

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File No. 001-36830

**CARBYLAN THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**39899 Balentine Drive , Suite 200, Newark, California**  
(Address of principal executive offices)

**20-0915291**  
(I.R.S. Employer  
Identification No.)

**94560**  
(Zip Code)

**510-933-8365**

(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 and 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  (Do not check if a smaller reporting company) 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 July 29, 2016, the registrant had 26,335,775 shares of common stock, \$0.001 par value per share, issued and outstanding.

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## Item 1. FINANCIAL STATEMENTS

## Carbylan Therapeutics, Inc.

**Condensed Balance Sheets**  
(in thousands, except share and per share amounts)  
(Unaudited)

	June 30, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,819	\$ 53,723
Prepaid expenses and other current assets	1,138	1,222
Total current assets	37,957	54,945
Property and equipment, net	—	805
Restricted cash	50	50
Other assets	—	991
Total assets	<u>\$ 38,007</u>	<u>\$ 56,791</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 187	\$ 1,460
Accrued expenses	1,713	1,327
Loan payable	—	1,455
Deferred licensing revenue	29	29
Total current liabilities	1,929	4,271
Loans payable, net of current portion	—	3,154
Deferred licensing revenue, net of current portion	42	56
Total liabilities	1,971	7,481
Commitments and contingencies (Note 5)		
Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized as of June 30, 2016 and December 31, 2015; no shares issued and outstanding as of June 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized as of June 30, 2016 and December 31, 2015; 26,335,775 shares issued and outstanding as of June 30, 2016 and 26,322,494 shares issued and outstanding as of December 31, 2015	27	27
Additional paid-in capital	122,586	121,904
Accumulated deficit	(86,577)	(72,621)
Total stockholders' equity	36,036	49,310
Total liabilities and stockholders' equity	<u>\$ 38,007</u>	<u>\$ 56,791</u>

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

**Carbylan Therapeutics, Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share amounts)  
(Unaudited)

	Three Months Ended				Six Months Ended			
	June 30,				June 30,			
	2016		2015		2016		2015	
<b>License Revenue</b>	\$	7	\$	7	\$	14	\$	14
<b>Operating Expenses:</b>								
Research and development		947		4,504		4,480		8,406
General and administrative		2,604		1,170		4,146		2,176
Restructuring and lease termination charges		3,420		—		3,420		—
Impairment of long-lived assets		—		—		1,460		—
<b>Total operating expenses</b>		<b>6,971</b>		<b>5,674</b>		<b>13,506</b>		<b>10,582</b>
<b>Loss from Operations</b>		<b>(6,964)</b>		<b>(5,667)</b>		<b>(13,492)</b>		<b>(10,568)</b>
<b>Other Income (expense):</b>								
Interest income		20		2		32		2
Interest expense		(406)		(169)		(493)		(1,005)
Loss on extinguishment of convertible promissory notes		—		(3,177)		—		(3,177)
Other income (expense), net		—		(1)		(3)		552
<b>Net Loss and Comprehensive Loss</b>	<b>\$</b>	<b>(7,350)</b>	<b>\$</b>	<b>(9,012)</b>	<b>\$</b>	<b>(13,956)</b>	<b>\$</b>	<b>(14,196)</b>
Net loss per share to common stockholders, basic and diluted	\$	(0.28)	\$	(0.40) <sup>(1)</sup>	\$	(0.53)	\$	(1.21) <sup>(1)</sup>
Weighted average common shares outstanding, basic and diluted		26,334,622		22,622,127 <sup>(1)</sup>		26,333,558		11,722,606 <sup>(1)</sup>

(1) Revised from a net loss per share to common stockholders, basic and diluted, of \$0.37 per share and 24,303,819 weighted average common shares outstanding, basic and diluted, as previously reported for the three months ended June 30, 2015, and a net loss of \$1.13 per share to common stockholders, basic and diluted, and 12,568,098 weighted average common shares outstanding, basic and diluted, as previously reported for the six months ended June 30, 2015.

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

**Carbylan Therapeutics, Inc.**  
**Condensed Statements of Cash Flows**  
(In thousands, unaudited)

	Six Months Ended	
	June 30,	
	2016	2015
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (13,956)	\$ (14,196)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	34	65
Gain on sale of property and equipment	(23)	—
Stock based compensation expense	680	155
Change in fair value of preferred stock warrant liability and derivative liability	—	(520)
Non-cash interest expense	58	157
Amortization of loan and convertible promissory notes discount	83	758
Loss on extinguishment of convertible promissory notes	—	3,177
Loss on extinguishment of loan payable	(250)	—
Impairment of long-lived assets	1,460	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	412	(924)
Other assets	59	—
Accounts payable	(1,273)	793
Accrued expenses	386	59
Deferred licensing revenue	(14)	(14)
Net cash used in operating activities	<u>(12,344)</u>	<u>(10,490)</u>
<b>Cash Flows from Investing Activities</b>		
Purchase of property and equipment	(245)	(259)
Sale of property and equipment	183	-
Net cash used in investing activities	<u>(62)</u>	<u>(259)</u>
<b>Cash Flows from Financing Activities</b>		
Proceeds from issuance of common stock upon exercise of options, net	2	149
Proceeds from issuance of common stock, net	—	68,084
Proceeds from convertible promissory notes	—	4,000
Repayment of loan payable	(4,500)	—
Net cash provided by (used in) financing activities	<u>(4,498)</u>	<u>72,233</u>
Net increase (decrease) in cash and cash equivalents	(16,904)	61,484
Cash and cash equivalents at beginning of period	53,723	3,897
Cash and cash equivalents at end of period	<u>\$ 36,819</u>	<u>\$ 65,381</u>
<b>Supplemental Cash Flow Information</b>		
Cash paid for interest	\$ 606	\$ 45
<b>Supplemental Disclosures of Non-cash Investing Activities</b>		
Transfer of long-term deposits to property and equipment	\$ 824	\$ —
<b>Supplemental Disclosures of Non-cash Financing Activities</b>		
Conversion of preferred stock warrants to common stock warrants	\$ —	\$ 347
Conversion of preferred stock to common stock	\$ —	\$ 39,556
Increase accrual of deferred public offering costs	\$ —	\$ 175
Derivative related to convertible promissory notes at issuance	\$ —	\$ 1,196
Beneficial conversion feature for convertible promissory notes	\$ —	\$ 519

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

## 1. Formation and Business of the Company

Carbylan Therapeutics, Inc. (the “Company”) is a clinical-stage specialty pharmaceutical company. The Company’s initial focus was on the development of Hydros-TA, its proprietary, intra-articular injectable product candidate to treat pain associated with osteoarthritis of the knee. The Company was incorporated in the state of Delaware on March 26, 2004 as Sentrx Surgical, Inc. The name of the Company was changed to Carbylan Biosurgery, Inc. on December 14, 2005. The name of the Company was changed to Carbylan Therapeutics, Inc. on March 7, 2014.

Since commencing operations and until April 2016, the Company has devoted substantially all of its efforts to identifying and developing product candidates for therapeutic markets, recruiting personnel and raising capital. The Company has devoted predominantly all of its resources to the preclinical and clinical development of, and manufacturing capabilities for, Hydros-TA. The Company has never been profitable and has not yet commenced commercial operations. At June 30, 2016, the Company had an accumulated deficit of approximately \$86.6 million.

In February 2016, the Company announced topline results of its COR1.1 trial, a Phase 3 clinical trial comparing treatment with Hydros-TA to treatment with Hydros and with TA, on a standalone basis. Hydros-TA met the first of its two primary endpoints but did not meet its second primary endpoint. In March 2016, the Company engaged a financial and strategic advisor, Wedbush PacGrow, to advise it on strategic alternatives. In April 2016, the Company announced that it had suspended further clinical development of Hydros-TA and that it is actively pursuing a strategic transaction, including a merger or acquisition of the Company. In April 2016, the board of directors approved a restructuring plan effective as of April 15, 2016 resulting in a reduction in force affecting 14 of the Company’s 17 employees, including two executive officers. The restructuring plan is intended to reduce operational costs to preserve capital and streamline the Company’s operations as it pursues a strategic transaction. As a result of the restructuring plan, the Company incurred one-time cash severance payments of approximately \$0.3 million and an aggregate of \$0.7 million in severance expenses, including the severance payments to the two executive officers. The charges associated with the restructuring plan were recorded in the quarter ended June 30, 2016.

In June 2016, the Company entered into a definitive share purchase agreement (“Share Purchase Agreement”), with KalVista Pharmaceuticals Ltd. (“KalVista”), a private company limited by shares incorporated and registered in England and Wales and the shareholders of KalVista, pursuant to which the shareholders of KalVista will become the majority owners of the Company. The number of shares of common stock of the Company to be issued in respect of each KalVista share will be based upon the relative stipulated values of each of the Company and KalVista as determined pursuant to the Share Purchase Agreement. The stipulated value of the Company is subject to downward adjustment based upon the Company’s net cash balance at the closing of the transaction. Assuming that no such adjustment is applicable, immediately following the closing of the transaction, KalVista equity holders are expected to own approximately 81.0% of the outstanding common stock of the Company on a fully-diluted basis. Consummation of the transaction is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company of the transactions contemplated by the Share Purchase Agreement and related matters. The Share Purchase Agreement contains certain termination rights for both the Company and KalVista, and further provides that, upon termination of the Share Purchase Agreement under specified circumstances, the Company may be required to pay KalVista a termination fee of \$3.0 million and/or to reimburse certain expenses incurred by KalVista in an amount up to \$1.0 million.

