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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 March 31, 2015

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	**20-0915291**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3181 Porter Drive, Palo Alto, California	**94304**
(Address of principal executive offices)	**(Zip Code)**

(650) 855-6777
(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 April 30, 2015, the registrant had 26,214,107 shares of common stock, $0.001 par value per share, issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

Carbylan Therapeutics, Inc.

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

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 3,181	$ 3,897
Prepaid expenses and other current assets	1,127	690
Total current assets	4,308	4,587
Property and equipment, net	329	180
Restricted cash	50	50
Deferred public offering costs	2,846	1,648
Other assets	179	179
Total assets	**$ 7,712**	**$ 6,644**
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,545	$ 1,024
Accrued expenses	1,832	1,605
Loans payable	1,075	4,435
Convertible promissory notes	5,524	—
Deferred licensing revenue	29	29
Total current liabilities	11,005	7,093
Loans payable, net of current portion	3,404	—
Convertible promissory notes	—	2,131
Derivative liability	2,287	1,495
Preferred stock warrant liability	349	463
Deferred licensing revenue, net of current portion	78	85
Deferred rent, net of current portion	2	2
Total liabilities	17,125	11,269
Commitments and contingencies (Note 5)		
Convertible preferred stock, $0.001 par value; 34,371,305 shares authorized, 8,268,531 issued and outstanding at March 31, 2015 and at December 31, 2014	39,556	39,556
Stockholders' deficit		
Common stock, $0.001 par value; 45,000,000 authorized; 708,457 shares issued and outstanding as of March 31, 2015 and 691,312 shares issued and outstanding as of December 31, 2014	1	1
Additional paid-in capital	3,989	3,593
Accumulated deficit	(52,959)	(47,775)
Total stockholders' deficit	(48,969)	(44,181)
Total liabilities, convertible preferred stock and stockholders' deficit	**$ 7,712**	**$ 6,644**

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 March 31,	
	2015	2014
License Revenue	**$ 7**	**$ 6**
Operating Expenses:		
Research and development	3,902	1,425
General and administrative	1,006	437
Total operating expenses	4,908	1,862
Loss from Operations	**(4,901)**	**(1,856)**
Other Income (expense):		
Interest expense	(836)	(80)
Other income (expense), net	553	(79)
Total other income (expense)	(283)	(159)
Net Loss and Comprehensive Loss	**$ (5,184)**	**$ (2,015)**
Net loss attributable to common stockholders	$ (5,184)	$ (2,015)
Net loss per share attributable to common stockholders, basic and diluted	($ 7.38)	($ 4.39)
Weighted average common shares outstanding, basic and diluted	701,980	459,286

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

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

	Three Months Ended March 31,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	$(5,184)	$(2,015)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	31	10
Stock based compensation expense	118	59
Change in fair value of preferred stock warrant liability and derivative liability	(518)	76
Non-cash interest expense	84	—
Amortization of loan and convertible promissory notes discount	707	48
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(437)	(68)
Accounts payable	1,011	24
Accruals	146	118
Deferred licensing revenue	(7)	(6)
Net cash used in operating activities	(4,049)	(1,754)
Cash Flows from Investing Activities		
Purchase of property and equipment	(180)	(1)
Net cash used in investing activities	(180)	(1)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net	120	—
Deferred public offering costs	(607)	—
Proceeds from loans payable	—	1,250
Proceeds from convertible promissory notes	4,000	—
Net cash provided by financing activities	3,513	1,250
Net decrease in cash and cash equivalents	(716)	(505)
Cash and cash equivalents at beginning of period	3,897	9,781
Cash and cash equivalents at end of period	$ 3,181	$ 9,276
Supplemental Cash Flow Information		
Cash paid for interest	$ 44	$ 28
Supplemental Disclosures of Non-cash Financing Activities		
Issuance of preferred stock warrants	—	$ 20
Deferred public offering costs	$ 591	—
Derivative related to convertible promissory notes upon issuance	$ 1,196	—
Beneficial conversion feature of convertible promissory notes	$ 158	—

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

Notes to the Condensed Financial Statements (unaudited)

1. Formation and Business of the Company

Carbylan Therapeutics, Inc. (the "Company") is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel and proprietary combination therapies that address significant unmet medical needs. The Company's initial focus is on the development of Hydros-TA, its proprietary, potentially best-in-class 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 in 2004, 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 March 31, 2015, the Company had an accumulated deficit of $53.0 million. The Company expects to incur increased research and development expenses during the current Phase 3 trail of Hydros-TA and when the Company initiates the second Phase 3 trial of Hydros-TA. Management's plans with respect to these matters include utilizing a substantial portion of the Company's capital resources and efforts in completing the development and obtaining regulatory approval for Hydros-TA and expanding the Company's organization.

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 issued and outstanding common stock, convertible preferred stock, warrants for preferred stock, options for common stock and per share amounts contained in the condensed financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

On April 8, 2015, the Company's registration statement on Form S-1 (File No. 333-201278) relating to the Initial Public Offering ("IPO") of its common stock was declared effective by the SEC. The IPO 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 $66.1 million from the IPO, net of underwriting discounts and commissions and estimated IPO expenses paid by the Company.

On April 14, 2015, prior to the closing of the IPO, 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.

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 on a basis consistent with the annual financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the periods presented. These interim financial results are not necessarily indicative of the results to be expected for the year ending December 31, 2015, 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 Prospectus filed pursuant to Rule 424(b)(4) on April 8, 2015 with the SEC (the "Prospectus").

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

The product candidates 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 the Company's current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company's business and its financial statements.

The Company is 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.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any products or product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

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 combination 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 accompanying interim condensed financial statements.

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).

Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities, and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

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 other income (expense), net. Maintenance and repairs are charged to operations as incurred.

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 timelines or 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 inventive 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

The Company calculates its basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities, which are securities other than common stock that are entitled to receive dividends. The Company's convertible preferred stockholders are entitled to participate in dividends and earnings of the Company when dividends are paid on common stock. Under the two-class method, the Company determines whether it has net income attributable to common stockholders, which includes the results of operations, capital contributions and deemed dividends less current period convertible preferred stock non-cumulative dividends. If it is determined that the Company does have net income attributable to common stockholders during a period, the related undistributed earnings are then allocated between common stock and the convertible preferred stock based on the weighted average number of shares outstanding during the period to determine the numerator for the basic net income per share attributable to common stockholders. In computing diluted net income attributable to common stockholders, undistributed earnings are re-allocated to reflect the potential impact of dilutive securities to determine the numerator for the diluted net income per share attributable to common stockholders.

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, options to purchase common stock and common stock warrants are considered common stock equivalents. For periods in which the Company has reported net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for the three months ended March 31, 2015 and 2014.

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. The money market funds comply with Rule 2a-7 of the Investment Company Act of 1940 and are required to be priced and have a fair value of $1.00 net asset value per share. These money market funds are actively traded and reported daily through a variety of sources. Due to the structure and valuation required by the Investment Company Act of 1940 regarding Rule 2a-7 funds, 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.

As of March 31, 2015, based on borrowing rates that are available to the Company for loans of similar terms and consideration of the Company's credit risk, the carrying value of the loan payable approximates the fair value using Level 2 inputs. The fair value of the convertible promissory notes approximates the carrying value of the convertible promissory notes, after considering the related beneficial conversion feature and the derivative liability.

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. On a recurring basis, the Company estimates 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 would result 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. At March 31, 2015 and December 31, 2014, the Company remeasured the fair value of the derivative for the September 2014 and February 2015 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.

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

	Fair Value Measurements as of March 31, 2015 (in thousands)			
	Quoted Price in Active Markets for Identical Assets Level 1	Significant other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
Assets				
Money market funds[1]	$ 3,115	$ —	$ —	$3,115
Certificate of deposit	—	$ 50	—	$ 50
	$ 3,115	$ 50	—	$3,165
Liabilities				
Derivative liability	—	—	$ 2,287	2,287
Preferred stock warrant liability	—	—	$ 349	349
	$	$	$ 2,636	$2,636

	Fair Value Measurements as of December 31, 2014 (in thousands)			
	Quoted Price in Active Markets for Identical Assets Level 1	Significant other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
Assets				
Money market funds[1]	$ 3,825	$ —	$ —	$ 3,825
Certificate of deposit	—	$ 50	—	$ 50
	$ 3,825	$ 50	—	$ 3,875
Liabilities				
Derivative liability	—	—	$ 1,495	$ 1,495
Preferred stock warrant liability	$ —	$ —	$ 463	$ 463
	$ —	$ —	$ 1,958	$ 1,958

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

The change in the fair value of the preferred stock warrant liability is summarized below:

Fair value as of December 31, 2014	$ 463
Change in fair value recorded in other income (expense), net	$(114)
Fair value as of March 31, 2015	$ 349

The following is a summary of the activity of the derivative liability for the three months ended March 31, 2015:

Fair value as of December 31, 2014	$1,495
Embedded derivative liability upon issuance of convertible promissory notes	1,196
Change in fair value recorded in other income (expense), net	(404)
Fair value as of March 31, 2015	$2,287

4. Balance Sheet Components

Property and Equipment, Net

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

	March 31, 2015	December 31, 2014
Computer equipment	$ 30	$ 30
Lab equipment	655	543
Furniture and fixtures	21	21
Machinery and equipment	94	26
Leasehold improvement	55	55
	855	675
Less: Accumulated depreciation and amortization	(526)	(495)
Total property and equipment, net	$ 329	$ 180

Depreciation expense for the three months ended March 31, 2015 and 2014, was $31,000, and $10,000, respectively.

