Cara Therapeutics, Inc.
Form 10-Q
November 09, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

OR

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

COMMISSION FILE NUMBER 001-36279

CARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**75-3175693**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1 Parrott Drive

Shelton, Connecticut 06484

(Address of registrant s principal executive offices)

Registrant s telephone number, including area code: (203) 567-1500

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x 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). x 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 definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x	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 x No.

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of November 4, 2015 was: 27,231,583.

Table of Contents

CARA THERAPEUTICS, INC.

INDEX TO FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

PART I FINANCIAL INFORMATION

		PAGE NUMBER
Item 1.	Financial Statements (Unaudited):	
	Condensed Balance Sheets as of September 30, 2015 and December 31, 2014	1
	Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2015 and 2014	2
	Condensed Statements of Convertible Preferred Stock and Stockholders (Deficit) Equity for the Nine Months Ended September 30, 2015 and 2014	3
	Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2015 and 2014	4
	Notes to Condensed Financial Statements	5
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	24
Item 4.	Controls and Procedures	24
	PART II OTHER INFORMATION	
Item 1.	Legal Proceedings	26
Item 1A	Risk Factors	26
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	26
Item 3.	Defaults Upon Senior Securities	26
Item 4.	Mine Safety Disclosures	26
Item 5.	Other Information	26
Item 6.	Exhibits	27
	SIGNATURES	28

Table of Contents

PART I

FINANCIAL INFORMATION

Item 1. ***Financial Statements*.**

CARA THERAPEUTICS, INC.

CONDENSED BALANCE SHEETS

(amounts in thousands, excluding share and per share data)

(unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 111,116	$ 52,663
Income tax receivable	450	200
Other receivables	2,143	
Prepaid expenses	1,971	287
Total current assets	115,680	53,150
Property and equipment, net	1,517	2,084
Restricted cash	700	700
Total assets	$ 117,897	$ 55,934
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,374	$ 1,946
Deferred revenue		1,452
Total current liabilities	3,374	3,398
Deferred lease obligation	660	874
Commitments and contingencies *(Note 11)*		
Stockholders equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized at September 30, 2015 and December 31, 2014, zero shares issued and outstanding at September 30, 2015 and December 31, 2014		
Common stock; $0.001 par value; 100,000,000 shares authorized at September 30, 2015 and December 31, 2014, 27,231,583	27	23

shares and 22,802,039 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively				
Additional paid-in capital		209,197		131,840
Accumulated deficit		(95,361)		(80,201)
Total stockholders equity		113,863		51,662
Total liabilities and stockholders equity	$	117,897	$	55,934

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF OPERATIONS

(amounts in thousands, excluding share and per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Revenue:				
License and milestone fees	$ 1,710	$	$ 1,710	$ 302
Collaborative revenue	730	1,125	2,093	1,802
Clinical compound revenue				159
Total revenue	2,440	1,125	3,803	2,263
Operating expenses:				
Research and development	5,584	6,208	13,653	11,609
General and administrative	1,865	1,520	5,609	4,390
Total operating expenses	7,449	7,728	19,262	15,999
Operating loss	(5,009)	(6,603)	(15,459)	(13,736)
Interest income	22	26	49	104
Loss before benefit from income taxes	(4,987)	(6,577)	(15,410)	(13,632)
Benefit from income taxes	200	32	250	59
Net loss	$ (4,787)	$ (6,545)	$ (15,160)	$ (13,573)
Net loss per share -Basic and Diluted	$ (0.19)	$ (0.29)	$ (0.64)	$ (0.67)
Weighted average shares:				
Basic and Diluted	25,545,164	22,713,040	23,737,443	20,351,005

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK

AND STOCKHOLDERS (DEFICIT) EQUITY

(amounts in thousands except share and per share data)

(unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders (Deficit)	Convertible Preferred Stock	
	Shares	Amount	Capital	Deficit	Equity	Shares	Amount
Balance at December 31, 2013	4,288,243	$ 4	$ 8,377	$ (62,456)	$ (54,075)	29,186,929	$ 65,586
Preferred stock converted to common shares	12,554,171	13	65,573		65,586	(29,186,929)	(65,586)
Sale of common stock in initial public offering ($11.00 per share), net of underwriting discounts and commissions and offering expenses of $7,003	5,750,000	6	56,241		56,247		
Stock-based compensation expense			1,031		1,031		
Shares issued upon exercise of stock options	179,800		119		119		
Shares issued upon cashless exercise of warrants	6,383						
Net loss				(13,573)	(13,573)		
Balance at September 30, 2014	22,778,597	$ 23	$ 131,341	$ (76,029)	$ 55,335		$

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders	Convertible Preferred Stock	
	Shares	Amount	Capital	Deficit	Equity	Shares	Amount
Balance at December 31, 2014	22,802,039	$ 23	$ 131,840	$ (80,201)	$ 51,662		$
Sale of common stock in a follow-on public offering ($18.60 per share), net of underwriting discounts and commissions and offering expenses of $5,269	4,327,956	4	75,227		75,231		
Stock-based compensation expense			1,807		1,807		
Shares issued upon exercise of stock options	101,588		323		323		
Net loss				(15,160)	(15,160)		
Balance at September 30, 2015	27,231,583	$ 27	$ 209,197	$ (95,361)	$ 113,863		$

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(amounts in thousands)

(unaudited)

	Nine Months Ended	
	September 30, 2015	**September 30, 2014**
Operating activities		
Net loss	$ (15,160)	$ (13,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,807	1,031
Depreciation and amortization	580	590
Deferred rent costs	(214)	(194)
Changes in operating assets and liabilities:		
Income tax receivable	(250)	(28)
Other receivables	(2,143)	
Prepaid expenses	(1,649)	240
Accounts payable and accrued expenses	1,171	1,647
Deferred revenue	(1,452)	(1,531)
Net cash used in operating activities	(17,310)	(11,818)
Investing activities		
Purchases of property and equipment	(13)	(27)
Net cash used in investing activities	(13)	(27)
Financing activities		
Proceeds from initial public offering, net of issuance costs		57,762
Proceeds from follow-on offering of common stock, net of issuance costs	75,453	
Proceeds from the exercise of stock options	323	119
Net cash provided by financing activities	75,776	57,881
Net cash increase for the period	58,453	46,036
Cash and cash equivalents at beginning of period	52,663	12,357
Cash and cash equivalents at end of period	$ 111,116	$ 58,393
Noncash financing activities		
Conversion of convertible preferred stock to common stock	$	$ 65,586
Reclassification of prepaid IPO costs paid in 2013		1,465

Unpaid IPO/ follow-on offering issuance costs	222	50

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

1. Business

Cara Therapeutics, Inc. (the Company , we , our or us) is a clinical-stage biopharmaceutical corporation formed on July 2, 2004. The Company is focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. The Company s primary activities to date have been organizing and staffing the company, developing its product candidates, including conducting preclinical studies and clinical trials of CR845-based product candidates and raising capital.

As of September 30, 2015, the Company has raised aggregate net proceeds of approximately $204,800 from several rounds of equity financing, including its follow-on offering, which closed in August 2015 (see Note 5 of Notes to Condensed Financial Statements), and the issuance of debt. In addition, the Company earned approximately $32,500 (of which approximately $2,100 was due to the Company as of September 30, 2015 and received in October 2015) under its license agreements for CR845, primarily with Maruishi Pharmaceutical Co. Ltd. (Maruishi) and Chong Kun Dang Pharmaceutical Corp. (CKD), and for an earlier product candidate for which development efforts ceased in 2007.