In March 2016, the Company determined that it would not occupy the Newark Lease facility. (See Note 5.) As a result, the Company recorded an asset impairment charge consisting primarily of leasehold improvements for the Newark Lease of approximately \$1.1 million. In June 2016, the Company entered in to a lease termination agreement with the lessor and agreed to the termination of the lease and to surrender the leased premises by June 30, 2016. The Company paid a one-time termination fee of \$2.45 million on June 27, 2016 and surrendered the premises. (See Note 5.)

In June 2016, the Company repaid in full its outstanding loan with Silicon Valley Bank pursuant to its Loan and Security Agreement originally entered into in October 2011, as well as the final interest payment and various fees. The total payment was \$4.6 million, and the Loan and Security Agreement has terminated. There are no remaining aggregated annual payments under the Loan and Security Agreement as of June 30, 2016. (See Note 6.)

In March 2016, the Company received a deficiency letter from the Listing Qualifications Department (the “Staff”) of The NASDAQ Stock Market notifying the Company that, for the last 30 consecutive business days, the bid price for the Company’s common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(a)(1) (the “Rule”). In accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company was provided an initial period of 180 calendar days, or until September 12, 2016, to regain compliance with the Rule. If, at any time before September 12, 2016, the bid price for the Company’s common stock closes at \$1.00 or more for a minimum of 10 consecutive business days as required under Listing Rule 5810(c)(3)(A), the Staff would provide written notification to the Company that it complies with the Rule. On June 13, 2016, the Company received a notice from the Listing Qualifications Department of The NASDAQ Stock Market advising the Company that it has regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5450(a)(1) for continuous listing on The Nasdaq Global Market as a result of the bid price of the Company’s common stock having closed at or above \$1.00 per share for the 10 consecutive business days prior to the date of the notice.

In March 2015, the Company’s board of directors and stockholders approved a 4-for-1 reverse stock split of the Company’s common and preferred stock. The Company filed an amendment to its certificate of incorporation effecting the reverse stock split on March 13, 2015. All share and per share amounts contained in these financial statements and notes thereto, have been adjusted retroactively to reflect the reverse stock split.

On April 8, 2015, the Company’s registration statement on Form S-1 (File No. 333-201278) relating to the initial public offering of its common stock was declared effective by the SEC. The initial public offering closed on April 14, 2015 at which time the Company sold 14,950,000 shares of common stock, which included 1,950,000 shares of common stock purchased by the underwriters upon the full exercise of their option to purchase additional shares of common stock. The Company received cash proceeds of approximately \$66.3 million from the initial public offering, net of underwriting discounts and commissions and offering costs paid by the Company.

Prior to the closing of the initial public offering, all outstanding shares of convertible preferred stock converted into 8,268,531 shares of common stock with the related carrying value of \$39.6 million reclassified to common stock and additional paid-in capital. In addition, all convertible preferred stock warrants were converted into warrants exercisable for common stock and the convertible promissory notes were converted in to 2,287,120 shares of common stock.

On April 14, 2015, the Company filed its Amended and Restated Certificate of Incorporation, authorizing 105,000,000 shares of capital stock, including 100,000,000 shares of authorized common stock and 5,000,000 shares of authorized undesignated preferred stock. Both the common stock and preferred stock have a par value of \$0.001 per share. There are no shares of preferred stock outstanding at June 30, 2016.

## **2. Summary of Significant Accounting Policies and Basis of Presentation**

### ***Basis of Presentation***

The accompanying interim condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements and reflect all adjustments which are, in the opinion of management, necessary to a fair statement of the results for the period presented herein. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements. These interim financial results are not necessarily indicative of the results to be expected for the year ending December 31, 2016, or for any other future annual or interim period. The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Company’s Annual Report on Form 10-K filed on March 30, 2016 with the SEC.

### ***Use of Estimates***

The preparation of the interim condensed financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, the Company evaluates its estimates, including those related to common stock, stock-based compensation expense, warrant liabilities, accruals, derivative liability, deferred tax valuation allowance and revenue recognition. Management bases its estimates on historical experience or on various other assumptions, including information received from its service providers, which it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

### ***Risks and Uncertainties***

Medicinal drug product candidates, like those previously being developed by the Company, require approvals from the U.S. Food and Drug Administration (“FDA”) or foreign regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals and any failure to receive approval or delay in approval may have a material adverse impact on the business and financial statements of the sponsoring company.

If the Company’s strategic transaction with KalVista is not consummated and it decides to continue its historical business operations, the Company may require substantial additional funding to operate. There can be no assurance that such financing will be available or will be at terms acceptable by the Company. Additionally, the Company will then be subject to risks common to companies in the pharmaceutical industry with no commercial operating history, including, but not limited to, dependency on the clinical and commercial success of its product candidates, ability to obtain regulatory approval of its product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, significant competition and untested manufacturing capabilities.

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

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company invests its excess cash in money market accounts. The Company’s cash and cash equivalents are held by a single financial institution and all cash is held in the United States. Such deposits may, at times, exceed federally insured limits. The Company has not recognized any losses during the periods presented and management does not believe that the Company is exposed to significant credit risk from its cash and cash equivalents.

### ***Segment Reporting***

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company is a specialty pharmaceutical company focused on the development and commercialization of novel and proprietary therapies that address significant unmet medical needs. No product revenue has been generated since inception, and all assets are held in the United States.

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

The Company considers all highly liquid investments purchased with an original maturity date of 90 days or less on the date of purchase to be cash equivalents. The Company invests its cash in bank deposits and money market funds.

### ***Restricted Cash***

The Company is required to guarantee the credit limit on its corporate credit card with a certificate of deposit of \$50,000. The balance is included as restricted cash on the condensed balance sheets.

### ***Beneficial Conversion Feature***

From time to time, the Company may issue convertible promissory notes that have conversion prices that create an embedded beneficial conversion feature on the issuance date. A beneficial conversion feature exists on the date a convertible promissory note is issued when the fair value of the underlying common stock to which the note is convertible into is in excess of the remaining unallocated proceeds of the note after first considering the allocation of a portion of the note proceeds to the fair value of any attached equity instruments, if any related equity instruments were granted with the debt. The intrinsic value of the beneficial conversion feature is recorded as a debt discount with a corresponding amount to additional paid-in capital. The debt discount is amortized to interest expense over the term of the note using the effective interest method.

### ***Embedded Derivatives Related to Convertible Promissory Notes***

Embedded derivatives that are required to be bifurcated from the underlying debt instrument (i.e. host) are accounted for and valued as a separate financial instrument. The Company evaluated the terms and features of the convertible promissory notes issued in September 2014 and February 2015 and identified embedded derivatives requiring bifurcation and accounting at fair value because the economic and contractual characteristics of the embedded derivatives met the criteria for bifurcation and separate accounting due to the conversion features (see Note 7 for a description of the conversion features).



### ***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are as follows:

Computer equipment	3 years
Lab equipment	3 years
Furniture and fixtures	5 years
Machinery and equipment	3 years
Manufacturing equipment	7 years

Leasehold improvements are amortized over the lesser of their useful lives or the term of the lease. Upon sale or retirement of the assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is recognized in the accompanying interim condensed statement of operations and comprehensive loss in operating expenses. Maintenance and repairs are charged to operations as incurred.

### ***Long-lived assets***

The Company assesses the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value of such assets, or asset groups, may not be recoverable. Whenever events or changes in circumstances suggest that the carrying amount of long-lived assets may not be recoverable, the future undiscounted cash flows expected to be generated by the asset, or asset groups from its use or eventual disposition is estimated. If the sum of the expected future undiscounted cash flows is less than the carrying amount of those assets, or asset groups, an impairment loss is recognized based on the excess of the carrying amount over the fair value of the assets, or asset groups.

### ***Pre-clinical and Clinical Trial Accruals***

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with clinical research organizations that conduct and manage preclinical and clinical trials on the Company's behalf. If contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, the Company modifies the estimates of accrued expenses accordingly. To date, there have been no material differences from its estimates to the amount actually incurred.

### ***Preferred Stock Warrant Liability***

The Company accounts for its warrants as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on the Company's accompanying balance sheets at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense), net in the statements of operations and comprehensive loss.

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

Costs incurred to further the Company's research and development include salaries and related employee benefits, stock-based compensation expense, costs associated with clinical studies, nonclinical research and development activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contract research and manufacturing organizations that conduct certain research and development activities on behalf of the Company.

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

The Company maintains performance incentive plans under which incentive stock options and non-qualified stock options may be granted to employees and non-employees. The Company accounts for stock-based compensation arrangements with employees in accordance with ASC 718, *Compensation — Stock Compensation*. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all share-based payments including stock options.

The Company's determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option-pricing model, and is impacted by its common stock price as well as changes in assumptions regarding a number of subjective variables. These variables include, but are not limited to, expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends.

The fair value is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period), on a straight-line basis. Stock-based compensation expense recognized at fair value includes the impact of estimated forfeitures. The Company estimates future forfeitures at the date of grant and revises the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

### **Income Taxes**

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company accounts for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

### **Net Loss per Share Attributable to Common Stockholders**

Basic earnings per share to common stockholders is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the periods presented. The computation of diluted earnings per share is similar to the computation of basic earnings per share, except that the denominator is increased for the assumed exercise of dilutive options and other potentially dilutive securities using the treasury stock method unless the effect is antidilutive.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2014-09, "Revenue from Contracts with Customers," requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This guidance is based on the principle that revenue is recognized to depict the transfer of 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. This guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. This guidance can be adopted either retrospectively to each prior reporting period presented, or retrospectively with a cumulative-effect adjustment recognized as of the date of adoption. The original effective date of this guidance for public entities was for annual reporting period beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), to defer the effective date of this guidance by one year, to the annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. A reporting entity may choose to early adopt the guidance as of the original effective date. The FASB has issued several updates to the standard which i) defer the original effective date from January 1, 2017 to January 1, 2018, while allowing for early adoption as of January 1, 2017 (ASU 2015-14); ii) clarify the application of the principal versus agent guidance (ASU 2016-08); and iii) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10). In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers (Topic 606) Narrow-Scope Improvements and Practical Expedients, to address certain narrow aspects of the guidance including collectability criterion, collection of sales taxes from customers, noncash consideration, contract modifications and completed contracts. This issuance does not change the core principle of the guidance in the initial topic issued in May 2014. The Company does not anticipate an early adoption, and is currently evaluating the impact on its financial statements upon the adoption of this guidance.

