	Brazil	****	****			Filed	Filed
****	Brunei	****	****			Filed	Mailed
****	Canada	****	****			Filed	Filed
****	Chile	****	****			Filed	Filed
****	China P.R.	****	****			Filed	Published
****	Colombia	****	****			Filed	Published
****	Costa Rica	****	****			Filed	Filed
****	Dominican Republic	****	****			Filed	Published
****	Ecuador	****	****			Filed	Filed
****	Egypt	****	****			Filed	Filed
****	El Salvador	****	****			Filed	Filed
****	Eurasian Patent Convention	****	****			Filed	Published
****	European Patent Convention	****	****			Filed	Published
****	Guatemala	****	****			Filed	Filed
****	Gulf Cooperation Council	****	****			Filed	Filed
****	Honduras	****	****			Filed	Filed
****	Hong Kong	****	****			Filed	Published
****	India	****	****			Filed	Filed
****	Indonesia	****	****			Filed	Filed
****	Israel	****	****			Filed	Filed
****	Japan	****	****			Filed	Published
****	Jordan	****	****			Filed	Filed
****	Lebanon	****	****			Filed	Filed
****	Macao					Docketed	Mailed
****	Malaysia	****	****			Filed	Filed
****	Mexico	****	****			Filed	Published
****	Morocco	****	****			Filed	Filed
****	New Zealand	****	****			Filed	Filed

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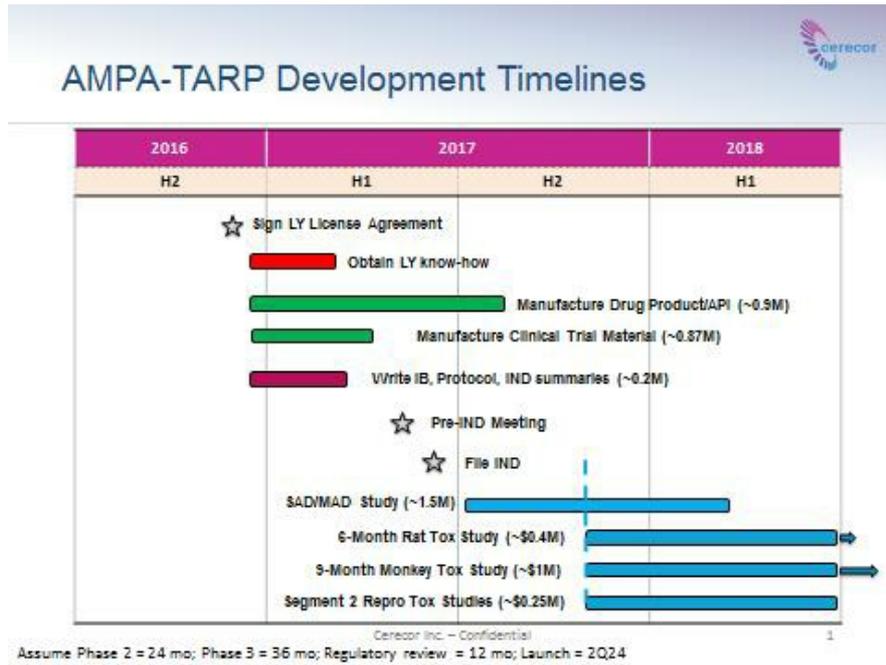
****	Nigeria	****	****			Filed	Case Allowed
****	Pakistan	****	****			Filed	Filed
****	Panama	****	****			Filed	Published
****	Patent Cooperation Treaty	****	****			Inactive	National
****	Peru	****	****			Filed	Published
****	Philippines	****	****			Filed	Filed
****	Korea South	****	****			Filed	Published
****	Singapore	****	****	****	****	Granted	Granted
****	South Africa	****	****			Filed	Filed
****	Sri Lanka	****	****			Filed	Filed
****	Taiwan	****	****			Filed	Published
****	Thailand	****	****			Filed	Filed
****	Trinidad & Tobago	****	****			Filed	Filed
****	Tunisia	****	****			Filed	Filed
****	Ukraine	****	****			Filed	Filed
****	United States	****	****	****	****	Granted	Granted
****	Venezuela	****	****			Filed	Published
****	Vietnam	****	****			Filed	Filed
****	AAAA- Series Summary					Docketed	Mailed
****	Patent Cooperation Treaty	****	****			Filed	Published
****	Taiwan	****	****			Filed	Published
****	United States	****	****			Filed	Filed

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Attachment 3.02(a)

**Initial Development Plan**



**Development Path for 2016/2017/2018**

**Technology Transfer:**

. \* \* \* \*

**Non-Clinical:**

- Write IND summaries
- . \* \* \* \*
- Plan and conduct 6-month Rat Toxicity Study (2017/2018)
- Plan and conduct 9-month Monkey Toxicity Study (2017/2018)
- Plan and conduct Segment 2 Repro Toxicity Studies (2017/2018)

**Regulatory:**

- IND development and submission to FDA
- . \* \* \* \*

**CMC:**

- Initiate discussion with SynTheAll Pharmaceutical CO., Ltd. (STA), a subsidiary of WuXi AppTec. regarding the product transfer from Lilly to Cerecor