In connection with the license of rights to CR845 in Japan to Maruishi and as part of the earnings described above, in April 2013, the Company received an upfront payment of $15,000, and in August 2014 and September 2015, the Company received an additional $480 and was due an additional $1,725 (net of contractual foreign currency exchange adjustments), respectively, in milestone payments. In connection with the license of rights to CR845 in South Korea to CKD and as part of the earnings described above, in 2012, the Company received aggregate upfront and milestone payments of $1,190, and in August 2015 and September 2015, the Company received an additional $209 and was due an additional $417 (net of South Korean withholding taxes), respectively, in milestone payments.

The Company has incurred substantial net losses and negative cash flows from operating activities in nearly every fiscal period since inception. As of September 30, 2015, the Company had unrestricted cash and cash equivalents of $111,116 and an accumulated deficit of $95,361. The Company had net cash used in operating activities of $17,310 and $11,818 for the nine months ended September 30, 2015 and 2014, respectively. The Company expects that cash and cash equivalents at September 30, 2015 will be sufficient to fund its operations beyond one year. The Company recognized net losses of $4,787 and $15,160 for the three and nine months ended September 30, 2015, respectively, and $6,545 and $13,573 for the three and nine months ended September 30, 2014, respectively, and expects to incur additional net losses and negative cash flows for the full year ending December 31, 2015 and for the foreseeable future.

The Company is subject to risks common to other life science companies including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability protection of proprietary technology, ability to raise additional financing, and compliance with U.S. Food and Drug Administration (FDA) and other government regulations. If the Company does not successfully commercialize any of

its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

2. Basis of Presentation

The unaudited interim condensed financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Accordingly, they do not include all information and disclosures necessary for a presentation of the Company s financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States of America (GAAP). In the opinion of management, these unaudited interim financial statements reflect all adjustments, consisting primarily of normal recurring accruals, necessary for a fair presentation of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by SEC rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The condensed balance sheet data for the year ended December 31, 2014 were derived from audited financial statements, but do not include all disclosures required by GAAP. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, as of the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from the Company s estimates and assumptions. Significant estimates include useful lives of fixed assets, the periods over which certain revenues will be recognized, including licensing and collaborative revenue recognized from non-refundable up-front and milestone payments, the determination of prepaid research and development clinical costs and accrued research projects, the amount of non-cash compensation costs related to share-based payments to employees and non-employees and the periods over which those costs are expensed and the likelihood of realization of deferred tax assets.

Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in Note 2 to the Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09). In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606) Deferral of the Effective Date*, which delays the effective date of ASU 2014-09 from January 1, 2017 to January 1, 2018. Earlier application will be permitted only as of January 1, 2017, including interim reporting periods within the year ending December 31, 2017. The Company does not expect to early adopt ASU 2014-09.

During April 2015, the FASB issued Accounting Standards Update 2015-03 (ASU 2015-03) *Interest Imputation of Interest (Subtopic 835-30) Simplifying the Presentation of Debt Issuance Costs*, which simplifies the presentation of debt issuance costs by requiring debt issuance costs (e.g., legal fees, printing costs) to be presented as a deduction from the corresponding debt liability rather than as assets, as under current guidance. In August 2015, the FASB issued ASU 2015-15 *Interest Imputation of Interest (Subtopic 835-30) Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements* to clarify that, in the absence of authoritative guidance within ASU 2015-03 for debt issuance costs related to line-of-credit arrangements, the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. ASU 2015-03 is effective for financial statements issued for periods beginning on January 1, 2016, including interim periods. Early adoption of ASU 2015-03 is permitted for financial statements that have not been previously issued. Upon adoption, the Company must apply the new guidance

retrospectively to all prior periods presented in the financial statements. The Company does not expect the adoption of ASU 2015-03 or ASC 2015-15 to have a material effect on its financial position, results of operations or cash flows.

Reclassifications

Certain revenue amounting to $159 within the Statements of Operations for the nine months ended September 30, 2014 has been reclassified from Collaborative revenue to Clinical compound revenue to conform to the current year presentation.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

3. Fair Value Measurements

As of September 30, 2015 and December 31, 2014, the Company s financial instruments consisted of cash and cash equivalents, restricted cash, accounts payable and accrued liabilities. As of September 30, 2015, the Company s financial instruments also included other receivables (see Note 6 of Notes to Condensed Financial Statements, *Collaborations*). The carrying amount of each of those financial instruments is generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

Current accounting guidance defines fair value, establishes a framework for measuring fair value in accordance with Accounting Standards Codification (ASC) section 820, and requires certain disclosures about fair value measurements.

The valuation techniques included in the guidance are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions and are classified into the following fair value hierarchy:

Level 1 Observable inputs quoted prices in active markets for identical assets and liabilities.

Level 2 Observable inputs other than the quoted prices in active markets for identical assets and liabilities such as quoted prices for similar instruments, quoted prices for identical or similar instruments in inactive markets, or other inputs that are observable or can be corroborated by observable market data.

Level 3 Unobservable inputs includes amounts derived from valuation models where one or more significant inputs are unobservable and require the Company to develop relevant assumptions.

The following table summarizes the financial assets measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014.

	September 30, 2015 Level 1	December 31, 2014 Level 1
Financial assets		
Cash equivalents:		
Money market savings account	$ 110,486	$ 52,663

Restricted cash:				
Bank certificate of deposit		700		700
Other receivables		2,143		
Total	$	113,329	$	53,363

4. Prepaid expenses

As of September 30, 2015, prepaid expenses were $1,971, consisting of $294 of prepaid insurance, $1,627 of prepaid research and development (R&D) clinical costs and $50 of other prepaid costs. As of December 31, 2014, prepaid expenses and other current assets were $287, consisting of $92 of prepaid insurance, $177 of prepaid R&D clinical costs and $18 of other prepaid costs.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

5. Stockholders Equity

On July 29, 2015, the Company entered into an underwriting agreement (the Underwriting Agreement) with Stifel, Nicolaus & Company, Incorporated and Piper Jaffray & Co., as representatives of the several underwriters named therein, relating to the issuance and sale by the Company of 3,763,440 shares of its common stock (the Offering). The Offering was made pursuant to the Company s Registration Statement on Form S-3 (File No. 333-203072), filed with the SEC on March 27, 2015 and declared effective on May 13, 2015, and a related prospectus supplement dated July 29, 2015, which was filed with the SEC on July 30, 2015. As part of the Offering, the Company granted the underwriters an option to purchase 564,516 additional shares of common stock.

On August 4, 2015, the Company closed the Offering, including the full exercise of the underwriters option to purchase 564,516 additional shares of common stock, at a public offering price of $18.60 per share. The Company received net proceeds of approximately $75,231, after deducting the underwriting discounts and commissions and offering expenses paid or payable by the Company.

6. Collaborations

Chong Kun Dang Pharmaceutical Corporation

In April, 2012, the Company entered into a license agreement with CKD (the CKD Agreement) that provides CKD with the exclusive rights to develop, manufacture and commercialize products containing CR845 in South Korea. Under the CKD Agreement, the Company is eligible to receive milestone payments totaling $3,750, relating to pre-defined clinical development ($2,250) and regulatory events ($1,500), as well as royalties on sales of any marketed products containing CR845. The Company has accounted for the milestones under ASC 605 *Revenue Recognition Milestone Method*. At the time of execution of the CKD Agreement, there was significant uncertainty as to whether the stated milestones would be achieved. In conjunction with this uncertainty, the Company has determined that the milestones are substantive in nature as they are commensurate with the enhancement of value of the delivered license because they relate to clinical success and advancement within the FDA drug development platform. The milestones also relate solely to past performance and monetary investment of the Company to achieve the clinical advancement.