In August 2014, the FASB issued ASU NO. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASU 2014-15. ASU 2014-15 requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company does not anticipate an early adoption, and is currently evaluating the impact on its financial statements upon the adoption of this guidance.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact on its financial statements upon the adoption of this guidance.

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718). This guidance identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance is effective for annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact on its financial statements upon the adoption of this guidance.

### 3. Fair Value Measurements

The Company follows ASC 820-10, Fair Value Measurements and Disclosures, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.
- Level 3 Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The Company's investments in money market funds are measured at fair value on a recurring basis. These money market funds are actively traded and reported daily through a variety of sources. The fair value of the money market fund investments is classified as Level 1.

The fair value of the certificates of deposit is classified as Level 2 due to the nature of a contractual restriction with a financial institution that requires the certificate of deposit to remain in place as collateral for the credit card, and therefore the ability to liquidate the investment is limited.

There were no transfers between Level 1 and Level 2 during the periods presented.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. During 2014 and through the date of the initial public offering in April 2015, the Company estimated the fair value of the warrant liability. The Company used the Black-Scholes option-pricing method to calculate the fair value of the warrant liability. Generally, increases or decreases in the fair value of the underlying convertible preferred stock resulted in a similar impact in the fair value measurement of the warrant liability.

The fair value of the derivative of the September 2014 and February 2015 convertible promissory notes (see Note 7) was recorded as a derivative liability instrument that is measured at fair value at each reporting period. In connection with the initial public offering, the convertible promissory notes were converted in to shares of common stock, and the derivative liability is therefore not present at June 30, 2016. At March 31, 2015, the Company remeasured the fair value of the derivative for the September 2014 and February 2015 convertible promissory notes by estimating the fair value of the convertible promissory notes with and without the conversion derivative. To calculate the fair value of the convertible promissory notes without the conversion derivative, the Company estimated the present value of the expected cash payments at an assumed discount rate. To calculate the fair value of the convertible promissory notes with the conversion feature, the Company calculated the present value of the convertible promissory notes upon conversion at an initial public offering, and the present value of the convertible promissory notes at an equity financing. The Company applied a probability of occurrence to all of the conversion scenarios and estimated a weighted value of the notes with the conversion feature. The difference between the fair value of the convertible promissory notes with and without the conversion features is the fair value of the derivative. In April 2015, the Company completed the initial public offering, and there was no further re-measurement of derivative.

The following table presents the Company's fair value hierarchy for assets and liabilities measured at fair value on a recurring and non-recurring basis:

	Fair Value Measurements as of June 30, 2016 (in thousands)			
	Quoted Price in Active Markets for Identical Assets Level 1	Significant other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
<b>Assets</b>				
Money market funds <sup>(1)</sup>	\$ 36,744	\$ —	\$ —	\$ 36,744
Certificate of deposit	—	50	—	50
	<u>\$ 36,744</u>	<u>\$ 50</u>	<u>\$ —</u>	<u>\$ 36,794</u>

	Fair Value Measurements as of December 31, 2015 (in thousands)			Total
	Quoted Price in Active Markets for Identical Assets Level 1	Significant other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	
<b>Assets</b>				
Money market funds <sup>(1)</sup>	\$ 53,625	\$ —	\$ —	\$ 53,625
Certificate of deposit	—	50	—	50
	<u>\$ 53,625</u>	<u>\$ 50</u>	<u>\$ —</u>	<u>\$ 53,675</u>

(1) Included in cash and cash equivalents in the Company's condensed balance sheet.

#### 4. Balance Sheet Components

##### Property and Equipment, Net

The following table represents the components of property and equipment (in thousands):

	June 30, 2016	December 31, 2015
Computer equipment	\$ -	\$ 30
Lab equipment	-	697
Furniture and fixtures	-	21
Machinery and equipment	-	262
Leasehold improvements	-	55
Construction in progress	-	368
	-	1,433
Less: Accumulated depreciation and amortization	-	(628)
Total property and equipment, net	<u>\$ -</u>	<u>\$ 805</u>

Depreciation expense for the six months ended June 30, 2016 and 2015, was \$34,000, and \$65,000, respectively.

The Company recorded an impairment charge of \$1.5 million during March 2016 in connection with its determination not to occupy the Newark Lease facility and to suspend further clinical development of Hydros-TA. An impairment charge of \$1.1 million was recorded, primarily related to leasehold improvements, furniture and fixtures for the Newark Lease facility that have no future use. Additionally, the Company determined that certain equipment used in the development of Hydros-TA was impaired and recorded an impairment charge of \$0.4 million. In May 2016, this equipment was sold for \$0.2 million, and an immaterial gain on the sale of the assets was recorded in operating expenses. Each of these impairment charges was measured using Level 1 inputs of the fair value hierarchy.

##### Accrued Liabilities

(in thousands)

	June 30, 2016	December 31, 2015
Accrued payroll and related expenses	\$ 94	\$ 727
Accrued restructuring	180	-
Accrued legal expenses	727	77
Accrued research and clinical trial expenses	153	338
Accrued professional services	529	185
Other accrued expenses	30	-
	<u>\$ 1,713</u>	<u>\$ 1,327</u>

## **5. Commitments and Contingencies**

### ***Operating Lease***

The Company leased its facilities in Palo Alto, California under a noncancelable operating lease which expired May 2016. The terms of the lease agreement required the Company to provide a security deposit of \$69,000. The security deposit is included in other assets on the accompanying condensed balance sheets. In June 2016, the Company vacated these premises. The Company had a sub-lease agreement with a tenant for approximately thirty-seven percent of the square footage of the corporate headquarters. Under this agreement, the Company received \$16,000 per month as rental income which is accounted for as a reduction of rent expense. The sub-lease agreement expired on February 29, 2016.

On July 13, 2015, the Company entered into a lease for an 18,704 square foot facility located in Newark, California (the "Newark Lease"), with office, R&D and laboratory space. Under the Newark Lease, the landlord provided an allowance of \$599,000 to fund certain improvements to the facility. The Newark Lease had an initial term of approximately six and a half years, with a monthly rental rate starting at \$2.65 per square foot in the first year of the lease, escalating each year by 3.0%. The annual rent obligation was expected to be approximately \$599,000 for the first year of the lease. The Company was responsible for certain other costs, such as insurance, taxes, utilities, maintenance and repairs, a property management fee, and reimbursement of certain expenses related to maintenance of common areas. The Company delivered a security deposit of approximately \$149,000 in connection with the execution of the Newark Lease, and this amount is recorded in other assets on the condensed balance sheets. In March 2016, the Company determined that it would not occupy the Newark Lease facility and recorded an asset impairment charge consisting primarily of leasehold improvements of approximately \$1.1 million. In June 2016, the Company entered in to a lease termination agreement with the lessor and agreed to the termination of the lease and to surrender the leased premises by June 30, 2016. The Company paid a one-time termination fee of \$2.45 million on June 27, 2016 and surrendered the premises.

As of June 30, 2016, there are no aggregate future minimum lease payments since there are no current operating leases.

Gross rent expense for the three months ended June 30, 2016 and 2015 was \$332,000 and \$110,000, respectively. The rental expense is reduced by the sublease rental income amounts of \$0 and \$48,000, respectively, for the three months ended June 30, 2016 and 2015. Gross rent expense for the six months ended June 30, 2016 and 2015 was \$507,000 and \$218,000, respectively. The rental expense is reduced by the sublease rental income amounts of \$37,000 and \$97,000, respectively, for the six months ended June 30, 2016 and 2015.

### ***Indemnification***

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. No amounts associated with such indemnifications have been recorded to date.

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that a liability has been incurred and that future expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual or disclosure at June 30, 2016.

## **6. Loan and Security Agreement**

In October 2011, the Company entered into a loan and security agreement (the "Loan and Security Agreement") with a financial institution. In September 2014, the Loan and Security Agreement was amended. The interest rate was 3.95% per annum and the loan was repayable in thirty-six equal monthly installments, following an eighteen-month interest only period. The final balloon interest payment was approximately \$0.5 million and was accreted over the life of the loan. The amendment was accounted for as a modification, and the unamortized debt discount as of the date of the modification was being amortized over the new loan period, using the effective interest rate method.

In June 2016, the Company repaid the loan in full, as well as the final interest payment and various fees. The total payment was \$4.6 million of accrued interest, the final balloon payment and principal, and the Loan and Security Agreement has terminated. There are no remaining aggregated annual payments under the Loan and Security Agreement as of June 30, 2016.

## **7. Convertible Promissory Notes**

On September 29, 2014 and February 19, 2015, the Company entered into convertible note purchase agreements and issued convertible promissory notes (the "Notes") in an aggregate principal amount of \$5.0 million and \$4.0 million, respectively, to several related parties that own more than 10% of the Company's capital stock. All principal and accrued interest on the Notes was converted to the Company's common stock upon the completion of the Company's initial public offering in April 2015. Upon conversion, 2,287,120 shares of common stock were issued.