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- Re-certify current API and reference standard by 2Q2016
- Manufacture, package and label CTM using the current API supply for the SAD/MAD studies by 1H2017
- Write CMC Module 2 and 3 sections of the IND by 2Q2017
- Manufacture API at STA for preliminary Tox studies by 3Q2-17

**Clinical:**

- \* \* \* \*
- Write IND summaries
- Finalize Phase 1 SAD/MAD protocols and Phase 2/3 strategy
- \* \* \* \*
- Anticipate Phase 1 study start: 2H2017; study end: 1H2018

**Intellectual Property:**

- \* \* \* \*

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Initial Press Release



**DRAFT – NOT FOR  
RELEASE**

**Cerecor Announces Acquisition of Phase 1-ready TARP- $\gamma$ 8-AMPA Receptor Antagonist  
(CERC-611) from Lilly**

*Phase 1 development for epilepsy expected to commence in 2017*

**BALTIMORE, September 12, 2016** - Cerecor Inc. (NASDAQ: CERC), a clinical-stage biopharmaceutical company developing treatments to make a difference in the lives of patients with neurological and psychiatric disorders, today announced that it has acquired exclusive, worldwide rights from Eli Lilly and Company (“Lilly”) to develop and commercialize LY3130418 (now designated as CERC-611). CERC-611 is a Phase 1-ready, potent and selective Transmembrane AMPA Receptor Regulatory Protein (TARP)- $\gamma$ 8-dependent AMPA receptor antagonist. TARPs are a fairly recently discovered family of proteins that have been found to associate with and modulate the activity of AMPA receptors. TARP- $\gamma$ 8-dependent AMPA receptors are localized primarily in the hippocampus, a region of importance in complex partial seizures and particularly relevant to seizure origination and/or propagation. Research also suggests that selectively targeting individual TARPs may enable selective modulation of specific brain circuits without globally affecting synaptic transmission which may lead to improved efficacy, safety and tolerability. Cerecor expects to submit an investigational new drug application (“IND”) to the United States Food and Drug Administration (“FDA”) and, upon acceptance of the IND by the FDA, commence Phase 1 development of CERC-611 in 2017.

CERC-611 was discovered and developed by Lilly for the treatment of epilepsy, a neurological disorder affecting over 50 million people worldwide, 150,000 new cases are diagnosed in the US annually, and 30-40% of treated patients are resistant to current pharmacotherapies with only 8% of treated patients being maintained seizure free. The disorder, if not controlled can lead to severe pathology and death. “There is a significant unmet need for new mechanisms that provide a new approach to treatment of epilepsy with improved efficacy, safety, tolerability and ease-of-use,” said Ron Marcus, MD, Chief Medical officer and Head, Regulatory Affairs at Cerecor.

AMPA receptor antagonists are known anticonvulsant agents and their ability to modulate excitatory neurotransmission is key to their anti-epileptic therapeutic potential. However, since AMPA receptor activity is so ubiquitous in the central nervous system (“CNS”), a non-selective AMPA antagonist approach affects many areas of the CNS resulting in undesired effects, such as ataxia, sedation, falls, and/or dizziness, which are shared by all known general or broad spectrum AMPA receptor antagonists. Typically, doses of these medications needed to obtain anti-convulsant activity are close to, or overlap with, doses at which undesired effects are observed. “Because of the predominant hippocampal location of TARP- $\gamma$ 8-dependent AMPA receptors, we believe that the efficacy and side effect profile of CERC-611 may represent an improvement compared to current antiepileptics,” said Uli Hacksell, Ph.D., Cerecor’s CEO, President and Chairman. “We are excited to make CERC-611 a key addition to our pipeline and we expect to file an IND and commence Phase 1 clinical in 2017.”

Under the terms of the agreement, Cerecor will immediately assume full development and commercialization responsibilities of CERC-611. Lilly will receive an upfront licensing fee as well as milestone and tiered royalty payments.

**About CERC-611**

CERC-611 (TARP- $\gamma$ 8-AMPA) is a potent and selective TARP- $\gamma$ 8-dependent AMPA receptor antagonist that we believe is the first molecule to selectively target and functionally block regionally-specific AMPA receptors after oral dosing. This selectivity was engineered into CERC-611 using structure-activity relationship information to achieve selective blockade of the AMPA receptor regulator protein or TARP gamma 8 ( $\gamma$ 8) (high density expression in hippocampus, a region of importance in partial epilepsies) while sparing AMPA receptors thought to be associated with TARP- $\gamma$ 2 (high density expression in cerebellum regulating the ataxia and falling associate with broad spectrum AMPA receptor antagonists).

CERC-611 has been observed to have positive preclinical activity in multiple animal models of epilepsy, neuropathic pain, and depression.

#### **About Cerecor**

Cerecor is a clinical-stage biopharmaceutical company developing innovative drug candidates to make a difference in the lives of patients with neurological and psychiatric diseases. We are committed to the development of drugs that improve lives by applying our extensive knowledge and experience in central nervous system disorders. Cerecor is currently pursuing the development of two clinical Phase 2-stage product candidates: CERC-301 and CERC-501.