In July 2015, the Company met the milestone criteria, as set forth in the CKD Agreement, for completion of a Phase 1b trial of Oral CR845 in the United States. As a result, in August 2015, the Company received a milestone payment of $209 (net of South Korean withholding tax of $41) from CKD. In September 2015, the Company met the milestone criteria, as set forth in the CKD Agreement, for completion of a Phase 2 trial of CR845 in uremic pruritus patients in the United States. As a result, as of September 30, 2015, the Company was due a milestone payment of $417 (net of South Korean withholding tax of $83) from CKD. In October 2015, the Company received the milestone payment from CKD. Both milestones were considered to be substantive and the full amount of the milestone payments was

recognized as milestone revenue when the milestones were achieved.

The next potential milestone that the Company could be entitled to receive under the CKD Agreement will be a clinical development milestone for completion of a Phase 3 trial of CR845 in the United States in uremic pruritus patients. If achieved, this milestone will result in a payment of $750 being due to the Company.

Maruishi Pharmaceutical Co., Ltd.

In April 2013, the Company entered into a license agreement with Maruishi (the Maruishi Agreement) under which the Company granted Maruishi an exclusive license to develop, manufacture, and commercialize drug products containing CR845 for acute pain and uremic pruritus in Japan. Under the Maruishi Agreement, the Company and Maruishi are required to use commercially reasonable efforts, at their own expense, to develop, obtain regulatory approval for and commercialize CR845 in the United States and Japan, respectively. In addition, the Company provided Maruishi specific clinical development services for CR845 used in Maruishi s field of use.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

The Company has identified two deliverables under ASC 605-25, *Revenue Recognition Multiple Element Arrangements*: (1) the license; and (2) the R&D services specific to the uremic pruritus field of use. The Company has determined that the license has standalone value because Maruishi has the right to sublicense and manufacture CR845 in Japan. The second deliverable is the R&D services, which also have standalone value as similar services are sold separately by other vendors. Since both the license and the R&D services separability criteria have been met, they have been accounted for as separate units of accounting from the outset of the arrangement.

Along with the R&D services performed by the Company for Maruishi, the Company supplied Maruishi with CR845 clinical material as an accommodation. The Company had previously entered into manufacturing and service agreements with third parties to manufacture CR845. Payments made by the Company to third parties based on firm and fixed commitments by Maruishi to purchase CR845 from the Company were capitalized as prepaid expense. During the manufacturing process, title and risk of loss remained with the third party until the Company paid in full for the material.

Once the Company had title to the CR845 and had delivered it to Maruishi, prepaid expense related to that CR845 was reduced with an offset to R&D expense. At that time, Maruishi reimbursed the Company for its external and internal costs for purchasing CR845 and processing the sale to Maruishi and the Company recognized clinical compound revenue for the reimbursement amount. During the nine months ended September 30, 2015 and 2014, the Company recognized clinical compound revenue of $0 and $159, respectively. Deposits received from Maruishi prior to delivery of CR845 were recorded as deferred revenue.

Under the terms of the Maruishi Agreement, the Company is also entitled to receive aggregate milestone payments of $8,000 for events performed by Maruishi in Japan and $2,500 for events performed by the Company in the United States. At the time of execution of the Maruishi Agreement, there was significant uncertainty as to whether the stated milestones would be achieved. In conjunction with this uncertainty, the Company has determined that the milestones achieved in the United States are substantive in nature as they are commensurate with the enhancement of value of the delivered license as they relate to clinical success and advancement within the FDA drug development platform. The Company will account for those milestone payments under ASC 605-28 *Revenue Recognition Milestone Method.* However, the milestones achieved by Maruishi in Japan are not substantive and will be accounted for in accordance with the multiple-element arrangement guidance in ASC 605-25.

In September 2015, Maruishi initiated a Phase 2 clinical trial of CR845 in Japan for uremic pruritus, which triggered a $1,725 milestone payment (net of contractual foreign currency exchange adjustments of $275) to the Company. As of September 30, 2015, such payment was due to the Company and was received in October 2015. At the time of achievement of the milestone, the Company had delivered all deliverables under the Maruishi Agreement. Since the milestone was achieved in Japan, it was deemed not to be substantive. Accordingly, the Company recognized $1,084 as milestone revenue and $641 as collaborative revenue during both the three months and nine months ended September 30, 2015 in connection with achievement of this milestone.

The next potential milestone that the Company could be entitled to receive under the Maruishi Agreement will be a clinical development milestone for the completion of the first Phase 3 pivotal trial of CR845 in acute pain in the United States. If achieved, this milestone will result in a payment of $1,000 being due to the Company.

The R&D services deliverable was completed in July 2015. As of September 30, 2015 and December 31, 2014, the Company had $0 and $1,452, respectively, of deferred revenue pursuant to the R&D services deliverable under the Maruishi Agreement.

Amortization of deferred revenue pursuant to the R&D services deliverable to collaborative revenue was $89 and $1,125, for the three months ended September 30, 2015 and 2014, respectively, and $1,452 and $1,802 for the nine months ended September 30, 2015 and 2014, respectively.

The Company incurred R&D expense related to the Maruishi Agreement of $108 and $1,326 (both consisting of clinical trial costs related to the R&D services deliverable) during the three months ended September 30, 2015 and 2014, respectively. During the nine months ended September 30, 2015 and 2014, the Company incurred R&D expense related to

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

the Maruishi Agreement of $1,583 (consisting of clinical trial costs related to the R&D services deliverable) and $2,438 (consisting of $2,324 of clinical trial costs related to the R&D services deliverable and $114 related to the cost of clinical compound sold to Maruishi), respectively.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
Accounts payable	$ 1,263	$ 515
Accrued research projects	969	549
Accrued professional fees	348	266
Accrued compensation and benefits	708	504
Accrued other	86	112
Total	$ 3,374	$ 1,946

8. Net Loss Per Share

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted average number of shares of common stock outstanding. Diluted net income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Potential common stock equivalents include convertible preferred stock and outstanding stock options and stock warrants, which are included using the treasury stock method when dilutive. The computation of diluted net loss per share does not include common stock equivalents since such inclusion would be anti-dilutive. For the three and nine months ended September 30, 2015 and 2014, the Company excluded the effects of potentially dilutive shares that were outstanding during those respective periods from the denominator as their inclusion would be anti-dilutive due to the Company s net losses during those periods.

The denominators used in the net loss per share computations are as follows:

	Three Months Ended September 30,	Nine Months Ended September 30,

	2015	2014	2015	2014
Basic:				
Weighted average common shares outstanding	25,545,164	22,713,040	23,737,443	20,351,005
Diluted:				
Weighted average common shares outstanding - Basic	25,545,164	22,713,040	23,737,443	20,351,005
Common stock options*				
Common stock warrants*				
Convertible preferred stock*				
Denominator for diluted net loss per share	25,545,164	22,713,040	23,737,443	20,351,005

* No amounts were considered as their effects would be anti-dilutive.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

Basic and diluted net loss per share are computed as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (4,787)	$ (6,545)	$ (15,160)	$ (13,573)
Weighted-average common shares outstanding:				
Basic and Diluted	25,545,164	22,713,040	23,737,443	20,351,005
Net loss per share, Basic and Diluted	$ (0.19)	$ (0.29)	$ (0.64)	$ (0.67)

As of September 30, 2015 and 2014, 1,541,772 and 964,360 stock options were outstanding, respectively, which could potentially dilute basic earnings per share in the future, but were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive.