The Notes provided that upon completion of an initial public offering, the Notes would automatically convert into a number of shares of the Company's common stock equal to the quotient obtained by dividing the entire principal amount and accrued interest on the Notes by 80% of the initial public offering price per share of the Company's common stock. The Notes bore interest at a rate of 5% per annum, compounded annually.

Due to the automatic conversion features contained in the Notes, the actual number of shares of common stock or preferred stock that would be required if a conversion of the Notes was made through the issuance of the Company's common or preferred stock could not be predicted prior to the conversion taking place. In addition, the conversion that would occur upon a change in control of the Company met the definition of a put option and was not closely related to the debt. As a result, the automatic conversion features and put option, exclusive of the Series B conversion feature, required derivative accounting treatment and were bifurcated from the Notes and marked to market each reporting period through the statement of operations and comprehensive loss. The fair value of the automatic conversion features and put option of the Notes, exclusive of the Series B conversion feature, were recorded as a derivative liability instrument and measured at fair value at each reporting period.

As of December 31, 2014, the Company estimated the fair value of the derivative by estimating the fair value of the Notes with and without the conversion derivative. To calculate the fair value of the Notes without the conversion derivative, the Company estimated the present value of the expected cash payments at an assumed discount rate of 8.25%. To calculate the fair value of the Notes with the conversion feature, the Company calculated the present value of the Notes upon conversion at an initial public offering, and the present value of the Notes at an equity financing. The risk-free rate for the assumed discount period is estimated at 0.05% and 0.15% in the respective conversion scenarios. The risk-free rate for the assumed discount period is estimated at 0.05% and 0.12% in the respective conversion scenarios at the valuation date of December 31, 2014. The Company applied a probability of occurrence to all of the conversion scenarios associated with the derivative and estimated a weighted value of the Notes with the conversion feature. The difference between the fair value of the Notes with and without the conversion features is the derivative. The fair value of the derivative was \$1,495,000 as of December 31, 2014.

Upon issuance of the February 2015 Notes, the Company calculated the derivative liability using the same methodology and assumptions as those used as of December 31, 2014 because there were not significant changes in the Company or in the operations of the Company that had occurred in that intervening time period. The additional derivative liability recorded upon issuance of the February 2015 Notes was \$1,196,000.

At March 31, 2015, the Company remeasured the fair value of the derivative liability for the Notes using a methodology similar to the methodology used at December 31, 2014, with a minimal discount period. The fair value of the derivative was \$2,287,000.

The Company determined that the Notes contain a beneficial conversion feature related to the conversion feature of the Notes into Series B convertible preferred stock. The beneficial conversion feature results from the difference between the fair value of the Company's common stock at the date of issuance and the Series B Preferred Stock Conversion price of \$4.8104 at the date of issuance. The beneficial conversion feature amounted to \$2,275,000 for the September 2014 Notes and \$158,000 for the February 2015 Notes as of the date of issuance of the respective Notes, and was recorded as a debt discount that would be amortized through the maturity date of the Notes.

## **8. Convertible Preferred Stock Warrants**

The Company issued warrants to purchase shares of the Company's convertible preferred stock at various times in connection with loans payable. Immediately prior to the closing of the initial public offering, all convertible preferred stock warrants were converted in to warrants exercisable for common stock.

The fair value of the convertible preferred stock warrant liability was remeasured as of each reporting period end. As of March 31, 2015 (the last reporting period end prior to the initial public offering), the Company remeasured the fair value of the convertible preferred stock warrant liability using a Black-Scholes option-pricing method with the following assumptions: the Company's initial public offering price of \$5.00 per share, a weighted average remaining life of 6.5 years, an expected volatility of 58.3%, a weighted average risk-free interest rate of 1.55% and no expected dividend. The Company evaluated the down-round protection provisions of the warrant agreements by using a Monte Carlo simulation model and determined that the impact of such provisions was immaterial to the fair value of the warrants at the reporting dates. The assumptions are further described as follows:

*Expected Time to liquidity event* — The Company estimated the time to liquidity event based on management’s analysis of the business, market conditions and clinical development.

*Expected Volatility* — The Company estimates the expected volatility based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected time to liquidity event. When selecting the publicly traded biopharmaceutical companies, the Company selected companies with comparable characteristics to it, including enterprise value and risk profiles, and with historical share price information sufficient to meet the time to liquidity event. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-Free Interest Rate* — The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected time to the liquidity event.

*Expected Dividend Rate* — The Company has never paid any dividends and does not plan to pay dividends in the foreseeable future, and, therefore, used an expected dividend rate of zero in the valuation model.

## **9. Common Stock**

As of June 30, 2016 the Company’s Amended and Restated Certificate of Incorporation, as amended, has authorized 100,000,000 shares of common stock at \$0.001 par value.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the holders of the Series A and B convertible preferred stock. As of June 30, 2016, no dividends have been declared.

## **10. Stock Option Plan**

Incentive stock options are granted with exercise prices not less than the estimated fair value of common stock, and non-statutory stock options may be granted with an exercise price of not less than 100% of the estimated fair value of the common stock on the date of grant. Options granted under the Plan expire no later than 10 years from the date of grant. Incentive stock options granted under the Plan vest over periods determined by the Board of Directors, generally over four years. Non-statutory stock options vest based on the terms of the individual agreement, generally from nine months to four years.

As of June 30, 2016, options for 1,420,806 shares have been issued under the 2015 Equity Plan. The number of shares available for issuance under the Company’s 2015 Equity Plan will be increased on the first day of each fiscal year beginning in 2016, by an amount equal to the lesser of (1) 1,200,000 shares of stock and (2) four percent (4%) of the outstanding shares of stock on the last day of the immediately preceding year. The maximum number of shares of the Company’s common stock that may be delivered in satisfaction of awards under the 2015 Equity Plan is 2,585,833 shares, inclusive of 750,000 shares authorized upon creation of the 2015 Plan and 1,053,299 shares added January 1, 2016.

### ***Stock Option Modifications***

On April 12, 2016, the Company’s Board of Directors approved a restructuring plan effective as of April 15, 2016 and resulting in a reduction in force of the Company’s employees. As part of the reduction in force, the Company terminated the employment of an executive officer and retained his services as a consultant to the Company. The executive will serve as a consultant to the Company through October 15, 2016, unless the consulting agreement is terminated earlier by either party. The related option awards will continue to vest during the consulting period and if the consulting period is terminated prior to the end date, the executive will receive accelerated vesting of the portion of the stock options that would have vested had the services continued to the end of the consulting period. Additionally, all options awarded to the executive will remain outstanding, though they will not continue to vest, until the earliest to occur of (1) the consummation of a change of control, (ii) March 8, 2017 and (iii) the original expiration date of the stock option. After the earliest to occur of such dates, all of the stock options will terminate to the extent still outstanding. If a change in control occurs prior to the termination of the stock options the vesting will accelerate for 100% of the executive’s then-unvested stock options. The incremental fair value that is attributable to the modified options was insignificant.

The Company terminated the employment of another executive as part of the reduction in force described in the preceding paragraph. The executive received accelerated vesting of his option awards that would have vested during the six month period following April 15, 2016. The incremental fair value of the modified awards was insignificant.

As of June 30, 2016, the Company had 2,295,424 shares issuable upon exercise of outstanding option awards.



Total stock-based compensation expense related to options and awards granted was allocated as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and Development	\$ 56	\$ 1	\$ 208	\$ 10
General and administrative	256	36	472	145
Total	\$ 312	\$ 37	\$ 680	\$ 155

### 11. Related Party Transactions

In September 2014 and February 2015, the Company issued the Notes to several related parties that own more than 10% of the Company’s capital stock (see Note 7). Upon completion of the initial public offering, those Notes were converted in to shares of the Company’s common stock.

### 12. Income Taxes

The Company’s effective tax rate is 0% for income tax for the three and six months ended June 30, 2016 and the Company expects that its effective tax rate for the full year 2016 will be 0%. Based on the weight of available evidence, including cumulative losses since inception and expected future losses, the Company has determined that it is more likely than not that the deferred tax asset amount will not be realized and therefore a valuation allowance has been provided on net deferred tax assets.

The Company has substantial net operating loss carry forwards available to offset future taxable income for federal and state income tax purposes. The ability to utilize the net operating losses may be limited due to changes in our ownership as defined by Section 382 of the Internal Revenue Code (the “Code”). Under the provisions of Sections 382 and 383 of the Code, a change of control, as defined in the Code, may impose an annual limitation on the amount of the Company’s net operating loss and tax credit carryforwards, and other tax attributes that can be used to reduce future tax liabilities.

The Company files tax returns for U.S. Federal and State of California. The Company is not currently subject to any income tax examinations. Since the Company’s inception, the Company had incurred losses from operations, which generally allows all tax years to remain open.

The gross amount of unrecognized tax benefits as of June 30, 2016 is approximately \$0.8 million related to the reserve on R&D credits, none of which will affect the effective tax rate if recognized due to the valuation allowance. The Company does not expect any material changes in the next twelve months in unrecognized tax benefits.

The Company recognizes interest and/or penalties related to uncertain tax positions. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected in the period that such determination is made. Any interest and penalties are recognized in income tax expense. The Company currently has no interest and penalties related to uncertain tax positions.

### 13. Subsequent Events

On July 28, 2016, we received a deficiency letter from the Listing Qualifications Department of The NASDAQ Stock Market notifying us that, for the preceding 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(a)(1). In accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company has been provided an initial period of 180 calendar days, or until January 24, 2017, to regain compliance with the Rule. If, at any time before January 24, 2017, the bid price for the Company’s common stock closes at \$1.00 or more for a minimum of 10 consecutive business days as required under Listing Rule 5810(c)(3)(A), the Staff will provide written notification to the Company that it complies with the Rule.

