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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

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. ☒ Yes ☐ No.

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See 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	☒	Smaller reporting company	☐

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of November 5, 2014 was: 22,778,597.

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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, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 58,393	$ 12,357
Income tax receivable	89	61
Prepaid expenses	928	2,140
Total current assets	59,410	14,558
Property and equipment, net	2,262	2,825
Restricted cash	700	700
Total assets	$ 62,372	$ 18,083
Liabilities, convertible preferred stock and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,149	$ 1,958
Deferred revenue	1,944	3,475
Total current liabilities	6,093	5,433
Deferred lease obligation	944	1,139
Commitments and contingencies *(Note 13)*	—	—
Convertible Preferred stock; $0.001 par value; zero shares and 29,402,200 shares authorized at September 30, 2014 and December 31, 2013, respectively; zero shares and 29,186,929 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively; aggregate liquidation preference of zero and $65,969 at September 30, 2014 and December 31, 2013, respectively	—	65,586
Stockholders' (deficit) equity:		
Preferred stock; $0.001 par value; 5,000,000 shares and zero shares authorized at September 30, 2014 and December 31, 2013, respectively, zero shares issued and outstanding at September 30, 2014 and December 31, 2013	—	—
Common stock; $0.001 par value; 100,000,000 shares and 50,000,000 shares authorized at September 30, 2014 and December 31, 2013, respectively, 22,778,597 shares and 4,288,243 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	23	4
Additional paid-in capital	131,341	8,377
Accumulated deficit	(76,029)	(62,456)
Total stockholders' (deficit) equity	55,335	(54,075)
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	$ 62,372	$ 18,083

See Notes to Condensed Financial Statements.

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, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Revenue:				
License fees	$ —	$ —	$ 302	$ 9,637
Collaborative revenue	1,125	1,018	1,961	1,354
Total revenue	1,125	1,018	2,263	10,991
Operating expenses:				
Research and development	6,208	3,764	11,609	6,707
General and administrative	1,520	795	4,390	2,416
Total operating expenses	7,728	4,559	15,999	9,123
Operating (loss) income	(6,603)	(3,541)	(13,736)	1,868
Interest income (expense), net	26	(1,034)	104	(3,765)
Loss before benefit from income taxes	(6,577)	(4,575)	(13,632)	(1,897)
Benefit from income taxes	32	—	59	27
Net loss	$ (6,545)	$ (4,575)	$ (13,573)	$ (1,870)
Net loss available to common stockholders	$ (6,545)	$ (4,575)	$ (13,573)	$ (979)
Loss per share available to common stockholders				
Basic and Diluted	$ (0.29)	$ (1.07)	$ (0.67)	$ (0.24)
Weighted average shares:				
Basic and Diluted	22,713,040	4,288,243	20,351,005	4,080,869

See Notes to Condensed Financial Statements.

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 Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity	Convertible Preferred Stock		Beneficial Conversion Feature on Convertible Promissory Notes
	Shares	Amount				Shares	Amount	Amount
Balance at December 31, 2012	3,328,698	$ 3	$ 1,248	$ (59,384)	$ (58,133)	26,636,118	$58,522	$ 2,050
Issuance of Junior A convertible preferred stock, net	—	—	—	—	—	2,105,263	7,642	
Preferred stock converted to common shares	959,545	1	3,574	891	4,466	(2,246,743)	(4,466)	
Convertible promissory notes converted to Series D convertible preferred stock	—	—	—	—	—	2,692,291	3,888	
Beneficial conversion feature on convertible promissory notes	—	—	—	—	—			1,382
Reclassification of beneficial conversion feature			3,432		3,432			(3,432)
Stock-based compensation expense			110		110			
Net loss				(1,870)	(1,870)			
Balance at September 30, 2013	4,288,243	$ 4	$ 8,364	$ (60,363)	$ (51,995)	29,186,929	$65,586	$ —

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity	Convertible Preferred Stock		Beneficial Conversion Feature on Convertible Promissory Notes
	Shares	Amount				Shares	Amount	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	—	$ —	$ —