9. Stock-Based Compensation

2014 Equity Incentive Plan

The Company s 2014 Equity Incentive Plan (the 2014 Plan) is administered by the Company s Board of Directors or a duly authorized committee thereof (the Plan Administrator). The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation (collectively, Stock Awards). Additionally, the 2014 Plan provides for the grant of performance cash awards. Incentive stock options may be granted only to employees. All other awards may be granted to employees, including officers, non-employee directors, and consultants. No incentive stock options may be granted under the 2014 Plan after the tenth anniversary of the effective date of the 2014 Plan. Stock Awards granted under the 2014 Plan vest at the rate specified by the Plan Administrator, which, to date, has been 25% on the first anniversary of the date of grant and the balance ratably over the next 36 months. The Plan Administrator determines the term of Stock Awards granted under the 2014 Plan up to a maximum of ten years.

The aggregate number of shares of the Company s common stock reserved for issuance under the 2014 Plan automatically increases on January 1 of each year, beginning on January 1, 2015 and continuing through and including

January 1, 2024, by 3% of the total number of shares of the Company s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company s Board of Directors. On January 1, 2015, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the Company s 2014 Equity Incentive Plan automatically increased from 1,600,000 to 2,284,061. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2014 Plan is 30,000,000 shares.

Under the 2014 Plan, the Company granted 25,000 and 629,000 stock options during the three and nine months ended September 30, 2015, respectively, and 40,000 and 654,000 stock options during the three and nine months ended September 30, 2014, respectively. The fair values of stock options granted during the three and nine months ended September 30, 2015

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

and 2014 were estimated as of the dates of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.77%	1.92%	1.43% - 1.89%	1.80% - 2.72%
Expected volatility	64.1%	65.0%	64.0% - 67.1%	65.0% - 71.0%
Expected dividend yield	0%	0%	0%	0%
Expected life of employee options (in years)	6.25	6.25	6.25	6.25
Expected life of nonemployee options (in years)	10	10	10	10

The weighted average grant date fair value of options granted to employees and members of the Company s Board of Directors for their service during the three and nine months ended September 30, 2015 was $13.30 and $6.60, respectively, and during the three and nine months ended September 30, 2014 was $8.01 and $7.58, respectively.

The weighted average fair value of outstanding unvested options that had been granted to nonemployee consultants as re-measured in accordance with ASC 505-50 was $10.87 and $9.03 during the three and nine months ended September 30, 2015, respectively, and $5.87 and $11.79, during the three and nine months ended September 30, 2014, respectively.

During the three and nine months ended September 30, 2015 and 2014, the Company recognized compensation expense relating to stock options, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ 283	$ 38	$ 761	$ 269
General and administrative	378	184	1,046	762
Total stock option expense	$ 661	$ 222	$ 1,807	$ 1,031

A summary of stock option award activity as of and for the nine months ended September 30, 2015 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2014	1,022,360	$ 8.16
Granted	629,000	10.91
Exercised	(101,588)	3.18
Expired	(8,000)	0.25
Outstanding, September 30, 2015	1,541,772	9.65
Options exercisable, September 30, 2015	433,806	$ 7.00

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(amounts in thousands, except share and per share data)

(unaudited)

10. Income Taxes

For the three months ended September 30, 2015 and 2014, pre-tax losses were $4,987 and $6,577, respectively, and for the nine months ended September 30, 2015 and 2014, pre-tax losses were $15,410 and $13,632, respectively. The Company recognized a full tax valuation allowance against net deferred tax assets at September 30, 2015 and December 31, 2014.

The benefit from income taxes of $200 and $32 for the three months ended September 30, 2015 and 2014, respectively, and $250 and $59 for the nine months ended September 30, 2015 and 2014, respectively, relates to state research and development tax credits exchanged for cash pursuant to the Connecticut Research and Development Tax Credit Exchange Program, which permits qualified small businesses engaged in research and development activities within Connecticut to exchange their unused research and development tax credits for a cash amount equal to 65% of the value of the exchanged credits.

11. Commitments and Contingencies

Contractual obligations and commitments as of September 30, 2015 were as follows:

	Payment Due for the Year Ending December 31,					
	2015	2016	2017	2018	Thereafter	Total
Operating lease (1)	$ 226	$ 913	$ 740	$	$	$ 1,879

(1) The Company leases its operating facility located in Shelton, Connecticut.

Table of Contents

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

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words anticipate, believe, continue, could, estimate, expect, inte might, objective, ongoing, plan, predict, project, potential, should, will, or would, and or the nega or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the success and timing of our preclinical studies and clinical trials, including our planned Phase 3 clinical trials for I.V. CR845 in acute pain and uremic pruritus, and the reporting of clinical trial results;
- the potential regulatory development pathway for I.V. CR845 in uremic pruritus, including the potential request for breakthrough therapy and orphan drug status;
- our plans to develop and commercialize I.V. CR845 and our other product candidates, including Oral CR845;
- the potential results of ongoing and planned clinical trials and future regulatory and development milestones for our product candidates;
- the size and growth of the potential markets for pain management, including the postoperative and chronic pain markets, and for our other product candidates and our ability to serve those markets;
- our ability to obtain and maintain regulatory approval of our product candidates, including I.V. CR845 and Oral CR845, and the labeling under any approval we may obtain;
- the anticipated commercial launch of our lead product candidate, I.V. CR845;
- the potential of future scheduling of I.V. CR845 by the United States Drug Enforcement Administration (DEA), if regulatory approval is received;

the performance of our current and future collaborators, including Maruishi and CKD, and our ability to maintain such collaborations;

our ability to establish additional collaborations for our product candidates;

the continued service of our key scientific or management personnel;

our ability to establish commercialization and marketing capabilities;

the rate and degree of market acceptance of any approved products;

our ability to obtain and maintain coverage and adequate reimbursement from third-party payers for approved products;

our planned use of our cash and cash equivalents, including the net proceeds from our recently completed follow-on offering, and the clinical milestones we expect to fund with such proceeds;

the accuracy of our estimates regarding expenses, future revenues and capital requirements;

our ability to obtain funding for our operations;

our ability to maintain, obtain and protect our intellectual property portfolio; and

the performance of third-party manufacturers and clinical research organizations.

You should refer to Part I Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2014 and to Part II Item 1A Risk Factors of this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our

Table of Contents

actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The following *Management s Discussion and Analysis of Financial Condition and Results of Operations* should be read in conjunction with: (i) the Condensed Financial Statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our Annual Report on Form 10-K for the year ended December 31, 2014.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. We are developing a novel and proprietary class of product candidates that target the body s peripheral nervous system.

Our most advanced product candidate, intravenous, or I.V., CR845, has demonstrated significant pain relief and a favorable safety and tolerability profile in three Phase 2 clinical trials in patients with acute postoperative pain without inducing many of the undesirable side effects typically associated with currently available pain therapeutics. In addition, in the fourth quarter of 2014, we successfully completed a Human Abuse Liability, or HAL, trial of I.V. CR845 in which I.V. CR845 met the primary endpoint of demonstrating statistically significant lower drug liking scores as compared to the approved schedule IV opioid, pentazocine. We believe that the totality of results from the HAL trial are supportive of the potential for CR845 to be the first non-scheduled or low (schedule V) scheduled peripheral opioid for acute pain.