If the Company does not regain compliance with the Rule by January 24, 2017, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and will need to provide written notice to the Staff of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary.

*You should read the following discussion in conjunction with our condensed financial statements (unaudited) and related notes included elsewhere in this report. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “intend,” “predict,” “seek,” “contemplate,” “potential” or “continue” or the negative of these terms or other comparable terminology. These forward-looking statements, include, but are not limited to, the success, cost and timing of our product development activities and clinical trials and projections as to the timing and success of any potential strategic transaction. Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” in our Annual Report on Form 10-K or described elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Unless the context requires otherwise, in this Quarterly Report on Form 10-Q, the terms “Carbylan,” “Company,” “we,” “us” and “our” refer to Carbylan Therapeutics, Inc., a Delaware corporation.*

## **Overview**

We are a clinical-stage specialty pharmaceutical company. Our initial focus was on the development of Hydros-TA, our proprietary, intra-articular (“IA”), injectable product candidate to treat pain associated with osteoarthritis (“OA”), of the knee. Current joint injection, or intra-articular, treatments for OA pain include corticosteroids, which provide short-term relief, and viscosupplements, which provide relief over the longer-term. In contrast, Hydros-TA utilizes our proprietary cross-linking technology to deliver both rapid pain relief with a low dose corticosteroid triamcinolone acetonide, or TA, and sustained pain relief from our novel hyaluronic acid viscosupplement.

In February 2016, we announced topline results of our COR1.1 trial, a Phase 3, multi-center, international, randomized, double-blind, three-arm trial that enrolled 560 patients with grade two and grade three OA of the knee, comparing treatment with Hydros-TA to treatment with Hydros and with TA, on a standalone basis. The primary endpoints of the trial were changes from baseline in the WOMAC A pain scores at week 2 for Hydros-TA versus Hydros and at week 26 for Hydros-TA versus TA, as well as a safety assessment of adverse events. Hydros-TA met the first of its two primary endpoints, demonstrating a statistically significant improvement from baseline in the WOMAC A pain score at week 2 versus Hydros. In addition, Hydros-TA maintained a significant reduction in pain from baseline over 26 weeks. However, patients in the TA arm continued to show an unexpected significant reduction in pain through 26 weeks. Given the comparable effectiveness at 26 weeks, COR1.1 did not meet its second primary endpoint. Hydros-TA was generally well tolerated with no treatment related serious adverse events, or SAEs, and adverse events, or AEs, were mostly mild and included arthralgia (knee pain) and swelling.

In March 2016, we engaged a financial and strategic advisor, Wedbush PacGrow, to advise us on strategic alternatives. Wedbush PacGrow has provided a range of advisory services aimed to enhance shareholder value. In April 2016, we announced that we had suspended further clinical development of Hydros-TA and that we were actively pursuing a strategic transaction, including a merger or acquisition of the Company. In connection with this decision, we recorded a \$1.5 million asset impairment charge in the six months ended June 30, 2016 related to our determination in March 2016 not to occupy our recently leased facility in Newark and impairment of certain assets related to Hydros-TA.

In April 2016, we approved a restructuring plan effective as of April 15, 2016 resulting in a reduction in force affecting 14 of our 17 employees, including two executive officers. The restructuring plan is intended to reduce operational costs to preserve capital and streamline our operations as we pursue a strategic transaction. As a result of the restructuring plan, we incurred one-time cash severance payments of approximately \$0.3 million and an aggregate of \$0.7 million in severance expenses, including the severance payments to the two executive officers. The charges associated with the restructuring plan were recorded in the quarter ended June 30, 2016.

In June 2016, we entered into a definitive Share Purchase Agreement, with KalVista pursuant to which the shareholders of KalVista will become the majority owners of the Company. The number of shares of our common stock to be issued in respect of each KalVista share will be based upon the relative stipulated values of each of the Company and KalVista as determined pursuant to the Share Purchase Agreement. The stipulated value of Carbylan is subject to downward adjustment based upon the Company’s net cash balance at the closing of the transaction. Assuming that no such adjustment is applicable, immediately following the closing of the transaction, KalVista equity holders are expected to own approximately 81.0% of our outstanding common stock on a fully-diluted

basis. Consummation of the transaction is subject to certain closing conditions, including, among other things, approval by our stockholders of the transactions contemplated by the Share Purchase Agreement and related matters. The Share Purchase Agreement contains certain termination rights for both the Company and KalVista, and further provides that, upon termination of the Share Purchase Agreement under specified circumstances, we may be required to pay KalVista a termination fee of \$3.0 million and/or to reimburse certain expenses incurred by KalVista in an amount up to \$1.0 million.

In connection with the proposed transaction with KalVista, in June 2016, we terminated our lease for our facility in Newark and paid a one-time termination fee of \$2.45 million on June 27, 2016. In addition, in June 2016, we repaid all outstanding principal and accrued interest under our Loan and Security Agreement with Silicon Valley Bank. The total payment was \$4.6 million, and the Loan and Security Agreement has terminated.

We are currently devoting substantially all of our time and resources to consummating the strategic transaction with KalVista, however, there can be no assurance that such activities will result in the consummation of the transaction or that such transaction will deliver the anticipated benefits or enhance shareholder value.

As of June 30, 2016, we had an accumulated deficit of \$86.6 million and have incurred net losses of approximately \$14.0 million and \$14.2 million in the six months ended June 30, 2016 and 2015, respectively.

## **Financial Overview**

### ***Revenue***

We do not have any products approved for sale, and we have not generated any revenue from product sales since our inception. Our revenue to date has been generated from license revenue pursuant to our agreement with Jingfeng.

### ***Operating Expenses***

Most of our operating expenses to date have been related to the research and development activities of Hydros-TA.

*Research and Development Expenses.* Since our inception through April 2016, we have focused our resources on our research and development activities, including nonclinical and pre-clinical studies, clinical trials and chemistry manufacturing and controls. Our development expenses consist primarily of:

- expenses incurred under agreements with consultants, CROs and investigative sites that conduct our pre-clinical studies and clinical trials;
- costs of acquiring, developing and manufacturing clinical trial materials;
- personnel costs, including salaries, benefits, stock-based compensation and travel expenses for employees engaged in scientific research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated expenses for rent and maintenance of facilities, insurance and other general overhead.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our third-party vendors. We expect to continue to incur research and development costs as we complete the COR1.1 clinical trial.

We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past expenses have been in support of Hydros-TA.

The following table summarizes our research and development expenses by functional area:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Clinical development	\$ 332	\$ 1,617	\$ 1,273	\$ 2,584
Regulatory	102	453	411	845
Preclinical R&D	8	495	296	1,169
Personnel related	254	598	1,101	1,202
Manufacturing	251	1,341	1,399	2,606
Total research and development expenses	\$ 947	\$ 4,504	\$ 4,480	\$ 8,406

*General and administrative expenses.* General and administrative expenses consist of personnel costs, travel expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, bonus, benefits and stock-based compensation. General and administrative expenses are expensed as incurred.

For the three months ended June 30, 2016 and 2015 our general and administrative expenses totaled approximately \$2.6 million and \$1.2 million, respectively. For the six months ended June 30, 2016 and 2015, our general and administrative expenses totaled approximately \$4.1 million and \$2.2 million, respectively. We have implemented operating cost reductions to reduce overall cash burn as we pursue a strategic transaction. In June 2016, we entered into a definitive Share Purchase Agreement, with KalVista. We anticipate that our general and administrative expenses will increase in the future as a result of expenses related to this strategic activity.

*Asset impairment.* Whenever events or changes in circumstances suggest that the carrying amount of long-lived assets may not be recoverable, the future undiscounted cash flows expected to be generated by the asset from its use or eventual disposition is estimated. If the sum of the expected future undiscounted cash flows is less than the carrying amount of those assets, an impairment loss is recognized based on the excess of the carrying amount over the fair value of the assets.

During March, 2016, we recorded an impairment charge of \$1.5 million in connection with our determination not to occupy the Newark Lease facility and to suspend further clinical development of Hydros-TA.

*Restructuring and lease termination charges.* In June 2016, we entered in to a lease termination agreement with the lessor for the Newark lease facility and agreed to the termination of the lease and to surrender the leased premises by June 30, 2016. We paid a one-time termination fee of \$2.45 million on June 27, 2016 and surrendered the premises. Additionally, we incurred severance costs of \$0.6 million as a result of the restructuring plan effective as of April 15, 2016. Other restructuring and lease termination charges also include rental payments prior to the termination of the Newark lease facility of \$0.2 million and expenses for professional services of \$0.1 million.

#### **Other Income (Expense), Net**

*Interest income.* Interest income consists of interest earned on our cash and cash equivalents balances. The primary objective of our investment policy is capital preservation.

*Interest expense.* Interest expense consists of interest expense on amounts outstanding under our previously outstanding debt facility with Silicon Valley Bank ("SVB"), and convertible promissory notes that were issued, as well as non-cash interest expense related to the amortization of loan discounts and final loan interest payments.

*Other income (expense), net.* Other income (expense), net primarily consists of changes in the estimated fair value of the convertible preferred stock warrants and the derivative liability.

#### **Income Taxes**

The Company's effective tax rate is 0% for income tax for the three and six months ended June 30, 2016 and the Company expects that its effective tax rate for the full year 2016 will be 0%. Based on the weight of available evidence, including cumulative losses since inception and expected future losses, the Company has determined that it is more likely than not that the deferred tax asset amount will not be realized and therefore a valuation allowance has been provided on net deferred tax assets.

The Company files tax returns for U.S. Federal and State of California. The Company is not currently subject to any income tax examinations. Since the Company's inception, the Company had incurred losses from operations, which generally allows all tax years to remain open.