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(amounts in thousands)
(unaudited)

	Nine Months Ended	
	September 30, 2014	September 30, 2013
Operating activities		
Net loss	$ (13,573)	$ (1,870)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Non-cash compensation expense	1,031	110
Change in fair value of liability under license agreement	—	(35)
Accrued interest and amortization of beneficial conversion feature on promissory notes	—	3,605
Depreciation and amortization	590	592
Deferred rent costs	(194)	(175)
Amortization of financing costs	—	117
Changes in operating assets and liabilities:		
Income tax receivable	(28)	(27)
Prepaid expenses	240	(128)
Accounts payable and accrued expenses	1,647	1,270
Deferred revenue	(1,531)	4,434
Net cash (used in) provided by operating activities	(11,818)	7,893
Investing activities		
Purchases of property and equipment	(27)	(4)
Net cash (used in) investing activities	(27)	(4)
Financing activities		
Proceeds from convertible promissory notes	—	1,462
Financing costs on convertible promissory notes	—	(70)
Repayment of long-term debt	—	(307)
Proceeds from sale of Junior A convertible preferred stock, net	—	7,642
Proceeds from initial public offering, net of issuance costs	57,762	—
Proceeds from the exercise of stock options	119	—
Net cash provided by financing activities	57,881	8,727
Net cash increase for the period	46,036	16,616
Cash and cash equivalents at beginning of period	12,357	1,117
Cash and cash equivalents at end of period	$ 58,393	$ 17,733
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 24
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 issuance costs	50	—
Conversion of convertible promissory notes to Series D convertible preferred stock	—	3,888

See Notes to Condensed Financial Statements.

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.

On January 30, 2014, the Company's registration statement on Form S-1 (File No 333-192230) was declared effective by the Securities and Exchange Commission ("SEC") for its initial public offering ("IPO"), pursuant to which the Company registered the offering and sale of 5,750,000 shares of its common stock (including 750,000 shares upon exercise of an option by the underwriters) at a public offering price of $11.00 per share for aggregate gross offering proceeds of $63,250. As a result of the IPO, the Company received net proceeds of approximately $56,247 from the sale of 5,750,000 shares of its common stock, after deducting $4,427 of underwriting discounts and commissions and $2,576 of offering expenses, which had been paid or accrued as of September 30, 2014.

Prior to the IPO, the Company raised several rounds of equity financing and issued debt, resulting in aggregate net proceeds of approximately $73,309 through December 31, 2013. Upon closing of the IPO, all outstanding shares of the Company's convertible preferred stock were automatically converted to shares of the Company's common stock (see Note 8). The Company has incurred substantial losses and negative cash flows from operating activities in nearly every fiscal period since inception, and expects operating losses and negative cash flows to continue into the foreseeable future.

As of September 30, 2014, the Company has unrestricted cash and cash equivalents of $58,393 and an accumulated deficit of $(76,029). The Company had net cash (used in) provided by operating activities of $(11,818) and $7,893 for the nine months ended September 30, 2014 and 2013, respectively. The Company expects that cash and cash equivalents at September 30, 2014 will be sufficient to fund its operations beyond one year. The Company recognized net losses of $(6,545) and $(4,575) for the three months ended September 30, 2014 and 2013, respectively, and $(13,573) and $(1,870) for the nine months ended September 30, 2014 and 2013, respectively, and expects to incur additional losses for the full year ending December 31, 2014.

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 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 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, 2013 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, 2013.

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 non-substantive milestone payments, 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.

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, 2013.

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"). ASU 2014-09 provides a single authoritative source of guidance and, thereby, is meant to significantly enhance comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets. ASU 2014-09 changes the principle under which the Company will recognize revenue from contracts with customers from one which requires the Company to satisfy specific criteria before recognizing revenue to one which requires the Company to recognize revenue in an amount that reflects the consideration to which it expects to be entitled in exchange for the transfer of promised goods or services to customers. The amount of revenue to be recognized in any reporting period is determined by applying the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU 2014-09 is effective for the Company for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period (i.e., January 1, 2017). Early application is not permitted. The Company is allowed to adopt ASU 2014-09 either (1) retrospectively to each prior reporting period presented using several practical expedients related to completed contracts and required disclosures, or (2) retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application, including disclosure of the effect of using this method of adoption on the financial statement line items. The Company is currently in the process of deciding which method of adoption it will use and the effect of adoption of ASU 2014-09 on its results of operations, financial position and cash flows.