In April 2015, we completed an End-of-Phase 2 meeting with the FDA, to discuss the design of pivotal trials for our I.V. CR845 product candidate in acute pain. In September 2015, we initiated the Phase 3 program for our I.V. formulation of CR845 in postoperative pain with the dosing of the first subjects in an adaptive pivotal trial in patients undergoing a range of abdominal surgeries. This trial is a multi-center, randomized, double-blind, placebo-controlled, parallel-group adaptive design trial with repeated doses of I.V. CR845 or placebo administered both prior to and following abdominal surgery in male and female patients. The trial will enroll up to 600 patients undergoing either hysterectomy, prostatectomy, hemi-colectomy or ventral hernia, all of which are associated with moderate-to-severe postoperative visceral pain, at approximately 30 clinical sites within the United States. Three dose levels of I.V. CR845 (1.0, 2.0 and 5.0 ug/kg I.V.) will be compared to placebo, with an interim analysis to identify optimal doses that will be used to complete the enrollment of this study. The primary efficacy measure is the Change in Pain Intensity over the 24-hour postoperative period (AUC-24) using the patient-reported Numeric Rating Scale (NRS) score collected at pre-specified time points through 24 hours. Postoperative nausea and vomiting (PONV) will be evaluated as a secondary efficacy measure. The impact of I.V. CR845 treatment on inflammatory biomarkers will also be explored. Top-line data are expected in the first half of 2016.

We plan to initiate additional Phase 3 trials of I.V. CR845 in the first half of 2016. Based on guidance from the FDA, we will require 1,500 total exposures to I.V. CR845, including all Phase 1, Phase 2 and Phase 3 trials, prior to submitting a new drug application, or NDA. We believe our planned clinical trials and our clinical trials completed to date will result in a sufficient number of drug exposures to support an NDA.

We are also developing an oral version of CR845, or Oral CR845, for acute and chronic pain. In the second quarter of 2014, we initiated a Phase 1 trial of a tablet formulation of Oral CR845, for which we announced positive top-line data in the fourth quarter of 2014. In August 2015, we advanced this tablet formulation of Oral CR845 into a Phase 2a clinical trial in patients with osteoarthritis (OA), with top-line data expected by the end of 2015. The Phase 2 trial is a single-blind, randomized, multiple ascending dose trial designed to evaluate the safety, pharmacokinetics (PK) and effectiveness of Oral CR845 tablets dosed over a two-week treatment period in OA patients experiencing moderate-to-severe pain, defined as >4 on a 10-point Visual Analog Scale (VAS). The trial will enroll 80 OA patients at multiple sites in the United States. Four tablet strengths (0.25 mg, 0.5 mg, 1.0 mg and 5 mg) will be administered twice a day. In addition to safety and PK observations, pharmacodynamics endpoints will include change from baseline in joint pain using the Numeric Rating Scale (NRS), change from baseline in the Western Ontario and McMaster Osteoarthritis Index (WOMAC) and Patient Global Assessment (PGA) of OA. Exploratory measurements of inflammatory biomarkers will be assessed at baseline and post-Oral CR845 treatment. Subject to the successful completion of this trial, we intend to initiate a larger Phase 2b clinical trial of Oral CR845 in a chronic pain indication in the first half of 2016.

Table of Contents

We recently completed a proof-of-concept Phase 2 clinical trial of I.V. CR845 for the treatment of uremic pruritus, a systemic condition with high prevalence in dialysis patients, for which there are no approved therapeutics in the United States. In July 2015, we reported positive top-line efficacy results from this trial, in which we observed that I.V. CR845 achieved statistically significant results on the primary endpoint of reducing worst itch intensity as well as the secondary endpoint of quality of life improvements**.** We also observed I.V. CR845 to have a favorable safety and tolerability profile in the trial. Based on the results of this trial, we intend to engage the FDA in a formal meeting to guide the structure of a potential Phase 3 pivotal trial. In addition, we intend to request breakthrough therapy designation and orphan drug status for I.V. CR845 for the treatment of uremic pruritus. If granted by the FDA, breakthrough designation could provide for expedited regulatory review of I.V. CR845 for the treatment of uremic pruritus, and orphan drug status could confer marketing exclusivity benefits. Subject to the feedback from the FDA, we intend to initiate a first Phase 3 pivotal trial in uremic pruritus in the first half of 2016.

We commenced operations in 2004, and our primary activities to date have been organizing and staffing our company, developing our product candidates, including conducting preclinical studies and clinical trials of CR845-based product candidates and raising capital. To date, we have financed our operations primarily through sales of our equity and debt securities and payments from license agreements. We have no products currently available for sale, and substantially all of our revenue to date has been revenue from license agreements, although we have received nominal amounts of revenue under research grants.

Since our inception and through September 30, 2015, we have received net proceeds of $75.2 million from the sale of approximately 4.33 million shares of our common stock in a follow-on offering, which closed in August 2015, after deducting underwriting discounts and commissions and offering expenses paid or payable by us (see Note 5, *Stockholders Equity*, of Notes to Condensed Financial Statements elsewhere in this Quarterly Report on Form 10-Q), $56.3 million from the sale of 5.75 million shares of our common stock in our initial public offering (IPO), after deducting underwriting discounts and commissions and offering expenses paid by us, net proceeds of $65.9 million from the sale of various series of our convertible preferred stock, $3.6 million from the issuance of our convertible promissory notes and $3.8 million from the issuance of long-term debt.

In addition to our financing activities, we have received aggregate payments of $32.5 million pursuant to license agreements related to CR845 and an earlier product candidate for which development efforts ceased in 2007. Included in these payments, in April 2013, we received $15.0 million as an upfront payment, and in August 2014 and September 2015, we received an additional $0.5 million and were due an additional $1.7 million, net of contractual foreign currency exchange adjustment of $0.3 million, respectively, both related to achievement of milestones in connection with the license of rights to CR845 in Japan to Maruishi Pharmaceutical Co., Ltd., (Maruishi). Further, in 2012, included in these payments, we received aggregate upfront and milestone payments of $1.2 million and in August 2015 and September 2015, we received an additional $0.2 million and were due an additional $0.4 million (net of South Korean withholding taxes of $0.1 million), respectively, related to achievement of two milestones in connection with the license of rights to CR845 in South Korea to Chong Kun Dang Pharmaceutical Corporation (CKD). The $1.7 million milestone payment from Maruishi and the $0.4 million milestone payment from CKD were both received in October 2015.

Since our inception, we have incurred significant operating and net losses. Our net losses were $15.2 million and $13.6 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of $95.4 million. We expect to continue to incur significant expenses and operating and net losses over at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, the receipt of additional milestone payments, if any, under our collaborations with Maruishi and CKD, the receipt of payments under any future collaborations we may enter into, and our expenditures on other research and development activities.

We anticipate that our expenses will increase substantially as we:

- continue our I.V. CR845 pivotal clinical trial program in acute pain;
- continue the development of our I.V. CR845 uremic pruritus product candidate;
- continue the research and development of our Oral CR845 and other product candidates;
- seek regulatory approvals for I.V. CR845 and any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our global intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development and potential future commercialization efforts.

Table of Contents

Components of Operating Results

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. Substantially all of our revenue recognized to date has been generated by upfront and milestone payments under our license agreements with Maruishi and CKD for CR845, a portion of which was deferred upon receipt, as well as license agreements for CR665, our first generation drug program for which development efforts have ceased. To date, we have earned a total of $3.5 million (of which $2.1 million was due to us as of September 30, 2015 and was received in October 2015) in clinical development or regulatory milestone payments. To date, we have not received any royalties, under these collaborations.