The Company recognizes the financial statement effects of a tax position when it becomes more likely than not, based upon the technical merits, that the position will be sustained upon examination. The Company does not expect any material changes in the next twelve months in unrecognized tax benefits.

The Company recognizes interest and/or penalties related to uncertain tax positions. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected in the period that such determination is made. Any interest and penalties are recognized as a component of other expense and interest expense, respectively, as necessary. The Company currently has no interest and penalties related to uncertain tax positions.

## Results of Operations

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

The following table summarizes our results of operations for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30,	
	2016	2015
<b>License Revenue</b>	\$ 7	\$ 7
<b>Operating Expenses:</b>		
Research and development	947	4,504
General and administrative	2,604	1,170
Restructuring and lease termination charges	3,420	-
Total operating expenses	6,971	5,674
<b>Loss from Operations</b>	<b>(6,964)</b>	<b>(5,667)</b>
<b>Other Income (expense):</b>		
Interest income	20	2
Interest expense	(406)	(169)
Loss on extinguishment of convertible promissory notes	-	(3,177)
Other income (expense), net	-	(1)
Total other income (expense)	(386)	(3,345)
<b>Net Loss and Comprehensive Loss</b>	<b>\$ (7,350)</b>	<b>\$ (9,012)</b>
Net loss per share to common stockholders, basic and diluted	\$ (0.28)	\$ (0.40)
Weighted average common shares outstanding, basic and diluted	26,334,622	22,622,127

#### License revenue

Revenues from the deferred upfront payments related to our license agreement for the three months ended June 30, 2016 and 2015 were \$7,000 in each period.

#### Research and development expenses

Research and development expenses were \$0.9 million and \$4.5 million for the three months ended June 30, 2016 and 2015, respectively. The decrease in research and development expenses period over period of \$3.6 million, or (79%), was due to the following:

- a decrease in regulatory and clinical expenses of \$1.6 million primarily related to the decreased use of outside services and wind up of activity in the COR1.1 clinical trial;
- a decrease in manufacturing related expenses of \$1.1 million, primarily related to our decision to suspend further development of Hydros-TA and wind up of activity for the COR 1.1 clinical trial;
- a decrease in preclinical research and development expenses of \$0.5 million as the COR 1.1 trial commenced during 2015; and
- a decrease in personnel related costs of \$0.4 million primarily related to the reduction in personnel and stock-based compensation expense.

### General and administrative expenses

General and administrative expenses were \$2.6 million and \$1.2 million for the three months ended June 30, 2016 and 2015, respectively. The increase in general and administrative expenses period over period of \$1.4 million, or 123%, was primarily due to increased expenditures on insurance and outside services associated with being a public company and the pursuit of a strategic transaction, as well as payroll and related expenses, including stock-based compensation.

### Restructuring and lease termination charges

In June 2016, we entered in to a lease termination agreement with the lessor for the Newark lease facility and agreed to the termination of the lease and to surrender the leased premises by June 30, 2016. We paid a one-time termination fee of \$2.45 million on June 27, 2016 and surrendered the premises. Additionally, we incurred severance costs of \$0.6 million as a result of the restructuring plan effective as of April 15, 2016. Other restructuring and lease termination charges also include rental payments prior to the termination of the Newark lease facility of \$0.2 million and expenses for professional services of \$0.1 million.

### Interest expense

Interest expense is attributable to our debt facility with SVB and non-cash amortization of debt discounts and final interest payments. Interest expense was \$0.4 million and \$0.2 million for the three months ended June 30, 2016 and 2015, respectively. The increase in interest expense of \$0.2 million was primarily attributable to the acceleration of the final payment expense associated with the repayment of outstanding debt.

### Loss on extinguishment of convertible promissory notes

Loss on extinguishment of convertible promissory notes was \$0 million and (\$3.2) million for the three months ended June 30, 2016 and 2015, respectively. The decrease in expense occurred as a result of the conversion of the convertible promissory notes into common shares in connection with the IPO.

### Other income (expense), net

Other income (expense), net was \$0.0 million and \$0.0 million for the three months ended June 30, 2016 and 2015, respectively, resulting in no material changes for the period.

### Comparison of the Six Months Ended June 30, 2016 and 2015

The following table summarizes our results of operations for the six months ended June 30, 2016 and 2015:

	Six Months Ended	
	June 30,	
	2016	2015
<b>License Revenue</b>	<b>\$ 14</b>	<b>\$ 14</b>
<b>Operating Expenses:</b>		
Research and development	4,480	8,406
General and administrative	4,146	2,176
Restructuring and lease termination charges	3,420	-
Impairment charges	1,460	-
Total operating expenses	13,506	10,582
<b>Loss from Operations</b>	<b>(13,492)</b>	<b>(10,568)</b>
<b>Other Income (expense):</b>		
Interest income	32	2
Interest expense	(493)	(1,005)
Loss on extinguishment of convertible promissory notes	-	(3,177)
Other income (expense), net	(3)	552
Total other income (expense)	(464)	(3,628)
<b>Net Loss and Comprehensive Loss</b>	<b>\$ (13,956)</b>	<b>\$ (14,196)</b>
Net loss per share to common stockholders, basic and diluted	\$ (0.53)	\$ (1.21)
Weighted average common shares outstanding, basic and diluted	26,333,558	11,722,606

#### *License revenue*

Revenues from the deferred upfront payments related to our license agreement for the six months ended June 30, 2016 and 2015 were \$14,000 in each period.

#### *Research and development expenses*

Research and development expenses were \$4.5 million and \$8.4 million for the six months ended June 30, 2016 and 2015, respectively. The decrease in research and development expenses period over period of \$3.9 million, or (47%), was primarily due to the following:

- a decrease in regulatory and clinical expenses of \$1.7 million primarily related to our decision to suspend further development of Hydros-TA and wind up of activity in the COR1.1 clinical trial;
- a decrease in manufacturing related expenses of \$1.2 million, primarily related to the declining activity for the COR 1.1 clinical trial and;
- a decrease in preclinical research and development expenses of \$0.9 million as the COR 1.1 trial commenced during 2015; and
- a decrease in personnel related costs of \$0.1 million primarily related to the reduction in personnel and stock-based compensation expense.

#### *General and administrative expenses*

General and administrative expenses were \$4.1 million and \$2.2 million for the six months ended June 30, 2016 and 2015, respectively. The increase in general and administrative expenses period over period of \$1.9 million, or 91%, was primarily due to increased expenditures on insurance and outside services associated with being a public company and with the pursuit of a strategic transaction, as well as payroll and related expenses, including stock-based compensation.

#### *Restructuring and lease termination charges*

In June 2016, we entered in to a lease termination agreement with the lessor for the Newark lease facility and agreed to the termination of the lease and to surrender the leased premises by June 30, 2016. We paid a one-time termination fee of \$2.45 million on June 27, 2016 and surrendered the premises. Additionally, we incurred severance costs of \$0.6 million as a result of the restructuring plan effective as of April 15, 2016. Other restructuring and lease termination charges also include rental payments prior to the termination of the Newark lease facility of \$0.2 million and expenses for professional services of \$0.1 million.

#### *Impairment of long-lived assets*

During the March 2016, we recorded an impairment charge of \$1.5 million in connection with our determination not to occupy the Newark Lease facility and to suspend further clinical development of Hydros-TA. An impairment charge of \$1.1 million was recorded, primarily related to leasehold improvements, furniture and fixtures for the Newark Lease facility that have no future use. Additionally, we determined that certain equipment used in the development of Hydros-TA was impaired and recorded an impairment charge of \$0.4 million, reducing the carrying value of the assets to \$0.1 million, which was their fair value at that time.

#### *Interest expense*

Interest expense is attributable to our debt facility with SVB and non-cash amortization of debt discounts and final interest payments. Interest expense was \$0.5 million and \$1.0 million for the six months ended June 30, 2016 and 2015, respectively. The decrease in interest expense of \$(0.5) million was primarily attributable to higher expense for the six months ended June 30, 2015 that included expense for discount amortization on our convertible promissory notes.

#### *Loss on extinguishment of convertible promissory notes*

Loss on extinguishment of convertible promissory notes was \$0 million and (\$3.2) million for the six months ended June 30, 2016 and 2015, respectively. The decrease in expense occurred as a result of the conversion of the convertible promissory notes into common shares in connection with the IPO.

#### *Other income (expense), net*

Other income (expense), net was \$0.0 million and \$0.6 million for the six months ended June 30, 2016 and 2015, respectively. The decrease in income of \$(0.6) million resulted primarily from changes in fair value of the Company's derivative liability and convertible preferred stock warrant liability that were recorded during 2015.

## Liquidity and Capital Resources

We have not generated any revenue from product sales and have incurred losses since our inception in 2004. As of June 30, 2016, we had an accumulated deficit of \$86.6 million. We anticipate that we will continue to incur losses for the foreseeable future.

Since our inception and prior to our initial public offering, we funded our operations principally through the receipt of funds from private placements of our equity, the issuance of convertible promissory notes and borrowings under our loan and security agreement with SVB. As of June 30, 2016, we had cash and cash equivalents of \$36.8 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

### Indebtedness

In October 2011, we entered into a loan and security agreement with SVB that provided for us to borrow \$3.0 million. In September 2014, we entered into a fourth amendment to the loan and security agreement to provide for a new loan of \$4.5 million and repayment in full of amounts owing under the prior loans, with net proceeds to us of \$0.5 million. We also issued a warrant to purchase 18,709 shares of Series B convertible preferred stock. The interest rate is 3.95% per annum and the loan is repayable in thirty-six equal monthly installments, following a nine month interest-only period. The amendment provided for an extension of the interest-only period by an additional nine months, to April 1, 2016, which became effective upon the completion of our initial public offering. In June 2016, we repaid the loan in full, as well as the final interest payment and various fees. The total payment was \$4.6 million, and the Loan and Security Agreement has terminated. There are no remaining aggregated annual payments under the Loan and Security Agreement as of June 30, 2016.