Accrued Liabilities
(in thousands)

	March 31, 2015	December 31, 2014
Accrued payroll and related expenses	$ 768	$ 723
Accrued legal expenses	128	159
Accrued research and clinical trial expenses	460	380
Accrued professional services	476	343
	$ 1,832	$ 1,605

5. Commitments and Contingencies

Operating Lease

The Company leases its facilities under a noncancelable operating lease which expires on February 29, 2016. The terms of the lease agreement require the Company to provide a security deposit of $69,000. The security deposit is included in other assets on the accompanying condensed balance sheets. The Company has 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 receives $16,000 per month as rental income which is accounted for as a reduction of rent expense. The sub-lease agreement continues until February 29, 2016.

The aggregate future minimum lease payments under this operating lease are as follows:

Years ending December 31,	(in thousands)
2015	$ 438
2016	73
Total minimum lease payments	$ 511

Gross rent expense for the three months ended March 31, 2015 and 2014 was $108,000 and $105,000, respectively. The rental expense is reduced by the sublease rental income amounts of $48,000 and $47,000, respectively, for the same periods.

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 future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual or disclosure at March 31, 2015 and 2014.

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 to provide for a new loan of $4,500,000 and repayment of the outstanding principal of the loan amounts previously disbursed in February 2013 and January 2014, with the remaining proceeds of approximately $0.5 million provided to the Company 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 final balloon interest payment is $517,500 and is accreted over the life of the loan. Additionally, the amendment provided for an extension of the interest only period to a eighteen-month period if certain financing events or a combination of clinical trial and financing events occur. The amendment was accounted for as a modification of loans payable, and the unamortized debt discount as of the date of the modification will be amortized over the new loan period, using the effective interest rate method.

The Loan and Security Agreement contains customary representations and warranties, covenants, closing and advancing conditions, events of defaults and termination provisions. The Loan and Security Agreement provides that an event of default will occur if (1) the financial institution determines that it is the clear intention of the Company's investors to not continue to fund the Company in the amounts and timeframe necessary to enable the Company to satisfy the Company's financial obligations, (2) there is a material impairment in the financial institution's security interest in the personal property that is the collateral, (3) the Company defaults in the payment of any amount payable under the agreement when due or (4) the Company breaches any negative covenant or certain affirmative covenants in the agreement (subject to a grace period in certain cases). The repayment of the loan is accelerated following the occurrence of an event of default or otherwise, which would require the Company to immediately pay an amount equal to: (i) all outstanding principal plus accrued but unpaid interest, (ii) the final payment, plus (iii) all other sums, that shall have become due and payable but have not been paid, including interest at the default rate with respect to any past due amounts. As of March 31, 2015, the Company was in compliance with all the covenants in the Loan and Security Agreement.

As discussed in Note 1, the Company has completed its IPO and believes it will be able to meet its payment obligations under the Loan and Security Agreement during the twelve months following the most recent balance sheet date. The Company has reclassed loan payments beyond twelve months to long term.

Aggregated annual payments due under the Loan and Security Agreement are as follows:

As of March 31, 2015 (in thousands)	
2015	$ 960
2016	1,595
2017	1,595
2018	1,181
Total payments	5,331
Less: Interest	(831)
Present value of loans payable	4,500
Less: Debt discount	(106)
Add: Final balloon payment	517
Less: Unamortized portion of final balloon payment	(432)
Loans payable	4,479
Less: Current portion	(1,075)
Loans payable, net of current portion	$ 3,404

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 (See Note 13).

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. If the Company, prior to the completion of an initial public offering, issues a next series equity financing with proceeds of at least $10,000,000, excluding conversion of the Notes, the Notes would automatically convert into the shares of the next equity series. The number of shares of the Company’s common stock at this conversion would be equal to the quotient obtained by dividing the entire principal amount and accrued interest on the Notes by 80% of the next equity series financing price per share. The Notes further provided that in the event that the Company did not complete an initial public offering or a next series equity financing on or before June 30, 2015, if holders of at least a majority of the principal amount of the then-outstanding Notes elect to convert the Notes, rather than electing to have the Notes repaid in cash following the maturity date of December 31, 2015, the conversion must be in to shares of the Series B convertible preferred stock. Additionally, the Notes provided that in the event that the Company sells or disposes of all or substantially all of its property or business or merges or consolidates with any other entity (other than its wholly-owned subsidiary) prior to the repayment or conversion of the Notes, holders of the Notes would be paid an amount equal to 120% of the outstanding principal amount, together with any accrued interest, so long as the Company’s indebtedness under the Loan and Security Agreement has been paid in full. The Notes bore interest at a rate of 5% per annum, compounded annually. Unless converted, the Notes provided that they would mature upon the demand by holders of at least a majority of the principal amount of the then-outstanding notes at any time on or after December 31, 2015, but in no event before the Company’s indebtedness under the Loan and Security Agreement has been paid in full.

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 occurs upon a change in control of the Company meets the definition of a put option and is not closely related to the debt. As a result, the automatic conversion features and put option, exclusive of the Series B conversion feature as described in previous paragraphs, require derivative accounting treatment and are 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 as described in previous paragraphs, are recorded as a derivative liability instrument that will be 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 is $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 is $2,287,000 as of March 31, 2015.

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 has been recorded as a debt discount that will 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. The convertible preferred stock warrants outstanding as of March 31, 2015 and December 31, 2014 were as follows (in thousands, except share and per share amounts):

	Number of Shares Underlying Warrants	Exercise Price per Share	Fair Value, as of March 31, 2015
Series A preferred stock	20,788	$ 4.81	$ 30
Series B preferred stock	103,941	$ 4.81	$ 319
	124,729		$ 349

	Number of Shares Underlying Warrants	Exercise Price per Share	Fair Value, as of December 31, 2014
Series A preferred stock	20,788	$ 4.81	$ 46
Series B preferred stock	103,941	$ 4.81	$ 417
	124,729		$ 463

The fair value of the convertible preferred stock warrant liability was remeasured as of each period end. As of December 31, 2014, the Company remeasured the fair value using a Black-Scholes option-pricing method with the following assumptions: a weighted average remaining life of 6.7 years, an expected volatility of 58.9%, a weighted average risk-free interest rate of 1.80% and no expected dividend. As of March 31, 2015, the Company remeasured the fair of the convertible preferred stock warrant liability using a Black-Scholes option-pricing method with the following assumptions: the Company's IPO 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 March 31, 2015, the Company's Amended and Restated Certificate of Incorporation, as amended, has authorized 45,000,000 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 March 31, 2015, 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.

In April 2014, the Company terminated the 2004 Plan and the board of directors approved the 2014 Stock Option Plan (the 2014 Plan), authorizing 250,000 shares for issuance under the 2014 Plan. Shares underlying any outstanding stock awards or stock option grants previously awarded remain subject to the terms of the 2004 Plan. Any shares available for grant or any shares canceled or forfeited prior to vesting or exercise subsequent to the termination of the 2004 Plan became available for use under the 2014 Plan. Upon the effectiveness of the 2014 Plan, the Company ceased granting any equity awards under the 2004 Plan. Subsequent awards have been and will be granted under the 2014 Plan.

In January and February 2015, the board of directors and stockholders, respectively, approved the 2015 Equity Plan (the “2015 Equity Plan”). In connection with the April 2015 IPO, the 2014 Plan terminated and all equity-based awards are granted under the 2015 Equity Plan. Shares underlying any outstanding stock option grants previously awarded under the 2004 Plan or the 2014 Plan remain subject to the terms of such plan. Any shares available for grant or any shares canceled or forfeited prior to vesting or exercise subsequent to the termination of the 2014 Plan and 2004 Plan became available for use under the 2015 Plan. Subsequent awards will be granted under the 2015 Plan.

As of March 31, 2015, no awards have been made under the 2015 Equity Plan. The maximum number of shares of the Company’s common stock that may be delivered in satisfaction of awards under the 2015 Equity Plan, including shares issuable, but not yet issued, and considering outstanding awards granted under the 2014 Plan, as well as shares available for future awards, will be 1,532,534 shares, inclusive of 750,000 shares authorized upon creation of the 2015 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 least of (1) 1,200,000 shares of stock, (2) four percent (4%) of the outstanding shares of stock on the last day of the immediately preceding year. As of March 31, 2015, the Company had 1,328,873 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 March 31,	
	2014	2015
Research and Development	$ 9	$ 9
General and administrative	50	109
Total	$ 59	$ 118

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).

12. Income Taxes

The Company’s effective tax rate is 0% for income tax for the three months ended March 31, 2015 and the Company expects that its effective tax rate for the full year 2015 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 March 31, 2015 is approximately $0.5 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 12 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 April 14, 2015, the Company issued and sold 14,950,000 shares of its 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, at a public offering price of $5.00 per share, for net proceeds of approximately $66.1 million, after deducting underwriting discounts and commissions of approximately $5.2 million and offering costs of approximately $3.4 million.