Research and Development

To date, our research and development expenses have related primarily to the development of CR845. Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, facilities expenses, including laboratory build-out costs, overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, third-party formulation expenses, fees paid to contract research organizations, or CROs, and other consultants, stock-based compensation for research and development employees and non-employee consultants and other outside expenses. Our research and development expenses also include expenses related to preclinical activities, such as drug discovery, target validation and lead optimization for CR845 and our other, earlier stage programs.

Research and development costs are expensed as incurred. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Most of our research and development costs have been external costs, which we track on a program-by program basis. Our internal research and development costs are primarily compensation expenses for our full-time research and development employees. We do not track internal research and development costs on a program-by-program basis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we seek to progress I.V. CR845 through Phase 3 trials in acute pain and uremic pruritus and the FDA approval process, and as we increase our development efforts for Oral CR845. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our 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:

- per patient trial costs;

the number of patients that participate in the trials;

the number of sites included in the trials;

the countries in which the trial is conducted;

the length of time required to enroll eligible patients;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

potential additional safety monitoring or other studies requested by regulatory agencies;

the duration of patient follow-up; and

the efficacy and safety profile of the product candidate.

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

Table of Contents

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees, patent costs and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel, fees to outside consultants, lawyers and accountants, and investor relations costs. In addition, if I.V. CR845 or any future product candidate obtains regulatory approval for marketing, we expect to incur expenses associated with building a sales and marketing team.

Interest Income

Interest income consists of income earned on our cash and cash equivalents.

Benefit from Income Taxes

The benefit from income taxes relates to state research and development tax credits exchanged for cash pursuant to the Connecticut Research and Development Tax Credit Exchange Program, which permits qualified small businesses engaged in research and development activities within Connecticut to exchange their unused research and development tax credits for a cash amount equal to 65% of the value of the exchanged credits.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2015 and 2014

Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	% change	2015	2014	% change
	Amounts in thousands			Amounts in thousands		
License and milestone fees revenue	$ 1,710	$	100%	$ 1,710	$ 302	466%
Collaborative revenue	730	1,125	-35%	2,093	1,802	16%
Clinical compound revenue					159	-100%
Total revenue	$ 2,440	$ 1,125	117%	$ 3,803	$ 2,263	68%

License and milestone fees revenue

License and milestone fees revenue for the three and nine months ended September 30, 2015 of $1.7 million consists of $1.1 million related to the portion of the $1.7 million milestone payment earned in September 2015 under our license agreement with Maruishi, which was attributable to the previously delivered license and $626 thousand from the two milestone payments earned by us under our license agreement with CKD in July and September 2015.

18

Table of Contents

License and milestone fees revenue for the nine months ended September 30, 2014 of $302 thousand represents the portion of the $480 thousand milestone achieved under our license agreement with Maruishi, which was attributable to the previously delivered license.

Collaborative revenue

Collaborative revenue for the three months ended September 30, 2015 of $730 thousand consists of $641 thousand related to the portion of the $1.7 million milestone payment earned in September 2015 under our license agreement with Maruishi, which was attributable to the fully-delivered research and development (R&D) services deliverable, and $89 thousand of revenue that had been deferred upon entry into the license agreement with Maruishi. For the three months ended September 30, 2014, collaborative revenue of $1.1 million consists of revenue that had been deferred upon entry into the license agreement with Maruishi.

Collaborative revenue for the nine months ended September 30, 2015 of $2.1 million consists of $641 thousand related to the portion of the $1.7 million milestone payment earned in September 2015 under our license agreement with Maruishi, which was attributable to the fully-delivered R&D services deliverable, and $1.5 million of revenue that had been deferred upon entry into the license agreement with Maruishi. For the nine months ended September 30, 2014, collaborative revenue of $1.8 million consists of revenue that had been deferred upon entry into the license agreement with Maruishi.

Clinical compound revenue

For the nine months ended September 30, 2015 and 2014, the Company recognized $0 and $159 thousand from sales of clinical compound to Maruishi.

Research and Development Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	% change	2015	2014	% change
	Amounts in thousands			Amounts in thousands		
Direct preclinical studies and clinical trial costs	$ 3,554	$ 5,016	-29%	$ 8,362	$ 8,482	-1%
Consultant services in support of preclinical studies and clinical trials	270	340	-20%	625	662	-6%
Stock-based compensation	283	38	647%	761	269	183%
Depreciation and amortization	104	106	-2%	311	318	-2%
Other R&D operating expenses	1,373	709	94%	3,594	1,878	91%
Total R&D expense	$ 5,584	$ 6,208	-10%	$ 13,653	$ 11,609	18%

For the three months ended September 30, 2015 compared to the three months ended September 30, 2014, the net decrease in direct preclinical studies and clinical trial costs and related consultant costs primarily resulted from decreases totaling $3.4 million for the Phase 2 I.V. CR845 uremic pruritus trial, the HAL study, and the Phase 1 Oral CR845 trial and a net decrease of $0.7 million in the cost of drug manufacturing of I.V. and Oral formulations of CR845. Those decreases in costs were partially offset by an increase of $2.4 million in connection with the I.V.

CR845 adaptive design trial and the Phase 2 Oral CR845 trial in patients with osteoarthritis. The increase in stock-based compensation expense during the three months ended September 30, 2015 reflects additional grants to more employees and an increase in the fair value of outstanding unvested options previously granted to non-employee consultants than in the same period in 2014. The increase in other R&D operating expenses was primarily the result of an increase in payroll and related costs associated with R&D personnel, recruiting costs and the cost of meetings and travel.

For the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014, direct preclinical studies and clinical trial costs and related consultant costs were essentially unchanged, which primarily resulted from increases totaling $3.7 million for the Phase 2 Oral CR845 trial in patients with osteoarthritis, the I.V. CR845 adaptive design trial and the Phase 2 I.V. CR845 uremic pruritus trial. Those increases in costs were offset by a decrease of $3.0 million in connection with the Phase 1 Oral CR845 trial, the HAL trial and the Phase 1 I.V. CR845 renal impairment trial and a net decrease of $0.7 million in the cost of drug manufacturing of I.V. and Oral formulations of CR845. There was also a net decrease in preclinical costs. The increase in stock-based

Table of Contents

compensation expense during the nine months ended September 30, 2015 reflects additional grants to more employees and an increase in expense of outstanding unvested options previously granted to non-employee consultants than in the same period in 2014. The increase in other R&D operating expenses was primarily the result of an increase in payroll and related costs associated with R&D personnel, recruiting costs and the cost of meetings and travel.

The following table summarizes our R&D expenses by product candidate for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	Amounts in thousands		Amounts in thousands	
External research and development expenses:				
I.V. CR845	$ 1,970	$ 3,448	$ 6,292	$ 5,541
Oral CR845	1,854	1,908	2,695	3,586
Internal research and development expenses	1,760	852	4,666	2,482
Total research and development expenses	$ 5,584	$ 6,208	$ 13,653	$ 11,609

General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	% change	2015	2014	% change
	Amounts in thousands			Amounts in thousands		
Professional fees and public/investor relations	$ 486	$ 462	5%	$ 1,455	$ 1,263	15%
Stock-based compensation	378	184	105%	1,046	762	37%
Depreciation and amortization	89	91	-2%	268	272	-1%
Other G&A operating expenses	912	783	16%	2,840	2,093	36%
Total G&A expense	$ 1,865	$ 1,520	23%	$ 5,609	$ 4,390	28%

For the three months ended September 30, 2015 compared to the three months ended September 30, 2014, the increase in stock-based compensation expense primarily reflects additional grants to more employees and members of our Board of Directors and an increase in the fair value of unvested outstanding options previously granted to non-employee consultants than in the same period in 2014. The increase in other general and administrative (G&A) operating expenses primarily includes an increase in payroll and related costs in connection with increased headcount.