On September 29, 2014 and February 19, 2015, we entered into convertible note purchase agreements and issued convertible promissory notes (collectively, the "Notes") in an aggregate principal amount of \$5.0 million and \$4.0 million, respectively, to several related parties that own more than 10% of our capital stock. The Notes automatically converted into 2,287,120 shares of our common stock immediately prior to the closing of our initial public offering.

The convertible preferred stock warrants converted in to warrants exercisable for common stock at the completion of our initial public offering. During June 2015, SVB exercised its common stock warrants and received 56,545 shares of common stock in a cashless exercise.

### Cash Flows

The following table shows a summary of our cash flows for each of the six months ended June 30, 2016 and 2015:

	<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>
	(\$ in thousands)	
Cash flows used in operating activities	\$ (12,344)	\$ (10,490)
Cash flows used in investing activities	(62)	(259)
Cash flows provided by/(used in) financing activities	(4,498)	72,233
Net increase/(decrease) in cash and cash equivalents	<u>\$ (16,904)</u>	<u>\$ 61,484</u>

*Operating Activities.* Operating activities used \$12.3 million of cash in the six months ended June 30, 2016. The cash flow used in operating activities resulted primarily from our net loss of \$14.0 million for the period, offset by net non-cash charges of \$2.0 million and net cash used by changes in our operating assets and liabilities of \$0.4 million. Our non-cash charges consisted primarily of \$0.7 million related to stock-based compensation expense and impairment of assets of \$1.5 million. Net cash used by changes in our operating assets and liabilities consisted primarily of a \$1.3 million decrease in our accounts payable, a \$0.4 million decrease in accruals and a decrease in prepaid expenses of \$0.4 million.



Operating activities used \$10.5 million of cash in the six months ended June 30, 2015. The cash flow used in operating activities resulted primarily from our net loss of \$14.2 million for the period, offset by net non-cash charges of \$3.8 million and net cash provided by changes in our operating assets and liabilities of \$0.1 million. Our non-cash charges consisted primarily of \$0.5 million related to a decrease in the fair value of the preferred stock warrant liability and derivative liability, \$0.2 million related to stock-based compensation expense and \$0.8 million related to the amortization of the convertible promissory notes discount. Net cash provided by changes in our operating assets and liabilities consisted primarily of a \$0.8 million increase in our accounts payable and a \$0.1 million increase in accruals, offset by a decrease in prepaid expenses of \$0.9 million.

*Investing activities.* Net cash used in investing activities was \$0.1 million and \$0.3 million in the six months ended June 30, 2016 and 2015, respectively. Net cash used in investing activities consisted primarily of cash paid to purchase property and equipment, offset by the proceeds from the sale of property and equipment in June 2016.

*Financing activities.* Net cash provided by or used in financing activities was \$(4.5) million and \$72.2 million in the six months ended June 30, 2016 and 2015, respectively. Net cash used in financing activities in the six months ended June 30, 2016 consisted of the payment of loans payable of \$4.5 million. Net cash provided by financing activities in the six months ended June 30, 2015 consisted of the receipt of \$69.5 million from the initial public offering, \$4.0 million from the issuance of the Notes and \$0.1 million from the issuance of common stock related to option exercise, partially offset by \$1.4 million in deferred costs associated with our IPO.

### ***Future Funding Requirements***

We do not have any products approved for sale, and we have not generated any revenue from product sales since our inception and do not expect to generate any revenue from the sale of products in the near future. Our revenue to date has been generated from license revenue pursuant to our agreement with Jingfeng.

We have implemented operating cost reductions to reduce overall cash burn as we pursue a strategic transaction. Our strategic process is both active and ongoing. We anticipate that our general and administrative expenses will increase in the future as a result expenses related to these activities.

We believe that with our existing cash and cash equivalents, we will be able to fund our operating expenses and capital requirements for at least the next 12 months. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

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

- our ability to identify and consummate the transaction with KalVista, or an alternative strategic transaction for the company; including the timing and operational costs thereof;
- our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements;
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of Hydros-TA or any other future product candidates; and
- the cost incurred in responding to disruptive actions by activist stockholders.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

### ***Contractual Obligations and Commitments***

There are no long-term debt payments or operating lease obligations as of June 30, 2016. A liability for unrecognized tax benefits related to various federal and state income tax matters is \$0.8 million at June 30, 2016. The timing of the settlement of these amounts was not reasonably estimable at June 30, 2016. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

We enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancellable obligations under these agreements are not material.

The Share Purchase Agreement contains certain termination rights for both the Company and KalVista, and further provides that, upon termination of the Share Purchase Agreement under specified circumstances, we may be required to pay KalVista a termination fee of \$3.0 million and/or to reimburse certain expenses incurred by KalVista in an amount up to \$1.0 million.

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

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, ("GAAP"). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of our financial statements and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

#### ***Preclinical and Clinical Trial Accruals***

We base our accrued expenses related to clinical trials on estimates of patient enrollment and related expenses at clinical investigator sites, as well as estimates for services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us and based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

If we do not identify costs that we have begun to incur, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not adjusted our estimates at any particular balance sheet date in any material amount.

#### ***Income Taxes***

We account for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

We account for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions are reassessed, and we determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

***Off-Balance Sheet Arrangements***

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC. Refer to Note 5, “Commitments and Contingencies” regarding the Company’s indemnification arrangements.

***Recent Accounting Pronouncements***

For information regarding recent accounting pronouncements, please refer to Note 2, Summary of Significant Accounting Policies and Basis of Presentation within our condensed financial statements.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As of June 30, 2016, our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates on June 30, 2016 would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our investment portfolio.

We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposit do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at a financial institution that are in excess of federally insured limits.

**Item 4. CONTROLS AND PROCEDURES***Evaluation of Disclosure Controls and Procedures*

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), our management, under the supervision and with the participation of our Chief Executive Officer and Principal Accounting Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2016, our Chief Executive Officer and Principal Accounting Officer have concluded that, as of June 30, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in Internal Controls over Financial Reporting*

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended June 30, 2016, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

## PART II OTHER INFORMATION

### Item 1. LEGAL PROCEEDINGS

We are not party to any material legal proceeding. We have been informed that certain law firms are investigating possible violations of federal securities laws by certain Company officers and directors. However, to date, we have not been served with a complaint regarding these matters.

### Item 1A. RISK FACTORS

*Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, cash flows, the trading price of our common stock and our growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

#### Risks Related to Our Business

##### ***Our strategic transaction with KalVista may not be consummated or may not deliver the anticipated benefits we expect.***

In March 2016, we engaged a financial and strategic advisor, Wedbush PacGrow, to advise us on strategic alternatives. In April 2016, we announced that we had suspended further clinical development of Hydros-TA and that we were actively pursuing a strategic transaction, including a merger or acquisition of the Company. In June 2016, we entered into a definitive Share Purchase Agreement with KalVista pursuant to which the shareholders of KalVista will become the majority owners of Carbylan. We are devoting substantially all of our time and resources to consummating this transaction, however, there can be no assurance that such activities will result in the consummation of this transaction or that such transaction will deliver the anticipated benefits or enhance shareholder value.

***Prior to April 2016, our business was almost entirely dependent on the success of Hydros-TA, and we have suspended further clinical development of Hydros-TA and we have now devoted all of our resources in pursuit of our strategic transaction with KalVista, which, makes it difficult to assess our future viability as a standalone entity.***

Prior to April 2016, we invested substantially all of our efforts and financial resources in the research and development of Hydros-TA. Hydros-TA is a new approach to treating osteoarthritis, or OA, pain in the knee by using a combination therapy treatment.

In February 2016, we announced topline results of our COR1.1 trial, a Phase 3, multi-center, international, randomized, double-blind, three-arm trial that enrolled 560 patients with grade two and grade three OA of the knee, comparing treatment with Hydros-TA to treatment with Hydros and with TA, on a standalone basis. The primary endpoints of the trial were changes from baseline in the WOMAC A pain scores at week 2 for Hydros-TA versus Hydros and at week 26 for Hydros-TA versus TA, as well as a safety assessment of adverse events. Hydros-TA met the first of its two primary endpoints, demonstrating a statistically significant improvement from baseline in the WOMAC A pain score at week 2 versus Hydros. In addition, Hydros-TA maintained a significant reduction in pain from baseline over 26 weeks. However, patients in the TA arm continued to show an unexpected significant reduction in pain through 26 weeks. Given the comparable effectiveness at 26 weeks, COR1.1 did not meet its second primary endpoint. Hydros-TA was generally well tolerated with no treatment related serious adverse events, or SAEs, and adverse events, or AEs, were mostly mild and included arthralgia (knee pain) and swelling.

In April 2016, we announced that we had suspended further clinical development of Hydros-TA and that we were actively pursuing a strategic transaction, including a merger or acquisition of the Company. In addition in April 2016, we approved a restructuring plan effective as of April 15, 2016 resulting in a reduction in force affecting 14 of our 17 employees, including two executive officers. The restructuring plan was intended to reduce operational costs to preserve capital and streamline our operations as we pursue a strategic transaction. The positions impacted were across all of our departments.

In June 2016, we entered into a definitive Share Purchase Agreement with KalVista pursuant to which the shareholders of KalVista will become the majority owners of Carbylan.