In August 2014, the FASB issued Accounting Standards Update 2014-15 *Presentation of Financial Statements – Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 codifies, for the first time within GAAP, management's responsibility to evaluate whether there is substantial doubt about the Company's ability to continue as a going concern and to provide related footnote disclosures in connection with preparing financial statements for each annual and interim reporting period. Substantial doubt about the Company's ability to continue as a going concern exists when there are conditions or events, considered in the aggregate, that are known and reasonably knowable at the date that the financial statements are issued, that indicate that the Company will be unable to meet its obligations as they become due within one year after that date. ASU 2014-15 requires the Company to disclose the nature of those conditions or events when they are present, management's plans to mitigate those conditions or events and whether or not such plans alleviated the substantial doubt. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted. Prior to adoption of ASU 2014-15, the Company evaluated the need to disclose its ability to continue as a going concern for a reasonable period of time based on projections of its ability to meet its obligations as they become due within a period of one year from the balance sheet date. Upon adoption of ASU 2014-15, that period will be extended to include one year from the date the financial statements are issued and the Company will be required to make the applicable disclosures in its financial statements. The Company does not expect that the adoption of ASU 2014-15 will have a material effect on its financial position, results of operations or cash flows.

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, 2014 and December 31, 2013, the Company's financial instruments consist of cash and cash equivalents, restricted cash, accounts payable and accrued liabilities. 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, 2014 and December 31, 2013.

	September 30, 2014 Level 1	December 31, 2013 Level 1
Financial assets		
Cash equivalents:		
Money market funds	$ 58,393	$ 12,357
Restricted cash:		
Bank certificate of deposit	700	700
Total	$ 59,093	$ 13,057

4. Prepaid expenses

As of September 30, 2014, prepaid expenses was $928, consisting of $277 of prepaid insurance, $639 of research and development ("R&D") clinical costs and $12 of other costs. As of December 31, 2013, prepaid expenses was $2,140, consisting of $1,833 of IPO costs, $262 of R&D clinical costs, $34 of prepaid insurance and $11 of other costs.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)
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5. Revenue Recognition

In general, the Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the Company's price to the customer is fixed or determinable and collectability is reasonably assured.

The Company has entered into license agreements to develop, manufacture and commercialize drug products. The terms of these agreements typically contain multiple elements, including licenses and research and development services. Payments to the Company under these agreements may include nonrefundable license fees, payments for research activities, payments based upon the achievement of certain milestones and royalties on any resulting net product sales. There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to the Company.

The Company records revenue related to these agreements in accordance with ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*. In order to account for these agreements, the Company identifies the deliverables included within the arrangement and evaluates which deliverables represent separate units of accounting based on whether certain criteria are met, including whether the delivered element has stand-alone value to the counterparty. The consideration received is then allocated among the separate units of accounting based on each unit's relative selling price. The identification of individual elements in a multiple-element arrangement and the estimation of the selling price of each element involve significant judgment, including consideration as to whether each delivered element has standalone value.

Arrangement consideration allocated to license deliverables that represent separate units of accounting are recognized as revenue at the outset of the agreement assuming the general criteria for revenue recognition noted above have been met. Arrangement consideration allocated to license deliverables that do not represent separate units of accounting are deferred. The Company has determined that its license deliverables represent separate units of accounting.

Arrangement consideration allocated to research and development services that represent separate units of accounting are recognized as the services are performed, assuming the general criteria for revenue recognition noted above have been met. The Company has determined that its research and developments services deliverables, as applicable, represent separate units of accounting.