For the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014, the increase in professional fees and public/investor relations costs primarily included increases in public/investor relations costs, in legal fees and in accounting and auditing fees. Those increases were partially offset by a decrease in consultant fees. The increase in stock-based compensation expense primarily reflects additional grants to more employees and

members of our Board of Directors than in the same period in 2014. The increase in other G&A operating expenses primarily included increases in payroll and related costs, in connection with increased headcount, and in insurance costs.

Interest Income

Three Months Ended September 30,			Nine Months Ended September 30,		
2015	**2014**	**% change**	**2015**	**2014**	**% change**
Amounts in thousands			**Amounts in thousands**		
$ 22	$ 26	-17%	$ 49	$ 104	-53%

Table of Contents

During the three months ended September 30, 2015 compared to the three months ended September 30, 2014, interest income was essentially unchanged primarily due to a higher average balance of cash and cash equivalents during the 2015 period related to our follow on stock offering (see Note 5 of Notes to Condensed Financial Statements elsewhere in this Quarterly Report on Form 10-Q), offset by a lower interest rate during the 2015 period.

During the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014, the decrease in interest income was primarily due to a lower interest rate during the 2015 period.

Benefit from Income Taxes

For the three months ended September 30, 2015 and 2014, pre-tax losses were $5.0 million and $6.6 million, respectively, and we recognized a benefit from income taxes of $200 thousand and $32 thousand, respectively.

For the nine months ended September 30, 2015 and 2014, pre-tax losses were $15.4 million and $13.6 million, respectively, and we recognized a benefit from income taxes of $250 thousand and $59 thousand, respectively.

The benefit from income taxes relates to state R&D tax credits exchanged for cash pursuant to the Connecticut Research and Development Tax Credit Exchange Program, as discussed above. The increase in the tax benefit in the 2015 periods primarily reflects increased payroll and related costs associated with the increased R&D headcount. We recognized a full valuation allowance against net deferred tax assets at September 30, 2015 and December 31, 2014.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception and through September 30, 2015, we have raised an aggregate of approximately $237.5 million to fund our operations, including proceeds of $75.2 million, net of underwriting discounts and commissions and offering expenses paid or payable by us from our follow-on offering of our common stock, which closed in August 2015 (see below), proceeds of $56.3 million, net of underwriting discounts and commissions and offering expenses paid by us, from our IPO, which closed in February 2014, $32.5 million (of which $2.1 was due to us as of September 30, 2015 and was received in October 2015) under our license agreements, primarily with Maruishi and CKD, and an earlier product candidate for which development efforts ceased in 2007, $65.9 million of proceeds from the sale of shares of our convertible preferred stock and $7.4 million of net proceeds from debt financings. As of September 30, 2015, we had unrestricted cash and cash equivalents of $111.1 million, which we expect will be sufficient to fund our planned operating expenses and capital expenditure requirements through the end of the third quarter of 2017, without giving effect to any potential milestone payments we may receive under our collaboration agreements with Maruishi and CKD.

In order to fund future operations, including our planned clinical trials, we filed a shelf registration statement on Form S-3 (File No. 333-203072), which the Securities and Exchange Commission (SEC) declared effective on May 13, 2015. This shelf registration statement provides for aggregate offerings of up to $150 million of common stock, preferred stock, debt securities, warrants or any combination thereof. As noted above, on August 4, 2015, we completed a follow-on public offering of 4,327,956 shares of our common stock, including 564,516 shares sold pursuant to the full exercise by the underwriters of their option to buy additional shares, pursuant to this shelf registration statement and a related prospectus supplement dated July 29, 2015, filed with the SEC on July 30, 2015. We received gross proceeds from the offering of approximately $80.5 million, or net proceeds of $75.2 million after deducting the underwriting discounts and commissions and offering expenses paid or payable by us. We may offer additional securities under this shelf registration statement from time to time in response to market conditions or other

circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that this shelf registration statement provides us with the flexibility to raise additional capital to finance our operations as needed.

In addition to our existing cash and cash equivalents, under our agreement with Maruishi, we are potentially eligible to earn up to an aggregate of $6.0 million in clinical development milestones and $4.5 million in regulatory milestones as well as tiered royalties, with percentages ranging from the low double digits to the low twenties, based on net sales of products containing CR845 in Japan, if any, and share in any sub-license fees. Under our agreement with CKD, we are potentially eligible to earn up to an aggregate of $2.3 million in clinical development milestones and $1.5 million in regulatory milestones as well as tiered royalties with percentages ranging from the high single digits to the high teens, based on net sales of products containing CR845 in South Korea, if any, and share in any sub-license fees.

Table of Contents

During the second quarter of 2014, Maruishi completed a Phase 1 clinical trial in Japan related to CR845 in acute post-operative pain for which we earned a clinical development milestone payment of $480 thousand, net of contractual foreign currency exchange adjustments of $20 thousand. During the third quarter of 2015, Maruishi initiated a Phase 2 trial in Japan related to CR845 for the treatment of uremic pruritus for which we earned a clinical development milestone payment of $1.7 million, net of contractual foreign currency exchange adjustments of $275 thousand, which we received in October 2015.

During the third quarter of 2015, we met the milestone criteria, as defined in our license agreement with CKD, for both completion of a Phase 1b trial of Oral CR845 in the United States and completion of a Phase 2 trial of CR845 in the United States for the treatment of uremic pruritus, for which we earned clinical development milestone payments totaling $626 thousand, net of South Korean withholding tax of $124 thousand. In October 2015, CKD paid the remaining $417 thousand of that amount, which was receivable by us as of September 30, 2015.

The next potential milestone payment that we could be entitled to receive under the Maruishi license agreement will be for a clinical development milestone for completion by us in the United States of the first Phase 3 pivotal trial of CR845 in acute pain. If achieved, this milestone will result in a payment of $1.0 million being due to us. The next potential milestone payment that we could be entitled to receive under the CKD license agreement will be for a clinical development milestone for completion of a Phase 3 trial of CR845 in the United States for uremic pruritus. If achieved, this milestone will result in a payment $750 thousand being due to us.

Our ability to earn these payments and their timing is dependent upon the outcome of I.V. and Oral CR845 development activities and, potentially, commercialization. However, our receipt of any further such amounts is uncertain at this time and we may never receive any more of these amounts.

Funding Requirements

Our primary uses of capital have been, and we expect will continue to be, compensation and related expenses, third-party clinical R&D services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

The successful development of any of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of I.V. CR845, Oral CR845 or our other current and future product candidates. We are also unable to predict when, if ever, we will generate any further material net cash inflows from CR845. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- successful enrollment in, and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;

- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;

- achieving meaningful penetration in the markets which we seek to serve; and

- obtaining adequate coverage or reimbursement by third parties, such as commercial payers and government healthcare programs, including Medicare and Medicaid.

A change in the outcome of any of these variables with respect to the development of I.V. CR845, Oral CR845 or any of our future product candidates would significantly change the costs and timing associated with the development of that product candidate.

Because our product candidates are still in clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements, including our existing collaboration agreements with Maruishi and CKD.