CERC-301 as an oral, NR2B specific N-methyl-D-aspartate receptor antagonist that is currently in a Phase 2 clinical trial as an oral, rapidly acting adjunctive treatment for patients with severe major depressive disorder (“MDD”) who are failing to achieve an adequate response to their current antidepressant treatment. We expect top-line data from this trial in the first half of 2017. Cerecor received fast track designation by the United States Food and Drug Administration in November 2013 for CERC-301 for the treatment of MDD. We believe CERC-301 has the potential to be a first-in-class medication that may significantly reduce depressive symptoms in a matter of days.

CERC-501 is a potent and selective kappa opioid receptor (“KOR”), antagonist that is currently in a Phase 2 clinical trial for smoking cessation that is expected to provide top-line data in December 2016. In addition to Cerecor’s Phase 2 trial, three externally-funded clinical trials are being conducted to evaluate the use of CERC-501 in treating depressive symptoms, stress related smoking relapse and cocaine addiction. One study is being conducted under the auspices of the National Institute of Mental Health, the second is a collaboration between Cerecor and Yale investigators with funding from the National Institutes of Health and the third study is being conducted at Rockefeller University Hospital and is funded by a private foundation.

Cerecor has one preclinical stage asset, CERC-406, a brain penetrant catechol-O-methyltransferase inhibitor with potential procognitive activity.

For more information about the Company and its products, please visit [www.cerecor.com](http://www.cerecor.com) or contact Mariam E. Morris, Chief Financial Officer, at (443) 304-8002.

#### **Forward-Looking Statements**

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Cerecor’s control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Cerecor’s plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “continue,” “seeks,” “aims,” “predicts,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential” or similar expressions (including their use in the negative), or by discussions of future matters such as the development of product candidates or products, technology enhancements, possible changes in legislation, and other statements that are not historical. These statements are based upon the current beliefs and expectations of Cerecor’s management but are subject to significant risks and uncertainties, including those detailed in Cerecor’s filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Cerecor expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Cerecor’s expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

#### **Media Contact:**

MacDougall Biomedical Communications  
Joe Rayne – 781-235-3060  
[ir@cerecor.com](mailto:ir@cerecor.com)

[Cerecor, Inc. Letterhead]

October 10, 2016

Via FedEx and Email

Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, Indiana 46285  
Attention: General Counsel  
Fax: 317-433-3000

Re: Addendum to Effective Date of License Agreement to develop and commercialize  
LY3130481

Sir or Madam:

The License Agreement entered into by and between Eli Lilly and Company (“Lilly”) and Cerecor, Inc. (“Cerecor”) for Cerecor to develop and commercialize the Transmembrane AMPA Receptor Regulatory Protein (TARP) gamma-8-dependent AMPA receptor antagonist designated as LY3130481 was dated and effective September 8, 2016. The actual date of signing was September 22, 2016.

This letter addendum hereby serves as notification by Cerecor of its intention, and by counter-signature below, of agreement and acceptance by Lilly, to amend the effective date of the License Agreement from September 8, 2016 to September 22, 2016. Due to the time-sensitive nature of the SEC filings and reporting procedures, Cerecor respectfully requests that Lilly provide the acknowledgement below, to amend the effective date of the License Agreement.

Sincerely,

/s/ Uli Hacksell

Uli Hacksell, PhD  
CEO & President  
Cerecor Inc  
400 East Pratt Street, Suite 606  
Baltimore, MD 21202

Acknowledgement and Agreement:

Lilly hereby acknowledges the correction to the effective date of the License Agreement and agrees that the License Agreement has become effective September 22, 2016, and that no further action is required to make this change to the effective date.

Name: /s/ Jan M. Lundberg

Title: Executive Vice President, Science and Technology, and President, Lilly Research  
Laboratories

Date: October 13, 2016

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**CERTIFICATION OF PERIODIC REPORT  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Uli Hacksell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cerecor 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 8, 2016

/s/ Uli Hacksell

Uli Hacksell  
President and Chief Executive Officer  
(Registrant's Principal Executive Officer)

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**CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Mariam E. Morris, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cerecor 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 8, 2016

/s/ Mariam E. Morris

Mariam E. Morris  
Chief Financial Officer  
(Registrant's Principal Financial and Accounting  
Officer)

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

In connection with the Quarterly Report of Cerecor Inc. (the "Registrant") on Form 10-Q for the quarter ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Uli Hacksell, Chief Executive Officer of the Registrant, and I, Mariam E. Morris, Chief Financial Officer of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 8, 2016

By: /s/ Uli Hacksell  
Name: **Uli Hacksell**  
Title: **Chief Executive Officer  
(Registrant's Principal Executive Officer)**

Date: November 8, 2016

By: /s/ Mariam E. Morris  
Name: **Mariam E. Morris**  
Title: **Chief Financial Officer  
(Registrant's Principal Financial and Accounting Officer)**

*The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Cerecor Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*

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