On April 14, 2015, the Company's Amended and Restated Certificate of Incorporation became effective and the number of shares of capital stock the Company is authorized to issue was increased to 105,000,000 shares, 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 May 21, 2015.

Item 2.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 of clinical studies and regulatory submissions; our ability to obtain and maintain regulatory approval of Hydros-TA, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate; our ability to obtain funding for our operations, including funding necessary to complete clinical development and file an NDA for Hydros-TA; the performance of our third-party suppliers and manufacturers; the success of competing therapies that are or become available; and the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing. 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 the Prospectus 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 focused on the development and commercialization of novel and proprietary combination therapies that address significant unmet medical needs. Our initial focus is on the development of Hydros-TA, our proprietary, potentially best-in-class intra-articular ("IA"), injectable product candidate to treat pain associated with osteoarthritis ("OA"), of the knee. Hydros-TA is a combination IA product designed to provide both rapid and sustained pain relief. We believe the low dose steroid component of Hydros-TA will provide rapid pain relief as well as sustained pain relief up to six months, from our proprietary hyaluronic acid component. Hydros-TA is currently being studied in a Phase 3 trial, which we refer to as COR1.1. We expect to initiate our second Phase 3 trial, which we refer to as COR1.2, to open an investigational new drug application ("IND"), and begin enrolling U.S. patients in mid-2015. We anticipate reporting top-line results from COR1.1 in early 2016 and COR1.2 by the end of 2016, and submitting our NDA for Hydros-TA in early 2017.

Since our inception, we have devoted substantially all our efforts and financial resources to identifying and developing product candidates utilizing our proprietary hyaluronic acid technology and to the clinical development of Hydros-TA. We have not generated any revenue from product sales and, as a result, we have incurred significant losses. Through March 31, 2015, we have funded substantially all of our operations through the sale and issuance of our convertible preferred stock and convertible promissory notes and through various credit facilities.

In November 2012, we entered into a technology license agreement with Shanghai Jingfeng Pharmaceutical Co., Ltd. ("Jingfeng"), pursuant to which we granted to Jingfeng an exclusive license to develop, manufacture and commercialize Hydros-TA in China, Taiwan, Hong Kong and Macau. In consideration for the exclusive license, we received a non-refundable up-front payment of $2.0 million ($1.7 million net of Chinese withholding tax). Additionally, we are eligible to receive future regulatory milestone payments of up to $1.5 million, which are considered non-substantive milestones for accounting purposes, and commercialization royalty payments of up to approximately $5.0 million (each excluding Chinese withholding tax).

Other than our arrangement with Jingfeng, we own global development and commercialization rights to Hydros-TA. Upon FDA approval, we expect to commercialize Hydros-TA for OA pain in the knee in the United States with an approximately 50 to 100 person specialty sales force targeting orthopedic surgeons, rheumatologists and pain specialists.

We do not have manufacturing facilities and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party clinical research organizations ("CROs"), to carry out our clinical trials and we do not yet have a sales organization. We expect to significantly increase our investment in costs relating to our clinical and commercial manufacturing process and inventory of Hydros-TA as we progress through our Phase 3 clinical trials and prepare for a possible commercial launch of Hydros-TA.

We have never been profitable and, as of March 31, 2015, we had an accumulated deficit of $ 53.0 million. We incurred net losses of approximately $5.2 million and $2.0 million in the three months ended March 31, 2015 and 2014, respectively. We expect to continue to incur net operating losses as we advance Hydros-TA through clinical development, seek regulatory approval and prepare for and, if approved, proceed to commercialization.

Initial Public Offering

On April 8, 2015, our registration statement on Form S-1 (File No. 333-201278) relating to the IPO of our common stock was declared effective by the SEC. The IPO closed on April 14, 2015 at which time we sold 14,950,000 shares of our 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. We received cash proceeds of approximately $66.1 million from the IPO, net of underwriting discounts and commissions and estimated offering costs incurred by us.

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 and do not expect to generate any revenue from the sale of products in the near future. We may generate revenue from product sales, license fees, milestone payments and royalties from the sale of products developed using our intellectual property in the future. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Hydros-TA and any other product candidates that we may advance. If we fail to complete the development of, or obtain regulatory approval for, Hydros-TA or any future product candidates we may advance, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Our revenue to date has been generated from license revenue pursuant to our agreement with Jingfeng. Revenue under our license arrangement is recognized based on the performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue that we are able to recognize could be adversely affected. We have identified all of the deliverables at the inception of the Jingfeng agreement, including an exclusive royalty bearing license to certain of our patents relating to Hydros-TA, know-how and reasonable professional services, clinical or nonclinical data and information, collectively referred to as services, to be provided by us to assist Jingfeng in manufacturing, developing and commercializing the licensed product over the performance period, which is currently estimated to be January 2019. We have determined that the Jingfeng license and the services thereunder, represent two separate units of accounting, as the license has standalone value apart from the services because the development, manufacturing and commercialization rights conveyed would allow Jingfeng to perform all efforts necessary to bring the product to commercialization and begin selling the product upon regulatory approval. Non-substantive regulatory milestone and commercialization royalty payments are recognized in proportion to the two units of accounting identified at the inception of the agreement. Each portion will be recognized in accordance with the underlying unit of accounting.

We determined the BESP for the license unit of accounting using a discounted cash flow analysis. This measurement is based on the value indicated by current estimates of future payments to be received under the agreement and reflects management determined estimates and assumptions. These estimates and assumptions include but are not limited to estimated sales prices, estimated market opportunity, expected market share, the likelihood that clinical trials will be successful, the likelihood that regulatory approval will be received, the likelihood that the products will be commercialized, the determination of the markets served and the discount rate. We reduced the future payment to be received by the estimated amount of the professional services costs plus an estimated margin, which was based on industry benchmarking of similar companies. These estimates and assumptions formed the basis of an expected net future cash flow that was discounted based on an estimated weighted average cost of capital. The BESP for the services unit of accounting was determined using a similar methodology. This measurement is based on the estimated cost of the professional services plus an estimated margin based on industry benchmarking of similar companies.

The considerations of the Jingfeng agreement have been allocated to the units of accounting based on the relative selling price method. Of the $1.7 million up-front payment received (net of Chinese withholding tax), $1.5 million was allocated to the license and $0.1 million to the services. We recognized license revenue upon execution of the agreement as the associated unit of accounting had been delivered pursuant to the terms of the agreement. The $0.1 million allocated to services will be recognized as revenue on a straight-line basis over the performance period, which is currently estimated to be January 2019.

In November 2013, we received a $0.4 million regulatory milestone payment (net of Chinese withholding tax), and all but $35,000 was allocated to the license. We recognized license revenue upon execution of the agreement as the associated unit of accounting had been delivered pursuant to the terms of the agreement. The $35,000 allocated to services will be recognized as revenue on a straight-line basis over the performance period, which is currently estimated to be January 2019.

We expect that any revenue we generate will fluctuate from year to year as a result of the timing and amount of milestone payments from our license agreement with Jingfeng and any future collaboration partner.

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, 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 do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Hydros-TA. We expect to increase our research and development expenses for the foreseeable future as we initiate further clinical trials.

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

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Clinical development	$ 967	$ 545
Regulatory	392	62
Preclinical R&D	674	168
Personnel related	604	422
Manufacturing	1,265	228
Total research and development expenses	$ 3,902	$ 1,425

It is difficult to determine with any certainty the duration and completion costs of our currently planned or future clinical trials of Hydros-TA and any future product candidates we may advance, or if, when or to what extent we will generate revenue from the commercialization and sale of Hydros-TA or future product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and pre-clinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

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. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission ("SEC"), Nasdaq listing standards, additional insurance expenses, investor relations activities and other administration and professional services. General and administrative expenses are expensed as incurred.

For the three months ended March 31, 2015 and 2014 our general and administrative expenses totaled approximately $1.0 million and $0.4 million, respectively. We anticipate that our general and administrative expenses will increase in the future as we continue to build our corporate infrastructure to support the continued development of Hydros-TA.

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. We anticipate that our interest income will increase in the future due to our receipt of the net proceeds of approximately $66.1 million from our IPO.

Interest expense. Interest expense consists of interest expense on amounts outstanding under our debt facility with Silicon Valley Bank ("SVB"), and the Notes, as well as non-cash interest expense related to the amortization of loan discounts and final loan interest payments. We expect to incur future interest expense related to the borrowing from SVB until June 2018.

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 months ended March 31, 2015 and the Company expects that its effective tax rate for the full year 2015 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 12 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 March 31, 2015 and 2014

The following table summarizes our results of operations for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,	
	2015	2014
License Revenue	**$ 7**	**$ 6**
Operating Expenses:		
Research and development	3,902	1,425
General and administrative	1,006	437
Total operating expenses	4,908	1,862
Loss from Operations	**(4,901)**	**(1,856)**
Other Income (expense):		
Interest expense	(836)	(80)
Other income (expense), net	553	(79)
Total other income (expense)	(283)	(159)
Net Loss and Comprehensive Loss	**$ (5,184)**	**$ (2,015)**
Net loss attributable to common stockholders	$ (5,184)	$ (2,015)
Net loss per share attributable to common stockholders, basic and diluted	($ 7.38)	($ 4.39)
Weighted average common shares outstanding, basic and diluted	701,980	459,286

License revenue

Revenues from the deferred upfront payments related to our license agreement for the three months ended March 31, 2015 and 2014 were $7,000 and $6,000 respectively, in each period.