There can be no assurance that the definitive share purchase agreement with KalVista will be consummated. In addition, there can be no assurance that any transaction, involving our company and/or assets, that is consummated would enhance shareholder value. There also can be no assurance that we will conduct drug development activities in the future.

Our net losses for the six months ended June 30, 2016 and 2015 were \$14.0 million and \$14.2 million, respectively. As of June 30, 2016, we had an accumulated deficit of \$86.6 million. Our history of net losses and our expectation of future losses, together with our limited operating history, may make it difficult to evaluate our business as a standalone entity and predict our future performance.

***If we do not successfully consummate the strategic transaction with KalVista, or an alternative transaction, we will require substantial additional funding and may need to curtail operations if we have insufficient capital.***

To date, we have not generated any revenue from product sales, and we do not know when, or if, we will generate any revenue from product sales. While we have entered into a definitive share purchase agreement with KalVista, our operating plan may change or the ability to consummation of a transaction may be delayed or may not occur at all.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital requirements for at least the next 12 months. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. However, if our current operating plans change we may require substantial additional funding to operate.

If the strategic transaction with KalVista is not consummated and we decide to continue our historical business operations, we may require substantial additional funding to operate.

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

- our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements;
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of Hydros-TA or any other future product candidates; and
- the cost incurred in responding to disruptive actions by activist stockholders.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail our operations.

***If we do not successfully consummate the strategic transaction with KalVista, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.***

There can be no assurance that we can successfully consummate the definitive share purchase agreement with KalVista. If the transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations in preparation for the consummation of the transaction with KalVista. Further, the Share Purchase Agreement with KalVista contains certain termination rights for each party, and provides that, upon termination under specified circumstances, we may be required to pay KalVista a termination fee of \$3.0 million and/or to reimburse certain expenses incurred by KalVista in an amount up to \$1.0 million which would further decrease our available cash resources. If our board of directors were to approve and recommend, and our

stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our COR1.1 trial; (ii) obligations under our employment and separation agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

***If we fail to continue to meet all applicable NASDAQ Global Market requirements and NASDAQ determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.***

Our common stock is listed on The NASDAQ Global Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a “public shell company.” On March 16, 2016, we received a deficiency letter from the Listing Qualifications Department of The NASDAQ Stock Market notifying us that, for the preceding 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(a)(1). On June 13, 2016, we received a notice from the Listing Qualifications Department of The NASDAQ Stock Market advising us that we have regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5450(a)(1); however, our stock price has again fallen below the minimum \$1.00 per share requirement and on July 28, 2016, we received a new deficiency letter from NASDAQ notifying us again that, for the preceding 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(a)(1). If we fail to continue to meet all applicable NASDAQ Global Market requirements, NASDAQ may determine to delist our common stock from The NASDAQ Global Market. If our common stock is delisted for any reason, it could reduce the value of our common stock and its liquidity.

***We are substantially dependent on our remaining employees to facilitate the consummation of a strategic transaction.***

Our ability to successfully complete a strategic transaction depends in large part on our ability to retain our remaining personnel, particularly David M. Renzi, our president and chief executive officer, Marcee M. Maroney, our vice president of clinical affairs, and John McKune our vice president of finance. In order to retain these employees, our Board of Directors approved an Executive Retention Bonus Plan in April 2016, which provides for cash retention bonuses to the remaining eligible executive officers who continue employment with the Company through the earlier to occur of (i) the closing of a change in control, including the transaction with KalVista, and (ii) March 8, 2017. However, despite our efforts to retain these members of our management, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate a strategic transaction, as well as fulfill our reporting obligations as a public company.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. A third-party defendant may also request post grant review or *inter partes* review by the USPTO of any patent we assert. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act signed into law on September 16, 2011. That Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and new venues and opportunities for competitors to challenge patent portfolios. Because of that Act, the U.S. patent system is now a “first to file” system, which may make it more difficult to obtain patent protection for inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners’ patent applications and the enforcement or defense of our or our collaboration partners’ issued patents, all of which could materially adversely affect our business, results of operations and financial condition.



The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

## Risks Related to Ownership of our Common Stock

### ***Our stock price is volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.***

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this “Risk Factors” section of this Quarterly Report on Form 10-Q and others such as:

- announcement related to the transaction with KalVista;
- departures of key personnel;
- communications or notifications from NASDAQ regarding the potential delisting of our common stock as a result of a failure to meet the NASDAQ listing requirements;
- announcements relating to collaboration partnerships or other strategic transactions undertaken by us;
- any intellectual property infringement actions in which we may become involved;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future; and
- general economic and market conditions and overall fluctuations in the United States equity markets.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

### ***An active, liquid and orderly market for our common stock may not develop or be sustained.***

We completed our initial public offering in April 2015. Prior to that, there had been no public market for shares of our common stock. Following our initial public offering, the trading volume of our common stock on The NASDAQ Global Market has been limited, and an active public market for our shares may not develop or, if it develops, be sustained. We cannot predict the extent in which investor interest in our company will lead to the development of, or sustain an active trading market on The NASDAQ Global Market or otherwise or how liquid that market might become. The lack of an active market may impair our stockholders’ ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. An inactive market may also impair our ability to raise capital by selling shares.

### ***We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements, and we will likely need to hire additional accounting and financial staff with appropriate public company reporting experience and technical accounting knowledge. Moreover, the reporting requirements, rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors’ and officers’ insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Market or other adverse consequences that would materially harm our business.

***If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting and, subject to exemptions allowed as an “emerging growth company,” our independent registered public accounting firm is required annually to deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting or if our independent registered public accounting firm is unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting for future periods as required by Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate financial statements, and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of June 30, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 67% of our outstanding voting stock. Therefore these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval, including the approval of any merger, sale of assets, or other major corporate transaction, as well as the elections of directors and amendments of our organizational documents.

***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 <sup>2</sup>/<sub>3</sub>% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal certain provisions of our bylaws and our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by or at the direction of our board of directors pursuant to a resolution adopted by a majority of the total number of directors that our board of directors would have if there were no vacancies, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

***Our ability to use our net operating losses to offset future taxable income, if any, may be subject to certain limitations.***

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. We experienced an ownership change in December 2005 that limited our use of approximately \$0.3 million of the NOLs available to us for federal income tax purposes as of June 30, 2016. If we undergo additional ownership changes (some of which changes may be outside our control), including the transaction with KalVista, our ability to utilize our NOLs could be further limited by Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs. See the risk factors described above under “—Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements.”

**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Not applicable.

**Item 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Item 5. OTHER INFORMATION**

None.

**Exhibits**

- 2.1\* (1) Share Purchase Agreement, dated as of June 15, 2016, by and among Carbylan Therapeutics, Inc., KalVista Pharmaceuticals Ltd., the shareholders of KalVista Pharmaceuticals Ltd., and, solely for purposes of being bound by certain provisions therein and solely in such person's capacity as the Seller Representative, Andrew Crockett
- 2.2 (2) Support Agreement, dated as of June 15, 2016, by and among KalVista Pharmaceuticals Ltd. and certain stockholders and optionholders of Carbylan Therapeutics, Inc.
- 2.3 (3) Form of Lock-up Agreement entered into by Carbylan Therapeutics, Inc. and certain stockholders and optionholders of Carbylan Therapeutics, Inc. and certain shareholders of KalVista Pharmaceuticals Ltd.
- 10.1 (4) Carbylan Therapeutics, Inc. Executive Retention Bonus Plan, effective April 15, 2016.
- 10.2 (5) Amended and Restated Offer Letter Agreement with John McKune, effective April 15, 2016.
- 10.3 (6) Transition and Separation Agreement with David Gravett, dated April 19, 2016
- 10.4 (7) Separation Agreement with Premchandran Ramiya, Ph.D., dated April 19, 2016
- 10.5 (8) Registration Rights Agreement, dated as of June 15, 2016, by and among Carbylan Therapeutics, Inc. and the shareholders of KalVista Pharmaceuticals Ltd.
- 10.6 (9) Lease Termination Agreement by and between Carbylan Therapeutics, Inc. and BMR-Pacific Research Center LP
- 31.1 Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Principal Accounting Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of Principal Executive Officer and Principal Accounting Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350.
- 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 Labels Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

\* All schedules and exhibits to the Share Purchase Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon its request.

- (1) Filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016.
- (2) Filed as Exhibit 2.2 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016.
- (3) Filed as Exhibit 2.3 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016.
- (4) Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 18, 2016.
- (5) Filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on April 18, 2016.
- (6) Filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2016.
- (7) Filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2016.
- (8) Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016.
- (9) Filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016.

**SIGNATURES**

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

**Carbylan Therapeutics, Inc.**

Date: August 12, 2016

By: /s/ David M. Renzi

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**David M. Renzi**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: August 12, 2016

By: /s/ John McKune

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**John McKune**  
**Vice President, Finance and Principal Accounting Officer**  
**(Principal Financial Officer)**

## CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David M. Renzi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Carbylan Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 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.

Dated: August 12, 2016

/s/ David M. Renzi

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David M. Renzi  
President and Chief Executive Officer  
(Principal Executive Officer)



## CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John McKune, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Carbylan Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 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.

Dated: August 12, 2016

/s/ John McKune

John McKune

Vice President, Finance

(Principal Accounting Officer)

**CERTIFICATION PURSUANT TO SECTION 906 OF  
THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)**

In connection with the accompanying Quarterly Report of Carbylan Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2016 (the "Report"), I, David M. Renzi, as President and Chief Executive Officer of the Company, and John McKune, as Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Dated: August 12, 2016

/s/ David M. Renzi

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David M. Renzi  
President and Chief Executive Officer

Dated: August 12, 2016

/s/ John McKune

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John McKune  
Principal Accounting Officer