We will require additional capital beyond our current balance of cash and cash equivalents and anticipated amounts as described above, and this additional capital may not be available when needed, on reasonable terms, or at all. In particular, because we do not have sufficient financial resources to meet all of our development objectives, especially the completion of our planned development of Oral CR845, we will need to raise additional capital. If we are not able to do so, we could be required to postpone, scale back or

Table of Contents

eliminate some, or all, of these objectives. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Outlook

Based on our current R&D plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents as of September 30, 2015 will be sufficient for us to fund our operating expenses and capital expenditure requirements through the end of the third quarter of 2017, without giving effect to any potential milestone payments we may receive under our collaboration agreements with Maruishi and CKD. Because the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain, it is possible that the assumptions upon which we have based this estimate may prove to be wrong, and we could use our capital resources sooner than we presently expect.

Cash Flows

The following is a summary of the net cash flows provided by (used in) our operating, investing and financing activities for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,	
	2015	**2014**
Net cash used in operating activities	$ (17,310)	$ (11,818)
Net cash used in investing activities	(13)	(27)
Net cash provided by financing activities	75,776	57,881
Net increase in cash and cash equivalents	$ 58,453	$ 46,036

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2015 consisted primarily of a net loss of $15.2 million and a $4.3 million outflow from net changes in operating assets and liabilities, partially offset by $2.2 million cash inflow from net non-cash charges. The net change in operating assets and liabilities primarily consisted of cash outflows of $2.1 million from an increase in other receivables related to milestone payments due from our collaborators, $1.6 million from an increase in prepaid expenses and other current assets, primarily related to an increase in prepaid R&D clinical costs, and $1.5 million from a decrease in deferred revenue from the Maruishi license transaction. Those cash outflows were partially offset by a cash inflow of $1.2 million from an increase in accounts payable and accrued expenses. Net non-cash charges primarily consisted of depreciation and amortization expense of $0.6 million and stock-based compensation expense of $1.8 million, partially offset by deferred rent costs of $0.2 million.

Net cash used in operating activities for the nine months ended September 30, 2014 consisted primarily of a net loss of $13.5 million, partially offset by a $0.3 million cash inflow from net changes in operating assets and liabilities and $1.4 million of net non-cash charges. The net change in operating assets and liabilities mostly consisted of cash inflows of $1.6 million from an increase in accounts payable and accrued expenses, and $0.2 million from a decrease in prepaid expenses, primarily related to prepaid insurance and prepaid clinical costs. Those cash inflows were partially offset by a cash outflow from a $1.5 million decrease in deferred revenue related to the Maruishi license transaction. Net non-cash charges primarily consisted of depreciation and amortization expense of $0.6 million and stock-based compensation expense of $1.0 million, partially offset by deferred rent costs of $0.2 million.

Net cash used in investing activities

Net cash used in investing activities was $13 thousand and $27 thousand for the nine months ended September 30, 2015 and 2014, respectively, related to the purchase of office and computer equipment.

Table of Contents

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2015 consisted primarily of gross proceeds of $80.5 million from our follow-on public offering, partially offset by $5.1 million of underwriting discounts and commissions and offering expenses paid by us during the nine months ended September 30, 2015, and proceeds of $0.3 million received from the exercise of stock options. An additional $0.2 million in expenses related to our follow-on offering was payable by us as of September 30, 2015.

Net cash provided by financing activities for the nine months ended September 30, 2014 consisted primarily of gross proceeds of $63.2 million from our initial public offering, partially offset by $5.4 million of underwriting discounts and commissions and offering expenses paid during the nine months ended September 30, 2014, and proceeds of $0.1 million received from the exercise of stock options.

Significant Contractual Obligations and Commitments

Contractual obligations and commitments as of September 30, 2015 consisted of operating lease obligations in connection with our operating facility in Shelton, Connecticut. See Note 11 of Notes to Condensed Financial Statements elsewhere in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

Please refer to Note 2 of Notes to Condensed Financial Statements elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have during the periods presented in our condensed financial statements included in this report, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Discussion of Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America (GAAP) requires us to use judgment in making certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in our condensed financial statements and accompanying notes. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require difficult, subjective and complex judgments by management in order to make estimates about the effect of matters that are inherently uncertain. During the nine months ended September 30, 2015, there were no significant changes to our critical accounting policies from those described in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk.***

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2015 and December 31, 2014, we had cash and cash equivalents of $111.1 million and $52.7 million, respectively. We generally hold our cash equivalents in interest-bearing money market savings accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash

equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

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

(a) **Disclosure Controls and Procedures**.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2015. 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 such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2015, our disclosure controls and procedures were effective.

Table of Contents

(b) **Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(f) and 15d-15(f) of the Exchange Act that occurred during the quarter ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II

OTHER INFORMATION

Item 1. ***Legal Proceedings***

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 1A. ***Risk Factors*****.**

Please refer to *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 27, 2015 and Item 1A Risk Factors in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 10, 2015 (the Second Quarter Form 10-Q), for a description of certain significant risks and uncertainties to which our business, operations and financial condition are subject. During the nine months ended September 30, 2015, we did not identify any additional risk factors or any material changes to the risk factors discussed in the Annual Report on Form 10-K for the year ended December 31, 2014, as supplemented and updated in the Second Quarter Form 10-Q.

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

Use of IPO Proceeds

On January 30, 2014, our registration statement on Form S-1 (File No 333-192230) was declared effective by the SEC for our initial public offering, pursuant to which we registered the offering and sale of 5,750,000 shares of common stock, $0.001 par value per share (including 750,000 shares issued upon the underwriters exercise of an option to purchase additional shares) at a public offering price of $11.00 per share for an aggregate public offering price of $63.2 million.

As a result of the initial public offering, we received net proceeds on February 5, 2014 of approximately $58.8 million, after deducting approximately $4.4 million of underwriting discounts and commissions but before giving effect to any offering expenses borne by us. In addition, we have paid approximately an additional $2.5 million of offering expenses in connection with the IPO. None of such payments were direct or indirect payments to any of (i) our directors or officers or their associates, (ii) persons owning 10 percent or more of our common stock, or (iii) our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the final prospectus related to the offering, which we filed with the SEC on February 3, 2014. As of September 30, 2015, we have used approximately $20.9 million of the funds received from our IPO for clinical trials and payments to research and development consultants.

Item 3. ***Defaults upon Senior Securities.***
None.

Item 4. ***Mine Safety Disclosures.***
Not applicable.

Item 5. ***Other Information.***
None.

Table of Contents

Item 6. ***Exhibits*****.**

Exhibit No.	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
31.1	Certification of Chief Executive Officer of Cara Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer of Cara Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer of Cara Therapeutics, Inc. pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive Data File
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.INS	XBRL Instance Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.
101.SCH	XBRL Taxonomy Extension Schema Linkbase.
101.DEF	XBRL Definition Linkbase Document.

(1) Filed as exhibit 3.1 to the Registrant s Current Report on Form 8-K (File No. 001-36279) filed with the Securities and Exchange Commission on February 7, 2014 and incorporated herein by reference.

(2) Filed as exhibit 3.2 to the Registrant s Current Report on Form 8-K (File No. 001-36279) filed with the Securities and Exchange Commission on February 7, 2014 and incorporated herein by reference.

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

Table of Contents

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.

CARA THERAPEUTICS, INC.

Date: November 9, 2015

By */s/ Derek Chalmers*
Derek Chalmers, Ph.D., D.Sc.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2015

By */s/ Josef Schoell*
Josef Schoell
Chief Financial Officer
(Principal Financial and Accounting Officer)