Research and development expenses

Research and development expenses were $3.9 million and $1.4 million for the three months ended March 31, 2015 and 2014, respectively. The increase in research and development expenses period over period of $2.5 million, or 174%, was primarily due to the following:

- an increase in clinical development expenses of $0.4 million related to our ongoing Phase 3 clinical trial, COR1.1;
- an increase in pre-clinical research and development expenses of $0.5 million primarily related to the increased use of CROs and other outside services driven by an increase in IND enabling activities;
- an increase in regulatory expenses of $0.3 million primarily related to the increase use of outside services driven by an increase in IND enabling activities;
- an increase in personnel related expenses of $0.2 million as we began to build out our in-house regulatory and clinical development team; and
- an increase in manufacturing related expenses of $1.0 million, primarily related to an increased use of contract manufacturers in preparation for the production of Hydros-TA as we began to produce materials for our COR1.2 clinical trial.

General and administrative expenses

General and administrative expenses were $1.0 million and $0.4 million for the three months ended March 31, 2015 and 2014, respectively. The increase in general and administrative expenses period over period of $0.6 million, or 130%, was primarily due to an increase of $0.2 million in salary and related costs and an increase of $0.4 million on an increase of outside professional fees.

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 $0.8 million and $80,000 for the three months ended March 31, 2015 and 2014, respectively. The increase in interest expense of $0.8 million was primarily due to $0.7 million in convertible promissory notes discount amortization and $0.1 million in accrued interest on the convertible promissory notes.

Other income (expense), net

Other income (expense), net was $0.6 million and $(79,000) for the three months ended March 31, 2015 and 2014, respectively. The increase in income of $0.6 million was based primarily on a decrease in the fair value of the warrant liability of $0.1 million and a decrease in the fair value of the derivative liability associated with our convertible promissory notes of $0.4 million.

Liquidity and Capital Resources

To date, we have not generated any revenue and have incurred losses since our inception in 2004. As of March 31, 2015, we had an accumulated deficit of $53.0 million. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

Since our inception through March 31, 2015 (prior to our April 2015 IPO), 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 March 31, 2015, we had cash and cash equivalents of $3.2 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 36 equal monthly installments, following a nine month interest-only period. The amendment provides for an extension of the interest-only period by an additional nine months, to March 2016, under certain conditions, including if we raise at least $30.0 million in our IPO.

The loan and security agreement is collateralized by our personal property but excludes our intellectual property. The agreement also contains customary representations and warranties, covenants, closing and advancing conditions, events of defaults and termination provisions. The negative covenants preclude, among other things, disposing of certain assets, engaging in any merger or acquisition, incurring additional indebtedness, encumbering any collateral or making prohibited investments, in each case, without the prior consent of SVB.

The loan and security agreement provides that an event of default will occur if, among other events, we default in the payment of any amount payable under the agreement when due. As of March 31, 2015, we were in compliance with all the covenants in the loan and security agreement.

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 IPO.

Cash Flows

The following table shows a summary of our cash flows for each of the three months ended March 31, 2015 and 2014:

	Quarter Ended March 31,	
	2015	2014
	($ in thousands)	
Cash flows used in operating activities	(4,049)	(1,754)
Cash flows used in investing activities	(180)	(1)
Cash flows provided by financing activities	3,513	1,250
Net decrease in cash and cash equivalents	(716)	(505)

Operating Activities. Operating activities used $4.0 million of cash in the first quarter of 2015. The cash flow used in operating activities resulted primarily from our net loss of $5.2 million for the period, offset by net non-cash charges of $0.4 million and net cash provided by changes in our operating assets and liabilities of $0.7 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, $0.1 million related to stock-based compensation expense and $0.7 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 $1.0 million increase in our accounts payable and a $146,000 increase in accruals, offset by a decrease in prepaid expenses of $0.4 million.

Operating activities used $1.8 million of cash in the first quarter of 2014. The cash flow used in operating activities resulted primarily from our net loss of $2.0 million for the period, offset by net non-cash charges of $0.2 million and net cash provided by changes in our operating assets and liabilities of $68,000. Our non-cash charges consisted primarily of $76,000 related to the change in fair value of preferred stock warrant liability, $59,000 related to stock-based compensation expense and $48,000 related to the amortization of our loan discount. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $0.1 million increase in our accruals offset by a decrease in prepaid expenses.

Investing activities. Net cash used in investing activities was $0.2 million and $1,000 in the three months ended March 31, 2015 and 2014, respectively. Net cash used in investing activities consisted primarily of cash paid to purchase property and equipment.

Financing activities. Net cash provided by financing activities was $3.5 million and $1.3 million in the three months ended March 31, 2015 and 2014, respectively. Net cash provided by financing activities in the three months ended March 31, 2015 consisted of the receipt of $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 $0.6 million in deferred costs associated with our IPO. Net cash provided by financing activities in the three months ended March 31, 2014 primarily consisted of the receipt of net proceeds of $1.3 million received from the second draw down under our Loan and Security Agreement with SVB.

Future Funding Requirements

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. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize Hydros-TA or any future product candidates that we may advance. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the development and clinical trials of, and seek regulatory approval for, Hydros-TA. We expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any product candidate, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that the net proceeds of approximately $66.1 million we received from our IPO, together with 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. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our product candidates.

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

- the progress, rate of enrollment, timing, scope, results and costs of our nonclinical and clinical trials for Hydros-TA, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for Hydros-TA and the costs of post-marketing studies that could be required by regulatory authorities;
- our ability to successfully commercialize Hydros-TA;
- the manufacturing, selling and marketing costs associated with Hydros-TA, including the cost and timing of building our sales and marketing capabilities;
- our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements;
- the scope of our research and clinical development activities to expand the use of Hydros-TA for treating OA in other joints;
- the sales price and the availability of adequate third-party reimbursement for Hydros-TA;
- the cash requirements of any future acquisitions or discovery of future product candidates;
- the number and scope of nonclinical, pre-clinical and discovery programs that we decide to pursue or initiate;
- the time and cost necessary to respond to technological and market developments; and
- 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.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements. 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

The following table summarizes our contractual obligations at March 31, 2015:

		Payments Due By Period			
	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
Long-term debt (including interest) (1)	$ 5,331	$ 960	$ 4,371	$ —	—
Convertible promissory notes (including interest) (2)	$ 9,148	$ 9,148		—	—
Operating lease obligations (3)	511	438	73	—	—
Total (4)	$14,990	$ 10,546	$ 4,444	$ —	—

(1) Represents the contractually required principal and interest payments on our credit facility in accordance with the required payment schedule. Amounts associated with future interest payments to be made were calculated using a weighted average interest rate of 10.2% per annum.

(2) Represents the contractually required payments under our convertible promissory notes in existence as of March 31, 2015. Amounts associated with the future interest payments to be made were calculated using the stated rate of 5% and an assumed maturity date of March 31, 2015.

(3) Represents the contractually required payments under our operating lease obligations in existence as of March 31, 2015 in accordance with the required payment schedule. No assumptions were made with respect to renewing the lease terms at the expiration date of their initial terms.

(4) This table does not include a liability for unrecognized tax benefits related to various federal and state income tax matters of $0.5 million at March 31, 2015. The timing of the settlement of these amounts was not reasonably estimable at March 31, 2015. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

The tables above reflect only payment obligations that are fixed or determinable. 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.

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.

Fair Value of Financial Instruments

We measure our finanical assets and liabilities, and our non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

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 the 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.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 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 Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2015. 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 March 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2015, 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 March 31, 2015, 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 currently a party to any material legal proceedings.

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 Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant losses since our inception and we will incur losses in the future. We have only one product candidate in clinical trials and no product sales, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical-stage specialty pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development activities on our lead product candidate, Hydros-TA. To date, we have not commercialized any products or generated any revenue from product sales. We are not profitable and have incurred losses in each year since our inception in 2004, and we do not know whether or when we will become profitable. We have only a limited operating history upon which to evaluate our business and prospects. We continue to incur significant research, development and other expenses related to our ongoing operations. Our net losses for the three months ended March 31, 2015 and 2014 were $5.4 million and $2.0 million, respectively. As of March 31, 2015, we had an accumulated deficit of $53.0 million. To date, we have financed our operations primarily through the sale of equity securities and debt facilities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity and/or debt financings and strategic collaborations. We have not completed a pivotal clinical study for Hydros-TA and it will be several years, if ever, before Hydros-TA is ready for commercialization.

We will continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly as we:

- continue our ongoing Phase 3 clinical trial of Hydros-TA and commence our second Phase 3 clinical trial of Hydros-TA;
- seek regulatory approvals for Hydros-TA;
- seek to expand the potential indications that we may treat with Hydros-TA, including performing preclinical studies and clinical trials evaluating the safety and effectiveness of Hydros-TA in treating OA in other joints;
- maintain, protect and expand our intellectual property portfolio;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;

- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies; and
- attract and retain skilled personnel.

Our history of net losses and our expectation of future losses, together with our limited operating history, may make it difficult to evaluate our current business and predict our future performance. In addition, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for sale and have never generated any revenue from product sales. Our ability to generate revenue from product sales and achieve profitability depends on our ability to successfully enroll and complete our clinical trials and obtain the regulatory and marketing approvals necessary to commercialize Hydros-TA. Even if we, or a collaboration partner, are successful in obtaining regulatory approvals to market Hydros-TA, our future revenue will depend upon many factors, including the size of any markets in which Hydros-TA has received approval, the accepted price for Hydros-TA, our ability to achieve sufficient market acceptance, reimbursement from third-party payors, the attractiveness of competing products and therapies, and whether we have royalty and/or co-promotion rights for that territory. We do not anticipate generating revenue from product sales until at least 2017 and may never realize any significant revenue from sales of Hydros-TA.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, which may include completing clinical trials of Hydros-TA, discovering additional product candidates, obtaining regulatory approval for such product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, or comparable foreign regulatory bodies to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of Hydros-TA, or any future product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

We expect to require additional financing to operate our business, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or other operations.

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. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize Hydros-TA or any future product candidates that we may advance. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the development and clinical trials of, and seek regulatory approval for, Hydros-TA. We expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any product candidate, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that the net proceeds of approximately $66.1 million we received from our IPO, together with 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. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our product candidates.

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

- the progress, rate of enrollment, timing, scope, results and costs of our nonclinical and clinical trials for Hydros-TA, including the ability to enroll patients in a timely manner for clinical trials;
- the time and cost necessary to obtain regulatory approvals for Hydros-TA and the costs of post-marketing studies that could be required by regulatory authorities;
- our ability to successfully commercialize Hydros-TA;
- the manufacturing, selling and marketing costs associated with Hydros-TA, including the cost and timing of building our sales and marketing capabilities;
- our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements;
- the scope of our research and clinical development activities to expand the use of Hydros-TA for treating OA in other joints;
- the sales price and the availability of adequate third-party reimbursement for Hydros-TA;
- the cash requirements of any future acquisitions or discovery of future product candidates;
- the number and scope of nonclinical, pre-clinical and discovery programs that we decide to pursue or initiate;
- the time and cost necessary to respond to technological and market developments; and
- 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.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements. 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 delay, limit, reduce or terminate our research and development activities, clinical trials for Hydros-TA for which we retain such responsibility and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize Hydros-TA.

Risks Related to Our Business

We are substantially dependent on the success of our lead product candidate, Hydros-TA, which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized

To date, we have invested substantially all of our efforts and financial resources in the research and development of Hydros-TA, which is our lead product candidate and only product candidate in clinical trials. Hydros-TA is a new approach to treating osteoarthritis, or OA, pain in the knee by using a combination therapy treatment. Our near-term prospects, including our ability to finance our operations and generate revenue from product sales, will depend heavily on our ability to successfully develop, obtain

regulatory approval for, and commercialize Hydros-TA. Our planned development, approval and commercialization of Hydros-TA may not be completed in a timely manner or at all. The clinical and commercial success of Hydros-TA will depend on a number of factors, many of which are beyond our control, including the following:

- the timely completion of the ongoing COR1.1 Phase 3 clinical trial and the initiation and timely completion of our planned COR1.2 Phase 3 clinical trial, both of which will depend substantially upon sufficient and timely patient enrollment, as well as the satisfactory performance of third-party contractors;
- whether Hydros-TA' s safety and efficacy profile is satisfactory to the FDA to warrant marketing approval;
- whether FDA requires additional clinical trials prior to approval to market Hydros-TA;
- the timely receipt of necessary marketing approvals from the FDA;
- our ability to successfully commercialize Hydros-TA, if approved for marketing and sale by the FDA, including educating physicians and patients about the benefits, administration and use of Hydros-TA;
- achieving and maintaining compliance with all regulatory requirements applicable to Hydros-TA;
- the prevalence and severity of any side effects and overall safety profile of Hydros-TA and the acceptance of Hydros-TA as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative convenience and ease of administration, relative safety and relative efficacy of alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for Hydros-TA by third-party payors;
- the effectiveness of our marketing, sales and distribution strategy and operations and of those of any of our current or future collaborators;
- our ability, or any third-party manufacturer we contract with, to successfully scale up the manufacturing process for Hydros-TA, which has not yet been demonstrated, and to manufacture supplies of Hydros-TA and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practice, or cGMP, requirements;
- enforcing intellectual property rights;
- avoiding third-party interference, opposition, derivation or similar proceedings with respect to our patent rights, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety profile of Hydros-TA following approval.

Further, as of May 15, 2015, over 450 subjects have been enrolled in the COR1.1 Phase 3 clinical trial. Our completed COR1.0 study demonstrated a statistically significant result between Hydros-TA and Hydros at the two week time point, but statistical significance was not achieved at any other time point and in any other comparison of treatment arms. As such, previously unseen results may appear as we obtain results in our ongoing COR1.1 Phase 3 clinical trial and our future COR1.2 Phase 3 clinical trial. We have not yet filed an IND for Hydros-TA and will not be able to commence any clinical trials in the United States until we have submitted our IND filing and the FDA has not objected to our commencement of such trials. As such, we do not anticipate filing a new drug application, or NDA, with the FDA until early 2017.

If the number of patients in the market for Hydros-TA or the price that the market can bear is not as significant as we estimate, we may not generate significant revenue from sales of Hydros-TA, even if the above factors are overcome. Accordingly, there can be no assurance that Hydros-TA will ever be successfully commercialized or that we will ever generate revenue from sales of Hydros-TA. If we are not successful in completing the development of, obtaining approval for, and commercializing Hydros-TA, or are significantly delayed in doing so, our business will be materially harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays in our clinical studies. Furthermore, results of earlier studies and trials may not be predictive of future trial results.

Before obtaining marketing approval from regulatory authorities for the sale of Hydros-TA, we must conduct extensive clinical studies to demonstrate the safety and efficacy of Hydros-TA in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical and clinical studies of Hydros-TA may not be predictive of the results of later-stage clinical trials. For example, the positive results generated in our COR1.0 Phase 2b clinical study of Hydros-TA, which was not designed to enroll a sufficient number of patients to demonstrate statistical significance, do not ensure that the ongoing COR1.1 clinical trial, or future clinical trials, will demonstrate similar results. Hydros-TA may fail to show the desired safety and efficacy despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for Hydros-TA.

We are actively enrolling patients internationally in our COR1.1 clinical trial, which is our first Phase 3 clinical trial of Hydros-TA, and we expect to initiate COR1.2, our second Phase 3 clinical trial of Hydros-TA, in mid-2015. However, we may experience delays in our ongoing COR1.1 or any other future clinical trials including COR1.2, and we do not know whether future clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all.

Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a trial, if applicable;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;
- recruit suitable patients in a timely manner to participate in our trials;
- have patients complete a trial or return for post-treatment follow-up;
- ensure that clinical sites observe trial protocol, comply with good clinical practices, or GCPs, or continue to participate in a trial;
- ensure adequate control of the clinical product handling and storage conditions;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of Hydros-TA for use in our COR1.1 and COR1.2 trials or other future clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including, in respect of our COR1.1 and COR1.2 trials, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by an independent data safety monitoring board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If there are delays in the completion of, or termination of, any clinical trial of Hydros-TA, the commercial prospects of Hydros-TA may be harmed, and our ability to generate revenue from product sales will be delayed. In addition, any delays in completing the clinical trials will increase costs, slow down the development and approval process of Hydros-TA and jeopardize the ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of Hydros-TA.

Conducting our COR1.1 and a portion of our COR1.2 clinical trials in foreign countries present risks that may delay the completion of COR1.1 and COR1.2.

Conducting our COR1.1 and a portion of our COR1.2 clinical trials in foreign countries presents risks that may delay completion of these clinical trials. Such risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and political and economic risks relevant to such foreign countries. In addition, the FDA may determine that the clinical trial results obtained in foreign subjects are inadequate to support an NDA approval in the United States.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize Hydros-TA.

We do not have the ability to independently conduct clinical trials. We currently, and will continue to, rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct our clinical trials of Hydros-TA. The third parties with whom we contract for execution of the clinical trials we are conducting play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely, and will continue to rely, on third parties to conduct our clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current GCPs for clinical studies. GCPs are regulations and guidelines enforced by the FDA through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase cost.

Our product candidates may cause undesirable side effects or have other properties that could delay our clinical trials, or delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approva4 if any. If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidate, the ability to market such product candidate could be compromised

Undesirable side effects caused by a product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials of the product candidate, result in the delay or denial of regulatory approval by the FDA or limit the commercial profile of an approved label. Some examples of drug-related side effects experienced by patients treated with Hydros-TA include injection site pain, arthralgia and injection site warmth. In the event that trials conducted by us of Hydros-TA or of future product candidates reveal an unacceptable severity and prevalence of these or other side effects, such trials could be suspended or terminated and the FDA could order us to cease further development of or deny approval of Hydros-TA, or any future product candidate, for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, in the event that Hydros-TA or any future product candidates receive regulatory approval and we or others later identify undesirable side effects caused by the product, a number of potentially significant negative consequences could occur, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or our collaboration partners, may be required to recall the product;

- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a Risk Evaluation and Mitigation Strategies, or REMS, plan that may require creation of a Medication Guide outlining the risks of such side effects for distribution to patients, as well as elements to assure safe use of the product, such as a patient registry and training and certification of prescribers;
- we, or our collaboration partners, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us or a collaboration partner from achieving or maintaining market acceptance of a particular product candidate, if approved, and could result in the loss of significant revenue to us, which would materially and adversely affect our results of operations and business.

If we are unable to differentiate Hydros-TA from steroid injections, viscosupplements or other combination therapies for the treatment of OA pain, the ability to successfully commercialize Hydros-TA would be adversely affected

Currently available steroid injections are effective at providing pain relief within a couple of days, but they do not last for more than two to four weeks and can have a damaging effect on the healthy cartilage. Most of these steroid injections are interchangeable with the choice usually stemming from cost to the patient and physician preference. These generic steroids also have well-established market positions and familiarity with physicians, healthcare payors and patients. There are five multi-injection viscosupplements (Hyalgan, Orthovisc, Supartz, Synvisc and Euflexxa) and three single-injection products (Synvisc-One, Gel-One and Monovisc) that are currently on the market, many of which are produced by large biopharmaceutical or pharmaceutical companies that have significant resources that they can devote to the development and promotion of their drug products. Of these viscosupplements, Synvisc-One represents over 50% of the U.S. viscosupplement market. Moreover, we believe that in at least some cases patients are treated with both a steroid injection and a viscosupplement injection within a relatively short proximity with an aim to achieve both rapid and sustained pain relief.

In addition to steroid injections and viscosupplements there are also a number of combination viscosupplement/steroid therapies currently in development. To our knowledge the most advanced of these candidates is currently in Phase 3 trials. To the extent that any of these therapies receive approval prior to Hydros-TA these competitors will have a first-mover advantage over us and, as such, will have the ability to begin developing brand recognition and customer loyalty that will increase the barriers that we will be required to overcome in order to gain commercial success.

Although we believe Hydros-TA has the potential for clinically meaningful differentiation in sustained pain relief as compared to currently available steroid injections and rapid pain relief as compared to viscosupplements, as clinical development of Hydros-TA advances and we receive data from additional clinical trials, it is possible that the data will not support such differentiation, which would adversely affect our ability to successfully commercialize Hydros-TA. Further, our ability to achieve commercial success will, at least in part, depend on our ability to differentiate ourselves from these existing therapies in such a way that physicians and patients will be willing to switch from existing therapies with which they are familiar to Hydros-TA. Once physicians incorporate a particular treatment into their practice they may not alter their practice absent compelling clinical evidence of safety and/or effectiveness and/or significant pricing reimbursement advantages.

If the FDA or other applicable regulatory authorities approve generic products that compete with Hydros-TA, the ability to successfully commercialize Hydros-TA would be adversely affected.

The FDA or other applicable regulatory authorities may approve generic products that could compete with Hydros-TA. Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient, dosage form, strength, route of administration and conditions of use, or labeling, as Hydros-TA and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as Hydros-TA. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that

produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to Hydros-TA would materially adversely impact our ability to successfully commercialize Hydros-TA.

We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.

The pharmaceutical, biotechnology and specialty pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the OA pain market is intense. We have competitors in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. In addition, we expect that injectable therapies such as Hydros-TA will continue to be used primarily after oral medications no longer provide adequate pain relief.

It is possible that our competitors will be able to leverage their large market share (for example, Sanofi S.A., the developer of Synvisc-One, holds more than 50% of the viscosupplement market as of 2012) to set prices at a level below that which is profitable for us. Our competitors may also be able to develop and market drugs or other treatments that are less expensive and more effective than Hydros-TA, or that will render Hydros-TA obsolete. It is also possible that our competitors will commercialize competing drugs or treatments before we can commercialize Hydros-TA. We also anticipate that we will face increased competition in the future as new companies enter into our target markets.

In addition to competitors in the viscosupplement market, as a result of the 2013 clinical practice guidelines released by the American Association of Orthopedic Surgeons, or AAOS, clinicians have been searching for alternatives to hyaluronic acid, or HA. To the extent additional alternative therapies are developed and receive positive support from AAOS, other professional medical societies and governmental agencies, these therapies would compete with Hydros-TA, if approved. For additional information regarding the AAOS guidelines, see the risk factor below "—Third-party payor coverage and reimbursement status of newly-approved products is uncertain and such coverage for viscosupplementation may be hampered by recommendations from AAOS. Failure to obtain or maintain adequate coverage and reimbursement for Hydros-TA, if approved, could limit our ability to market Hydros-TA and decrease our ability to generate revenue."

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do, as well as a significant share of the existing market for OA pain treatments. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in pre-clinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaboration partnerships or licensing relationships with our competitors.

We currently have no sales organization. If we are unable to establish sales capabilities on our own, we may not be able to commercialize Hydros-TA, if approved, or commercialize any future product candidates.

We currently do not have a sales organization. In order to commercialize Hydros-TA or any future product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If one or more of our product candidates receives regulatory approval, we expect to establish a specialty sales organization with technical expertise and supporting distribution capabilities to commercialize such product candidate, which will be expensive and time consuming. As a company, we have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of Hydros-TA or any future product candidates.

We rely completely on third parties, and in some cases a single third-party, to manufacture our clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate. Our business would be harmed if those third parties fail to maintain approval from the FDA, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical studies of Hydros-TA, and we lack the resources and the capability to manufacture Hydros-TA on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture any drug products must be approved by the FDA pursuant to inspections that will be conducted after an NDA is submitted to the FDA. We do not control the manufacturing process of Hydros-TA, and we are completely dependent on our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products.

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA withdraws approval of these facilities for the manufacture of Hydros-TA, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market Hydros-TA, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce Hydros-TA for our clinical studies. There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce Hydros-TA for our clinical studies, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical study unless we believe we have on hand, or will be able to manufacture, a sufficient supply of Hydros-TA to complete such study, any significant delay or discontinuity in the supply of Hydros-TA, or the raw material components thereof, for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of Hydros-TA, which could harm our business and results of operations.

We may not be successful in our efforts to develop Hydros-TA for indications beyond our initial target indication of treating the pain from OA in the knee.

Hydros-TA is our only product candidate in clinical trials (currently taking place outside of the United States) with a proposed initial indication for OA pain in the knee. While our primary focus is on developing Hydros-TA for this indication, a key element of our strategy is also to expand the use of Hydros-TA into other joints in the body that are afflicted by pain associated with OA. We used a portion of the proceeds from our IPO to develop Hydros-TA for the treatment of OA pain in other joints in the body; however, there is no guarantee that our development efforts will be successful and the potential indications of Hydros-TA would be expanded beyond that of OA pain in the knee.

We may not be successful in our efforts to expand our pipeline of other product candidates.

Another key element of our strategy is to develop a pipeline of other product candidates. Of the large number of drugs in development, only a small percentage of such drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to fund the initiation of other product development programs, there can be no assurance that any product candidates will reach the clinical-stage or be successfully developed or commercialized. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used and our drug discovery and design platform may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may on further study be shown to have harmful side effects or other characteristics

that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

Even if we are successful in expanding our pipeline, through our own research and development efforts or by pursuing in-licensing or acquisition of product candidates, the potential product candidates for which we identify or acquire rights may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize a product pipeline, we may not be able to generate revenue from product sales in future periods or ever achieve profitability.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Hydros-TA.

We face an inherent risk of product liability as a result of the clinical testing of Hydros-TA and will face an even greater risk if we commercialize Hydros-TA. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Hydros-TA. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Hydros-TA;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or co-promote Hydros-TA.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry $5 million of product liability insurance covering use in our clinical trials in amounts that we believe are customary and adequate for a clinical-stage biopharmaceutical company. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biopharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific and medical personnel, particularly David M. Renzi, our president and chief executive officer, Marcee M. Maroney, our vice president of clinical affairs, and David M. Gravett, Ph.D., our vice president of research and development. In order to induce valuable employees to remain with us, we have, among other things, provided stock-based compensation that vests over time. The value to employees of stock-based compensation will be significantly affected by movements

in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results and financial condition. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled scientific and medical personnel.

We may expend our limited resources to pursue a particular product candidate or indication for Hydros-TA and fail to capitalize on product candidates or indications for Hydros-TA that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications of Hydros-TA that later prove to have greater commercial potential than the use of Hydros-TA for the treatment of pain associated with OA in the knee. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for future product candidates and for specific indications of Hydros-TA may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration partnerships, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance Hydros-TA through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize Hydros-TA and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We may not realize the benefit of our existing collaboration partnership, may fail to form additional collaboration partnerships in the future and may not realize the benefits of such collaborations.

Our license agreement with Shanghai Jingfeng Pharmaceutical Co., Ltd., or Jingfeng, provides Jingfeng with the exclusive right and license to develop and commercialize Hydros-TA, or any improvements or modifications to Hydros-TA, for use in China, Taiwan, Hong Kong and Macau. Pursuant to the terms of the license agreement, Jingfeng is responsible for the manufacture and supply of Hydros-TA and the management and funding of all development activities, regulatory submissions and regulatory approvals for Hydros-TA within the applicable territory. Our ability to realize any of the approximately $65 million in remaining milestone payments pursuant to the terms of the license agreement is therefore outside of our control and as a result we can make no guaranty or assurance that all or a portion of such payments will be made. We may form additional collaboration partnerships, create joint ventures or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of pharmaceutical and biotechnology companies and could enter into new collaboration partnerships at any time. We face significant competition in seeking appropriate collaboration partners, and the negotiation process to secure appropriate terms is time-consuming and complex. Any delays in identifying suitable collaboration partners and entering into agreements to develop Hydros-TA could also delay the commercialization of Hydros-TA, which may reduce its competitiveness even if it reaches the market. Moreover, we may not be successful in our efforts to establish such a collaboration partnership for any future product candidates and programs on terms that are acceptable to us, or at all. This may be because such future product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient and/or third parties may not view such product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Even if we are successful in entering into a collaboration partnership or license arrangement, there is no guarantee that the collaboration partnership will be successful. Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;

- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- collaborators may cease to devote resources to the development or commercialization of Hydros-TA or future product candidates if the collaborators view such product candidates as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time-consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenues to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

If we seek and obtain approval to commercialize Hydros-TA outside of the United States, or otherwise engage in business outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may decide to seek marketing approval for Hydros-TA outside the United States or otherwise engage in business outside the United States, including entering into contractual agreements with third-parties. We expect that we will be subject to additional risks related to entering into these international business markets and relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing United States and foreign drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Our business involves the use of hazardous materials and we and third-parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of Hydros-TA and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for Hydros-TA could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of Hydros-TA or future product candidates could be delayed.

We may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

The terms of our loan and security agreement may restrict our ability to engage in certain transactions.

In October 2011, we entered into a loan and security agreement with Silicon Valley Bank, or SVB. Pursuant to the terms of the loan and security agreement subject to certain exceptions, we cannot engage in certain transactions, unless certain conditions are met or we receive the prior approval of SVB. Such transactions include:

- disposing of our business or certain assets;
- changing our business, management, ownership or business locations;
- incurring additional debt or liens or making payments on other debt;
- making certain investments and declaring dividends;
- acquiring or merging with another entity;
- engaging in transactions with affiliates; or

- encumbering intellectual property.

If SVB does not provide its consent to such actions we could be prohibited from engaging in transactions that could be beneficial to our business and our stockholders unless we were to repay the loans, which may not be desirable or possible. The loan and security agreement is collateralized by a pledge of substantially all of our assets, except for intellectual property. If we were to default under the loan and security agreement, including for an inability to repay amounts as they become due, and were unable to obtain a waiver for such a default, SVB would have a right to accelerate our obligation to repay the entire loan and foreclose on these assets in order to satisfy our obligations under the loan and security agreement. In addition, SVB would also have the right to place a hold on our accounts maintained at SVB and refuse to fund any then unfunded commitments under the loan and security agreement. Any such action on the part of SVB against us could have a materially adverse impact on our business, financial condition and results of operations.

Risks Related to Government Regulation

The regulatory approval processes of the FDA are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for Hydros-TA, our business will be substantially harmed

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any drug product in the United States until we receive marketing approval from the FDA. We have not submitted an application or obtained marketing approval for Hydros-TA anywhere in the world. Obtaining regulatory approval of a new drug application, or NDA, can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Prior to obtaining approval to commercialize a drug candidate in the United States or abroad, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that such drug candidates are safe and effective for their intended uses. We are actively enrolling patients internationally in COR1.1, which is our first Phase 3 clinical trial of Hydros-TA, and we expect to initiate COR1.2, our second Phase 3 clinical trial of Hydros-TA, in mid-2015. We expect to report primary endpoint results from COR1.1 in early 2016 and from COR1.2 by the end of 2016, and to submit our NDA for Hydros-TA in early 2017. The number of nonclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate and, as such, we may be required to perform additional clinical trials beyond our ongoing COR1.1 trial and our expected COR1.2 trial. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a drug candidate for any or all targeted indications.

Regulatory approval of an NDA is not guaranteed and the time required to obtain approval is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors. The FDA has substantial discretion in the approval process and we may encounter matters with the FDA that require us to expend additional time and resources and which may delay or prevent the approval of Hydros-TA. For example, the FDA may require us to conduct additional studies or trials for Hydros-TA either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the

United States. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of Hydros-TA' s clinical development, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage. An NDA for Hydros-TA could fail to receive FDA approval for many reasons, including but not limited to the following:

- the FDA may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which approval is sought;
- the FDA may disagree with the interpretation of data from pre-clinical studies or clinical studies;
- the data collected from clinical studies of Hydros-TA may not be sufficient to support the submission of a NDA or to obtain FDA approval;
- we may be unable to demonstrate to the FDA that Hydros-TA' s risk-benefit ratio for its proposed indication is acceptable;
- the FDA may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers responsible for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failure and/or that of a collaboration partner to obtain regulatory approval to market Hydros-TA, which would significantly harm our business, results of operations, and prospects. Additionally, if the FDA requires that we conduct additional clinical studies or delays or refuses approval to market Hydros-TA, our business and results of operations may be harmed.

In addition, even if we were to obtain approval, the FDA may approve Hydros-TA for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve Hydros-TA with a label that does not include the labeling claims necessary or desirable for successful commercialization. Any of the foregoing scenarios could materially harm the commercial prospects for Hydros-TA.

Third-party payor coverage and reimbursement status of newly-approved products is uncertain and such coverage for viscosupplementation may be hampered by recommendations from AAOS. Failure to obtain or maintain adequate coverage and reimbursement for Hydros-TA, if approved, could limit our ability to market Hydros-TA and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of Hydros-TA, if approved, must be adequate to support a commercial infrastructure. The availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford treatments such as ours, assuming approval. Sales of Hydros-TA will depend substantially, on the extent to which the costs of Hydros-TA will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize Hydros-TA. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies established. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

In addition to the risks faced by all newly-approved products, we face additional risks as a result of the current clinical practice guidelines issued by AAOS relating to viscosupplementation in OA of the knee. AAOS' s current clinical practice guidelines, which many payors rely upon when developing their coverage policies relating to viscosupplementation, do not recommend intra-articular use of HA in patients with symptomatic OA of the knee. While some third-party payors continue to cover HA for the treatment of OA of the knee after the publication of these guidelines, a number of third-party payors, including Blue Cross Blue

Shield, have reversed their coverage policies and no longer cover the use of HA for the treatment of OA of the knee. If AAOS does not revise these guidelines to reflect a more positive recommendation with respect to viscosupplementation or Hydros-TA, and/or other organizations (including, but not limited to, governmental agencies, other professional societies, private health and science foundations and practice management groups) release similar guidelines suggesting reduced use of HA or promote competitive or alternative therapies, additional payors may reverse currently positive coverage policies or refuse to approve Hydros-TA for coverage and reimbursement which could limit our ability to market Hydros-TA and decrease our ability to generate revenue.

Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement rates may vary depending on the payor, the insurance plan, and other factors. A current trend in the United States health care industry is toward cost containment Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels of, particular treatments. Such third-party payors, including Medicare, are questioning the coverage of, and challenging the prices charged for medical products and services. Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, these caps may not cover or provide adequate payment for Hydros-TA. We expect to experience pricing pressures in connection with the sale of Hydros-TA due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Adequate third-party coverage and reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development, which could adversely impact our revenue and prospects for profitability. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our drug candidates in whole or in part.

If the FDA does not conclude that Hydros-TA satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of Hydros-TA under Section 505(b)(2) are not as we expect, the approval pathway for Hydros-TA will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for Hydros-TA. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for Hydros-TA as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for Hydros-TA would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than Hydros-TA, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for Hydros-TA, there can be no assurance that we will receive the requisite or timely approvals for commercialization.

Even if we receive regulatory approval for Hydros-TA, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, if approved, Hydros-TA could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if a drug is approved by the FDA, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers and manufacturers' facilities are require to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs. As such, we and our third-party contract manufacturers will be subject to continual review and periodic inspections to assess compliance with regulatory requirements. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Regulatory authorities may also impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- warning letters or fines;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- injunctions or the imposition of civil or criminal penalties;
- suspension or revocation of existing regulatory approvals;
- suspension of any of our ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications submitted by us;
- restrictions on our or our contract manufacturers' operations; or
- product seizure or detention, or refusal to permit the import or export of products.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize Hydros-TA. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Hydros-TA. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing Hydros-TA. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of product candidates for clinical studies or commercial sale, including our existing contract manufacturers for Hydros-TA, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to cGMP regulations enforced by the FDA. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of Hydros-TA. In addition, the FDA may, at any time, inspect a manufacturing facility involved with the preparation of Hydros-TA or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates manufactured at these facilities may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, inspect the manufacturing facilities of our third-party contractors. If any such inspection identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third-party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent suspension of production or closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If a third-party manufacturer with whom we contract fails to maintain regulatory compliance, the FDA may impose regulatory sanctions including, among other things, refusal to approve Hydros-TA or withdrawal of approval for Hydros-TA if previously approved. In addition, we may be subject to fines, unanticipated compliance expenses, recall or seizure, total or partial suspension of production and/or enforcement actions, including injunctions and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a supplemental NDA, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals, or commercialization of Hydros-TA. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

If approved Hydros-TA may cause or contribute to adverse medical events that we are required to report to regulatory agencies, and if we fail to do so, we could be subject to sanctions that could materially harm our business.

Some participants in clinical studies of Hydros-TA have reported adverse effects after being treated with Hydros-TA, including injection site pain, arthralgia, meniscal lesion and cyst aspiration. If we are successful in commercializing Hydros-TA, FDA regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

If we fail to comply or are found to have failed to comply with FDA and other regulations related to the promotion of Hydros-TA for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. If we receive marketing approval for Hydros-TA, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of Hydros-TA for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses. Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

We are currently only seeking regulatory approval to market Hydros-TA in the United States, and if we want to expand the geographies in which we may market Hydros-TA, we will need to obtain additional regulatory approvals. Our failure to obtain regulatory approvals in foreign jurisdictions for Hydros-TA would prevent us from marketing internationally.

We currently plan to seek regulatory approval for Hydros-TA in the United States. In the future, we may attempt to seek regulatory approval to promote and commercialize Hydros-TA outside of the United States. In order to obtain such approvals, we may be required to conduct additional clinical trials or studies to support our applications, which would be time consuming and expensive, and may produce results that do not result in regulatory approvals. Further, we will have to expend substantial time and resources in order to establish the commercial infrastructure necessary to promote and commercialize Hydros-TA outside of the United States, or pursue a collaboration arrangement that would enable such promotion and commercialization. If we do not obtain regulatory approvals for Hydros-TA in foreign jurisdictions, our ability to expand our business outside the United States will be severely limited.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize our products in any market.

Healthcare legislative reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of Hydros-TA and to produce, market and distribute Hydros-TA after clearance or approval is obtained.

In the United States, there have been and continue to be a number of legislative initiatives that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the coverage and reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of Hydros-TA. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

In addition, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers.

Further, third-party payors regularly update payments to physicians and hospitals where our product candidates will be used. Because viscosupplement injection is performed by the physician, usually in the office or outpatient clinic, payors generally reimburse the physician for both the IA injection and for the viscosupplement. As a result, these payment updates could directly impact the demand for our product candidates, if approved.

It is likely that federal and state legislatures within the United States will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for Hydros-TA or any future product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Intellectual Property

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of Hydros-TA or any future product candidates.

Our commercial success depends in part on avoiding infringement and misappropriation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings asserting infringement or misappropriation of patents and other intellectual property rights in the pharmaceutical and biotechnology industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. As the pharmaceutical and biotechnology industries expand and more patents are issued in this area, the risk increases that Hydros-TA and any future product candidates may be subject to claims of infringement of the patent rights of third parties.

There can be no assurance that we will not be subject to claims alleging that the manufacture, use or sale of Hydros-TA or any future product candidates nor that any activities conducted by us, infringes existing or future third-party patents, or that such claims, if any, will not be successful. We cannot guarantee that we have identified each and every patent and pending application in the United States and abroad owned by others that is relevant or necessary to the commercialization of Hydros-TA. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of Hydros-TA or future product candidates or by the operation of our business. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of Hydros-TA or future product candidates. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that Hydros-TA or future product candidates either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/ or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before the courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may be subject to third-party patent infringement claims in the future against us or a collaboration partner that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third-party's patents. We may be required to indemnify our collaboration partners against such claims. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If a patent infringement suit were brought against us or our collaboration partners, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaboration partners may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaboration partners were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaboration partners are unable to enter into licenses on acceptable terms. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office, or the USPTO, to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to Hydros-TA or any future product candidates. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful in these proceedings, these proceedings may result in substantial costs and distract our management and other employees.

If our intellectual property related to Hydros-TA is not adequate or if we are not able to protect our trade secrets or our confidential information, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Hydros-TA, our drug discovery and development platform and our development programs. Any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents can be challenged by any person before the new USPTO Patent Trial and Appeals Board at any time before one year after that person is served an infringement complaint based on the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the United States, Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. For example, a third-party may develop a competitive product that provides therapeutic benefits similar to Hydros-TA but has a sufficiently different composition to fall outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to Hydros-TA is successfully challenged, then our market for Hydros-TA could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business. Further, if we encounter delays in our clinical trials, the period of time during which we could market Hydros-TA under patent protection would be reduced.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or a collaboration partner were to initiate legal proceedings against a third-party to enforce a patent covering Hydros-TA, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability against our intellectual property related to Hydros-TA, we would lose at least part, and perhaps all, of the patent protection on Hydros-TA. Such a loss of patent protection would have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do.

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

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to assign their inventions to us, and endeavor to execute confidentiality agreements with all such parties, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had

access to our proprietary information, nor can we be certain that our agreements will not be breached by such consultants, advisors or third parties, or by our former employees. The breach of such agreements by individuals or entities who are actively involved in the discovery and design of our potential drug candidates, could require us to pursue legal action to protect our trade secrets and confidential information, which would be expensive, and the outcome of which would be unpredictable. If we are not successful in prohibiting the continued breach of such agreements, our business could be negatively impacted. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of Hydros-TA.

We intend to rely on Section 505(b)(2) for our NDA submission of Hydros-TA. A 505(b)(2) application for Hydros-TA would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA. If a 505(b)(2) applicant makes a paragraph IV certification, it must give notice of that certification to the owner of the patent and the holder of the approved NDA for the reference drug.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approval for Hydros-TA. The FDA may also reject our 505(b)(2) submission and require us to file such submission under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize Hydros-TA.

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 a collaboration partners' patent applications and the enforcement or defense of our or a 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 that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third-party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, and do not perform work for us that is in conflict with their obligations to another employer or any other entity, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. In addition, an employee, advisor or consultant who performs work for us may have obligations to a third-party that are in conflict with their obligations to us, and as a result such third-party may claim an ownership interest in the intellectual property arising out of work performed for us. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Risks Related to Our Common Stock and being a Public Company

Our stock price may be 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 10Q and others such as:

- results from, or any delays in, clinical trial programs relating to Hydros-TA, including slower than anticipated enrollment;

- ability to commercialize or obtain regulatory approval for Hydros-TA, or delays in commercializing or obtaining regulatory approval;
- announcements of regulatory approval or a complete response letter to Hydros-TA, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- changes in reimbursement or third-party coverage of treatments for pain associated with OA, or changes to treatment recommendations or guidelines applicable to the treatment of OA or pain from OA;
- announcements relating to collaboration partnerships or other strategic transactions undertaken by us;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to Hydros-TA;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other U.S. regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- 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;
- general economic and market conditions and overall fluctuations in the United States equity markets; and
- the loss of any of our key scientific or management personnel.

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 IPO in April 2015. Prior to that, there had been no public market for shares of our common stock. Following our IPO, 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' 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 and may impair our ability to acquire other businesses or technologies or in-license new product candidates using our shares as consideration.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new 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 will 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 will increase our legal and financial compliance costs and will 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. See below, "We are eligible to be treated as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors" for a further discussion of the impacts of our decision to take advantage of the exceptions available to emerging growth companies.

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 will be 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.

We are eligible to be treated as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board providing for supplemental auditor's reports for additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" if the market value of our common stock held by non-affiliates is below $75.0 million as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this Quarterly Report on Form 10Q lapse, the trading price of our common stock could decline. Based upon the number of shares outstanding as of April 30, 2015, we had a total of 26,214,107 shares of common stock outstanding. Of those shares, the 14,950,000 shares sold in our IPO are freely tradable, without restriction, in the public market immediately.

The lock-up agreements pertaining to our IPO will expire October 5, 2015. After the lock-up agreements expire, as of March 31, 2015, and including the conversion of our convertible promissory notes and accrued interest thereon into 2,287,120 shares of common stock in connection with our IPO in April 2015, up to an additional 11,264,107 shares of common stock will be eligible for sale in the public market, 10,955,516 of which shares are beneficially owned by current directors, executive officers and other affiliates and may be subject to Rule 144 under the Securities Act of 1933, or the Securities Act.

In addition, as of March 31, 2015, 1,328,873 shares of common stock that are subject to outstanding options with a weighted average exercise price of $2.54 per share will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of approximately 8,268,531 shares of our outstanding common stock as of March 31, 2015 will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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 662/3% 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 acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 662/3% 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 acquiror from conducting a solicitation of proxies to elect the acquiror'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 March 31, 2015. If we undergo additional ownership changes (some of which changes may be outside our control), 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."

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, our stockholders are not likely to receive any dividends on their common stock for the foreseeable future. In addition, pursuant to our loan and security agreement with SVB, we are prohibited from paying cash dividends without the prior consent of SVB. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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.

Item 6. EXHIBITS

Exhibits

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 Financial 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 Financial 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

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: May 21, 2015

By: /s/ David M. Renzi
David M. Renzi
President Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.1

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: May 21, 2015

/s/ David M. Renzi

David M. Renzi
President and Chief Executive Officer

Exhibit 31.2

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

I, T. Michael White, 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: May 21, 2015

/s/ T. Michael White

T. Michael White
Chief Financial Officer and Vice President, Finance

Exhibit 32.1

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 March 31, 2015 (the "Report"), I, David M. Renzi, as President and Chief Executive Officer of the Company, and T. Michael White, as Chief Financial Officer and Vice President, Finance 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: May 21, 2015

/s/ David M. Renzi

David M. Renzi
President and Chief Executive Officer

Dated: May 21, 2015

/s/ T. Michael White

T. Michael White
Chief Financial Officer and Vice President, Finance