The Company's license agreements include contingent milestone payments related to specified clinical development milestones and regulatory milestones. The Company generally considers non-refundable development and regulatory milestones that the Company expects to be achieved as a result of the Company's efforts during the period of the Company's performance obligations under the license and research agreements to be substantive and recognizes them as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. If such milestones are considered not to be substantive because the Company does not contribute effort to their achievement, the Company initially defers those milestone payments, allocates them to the units of accounting and recognizes them as revenue over the remaining term of those performance obligations. If no such performance obligation exists, milestone payments that are considered not to be substantive are generally recognized as revenue upon achievement, assuming all other revenue recognition criteria are met.

Maruishi Pharmaceutical Co., Ltd.

In April 2013, the Company entered into a license agreement with Maruishi Pharmaceutical Co., Ltd. ("Maruishi") 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. The Company and Maruishi are responsible 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 will provide Maruishi specific clinical development services for CR845 used in Maruishi's field of use.

Under the terms of this license agreement, the Company received an upfront non-refundable, non-creditable license fee of $15,000. Also, in conjunction with this arrangement Maruishi purchased 2,105,263 shares of Junior A convertible preferred stock of the Company pursuant to a stock purchase agreement for a purchase price of $8,000. These shares were recorded at their fair value of $7,663. As a result, the premium of $337 was allocated to the arrangement consideration.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)
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The Company has identified two deliverables under ASC 605-25: (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 are being accounted for as separate units of accounting at the outset of the arrangement.

Along with the R&D services performed by the Company for Maruishi, the Company supplies Maruishi with CR845 clinical material as an accommodation. The Company has 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 are capitalized as prepaid expense. During the manufacturing process, title and risk of loss remains with the third party until the Company has paid in full for the material.

Once the Company has title to the CR845 and has delivered it to Maruishi, prepaid expense related to that CR845 is reduced with an offset to R&D expense. At that time, Maruishi reimburses the Company for its external and internal costs for purchasing CR845 and processing the sale to Maruishi and the Company recognizes collaborative revenue for the reimbursement amount. Deposits received from Maruishi prior to delivery of CR845 are recorded as deferred revenue.

Under the terms of the license 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 U.S. At the time of execution of this license 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 U.S. 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 *Revenue Recognition – Milestone Method*. However, the milestones achieved by Maruishi in Japan are not substantive and will be accounted for as contingent consideration.

During June 2014, Maruishi completed a Phase 1 clinical trial in Japan related to CR845 in acute post-operative pain, which constituted achievement of one of the milestones specified in the license agreement. As the milestone was considered not to be substantive, the payment was accounted for as contingent consideration. Accordingly, the Company allocated the non-refundable contingent payment of $480, net of a contractual foreign currency exchange adjustment, to the two deliverables in the same proportion as the initial upfront payment had been allocated. The portion of the contingent payment allocated to the previously delivered license deliverable was recognized as license revenue entirely in June 2014. A portion of the contingent payment allocated to the R&D services deliverable was recognized as collaborative revenue in June 2014 to the extent of R&D services provided through June 30, 2014 and the remainder was deferred and is being recognized as collaborative revenue through the period during which the Company provides R&D services to Maruishi. The payment due from Maruishi was received during the three months ended September 30, 2014.

As of September 30, 2014 and December 31, 2013, the Company had $1,944 and $3,475, respectively, of deferred revenue pursuant to the R&D services deliverable under the license agreement with Maruishi.

During the three months ended September 30, 2014 and 2013, the Company recognized no license fee revenue and $1,125 and $1,018, respectively, of collaborative revenue, including $1,125 and $960, respectively, of amortization of deferred revenue from the portion of the upfront payment received pursuant to the license agreement with Maruishi that was allocated to the R&D services deliverable and $0 and $58, respectively, from the sale of CR845 clinical compound.

During the nine months ended September 30, 2014 and 2013, the Company recognized $302 and $9,637, respectively, of license fee revenue and $1,961 and $1,354, respectively, of collaborative revenue, including $1,802 and $1,266, respectively, of amortization of deferred revenue from the portion of the upfront payment received pursuant to the license agreement with Maruishi that was allocated to the R&D services deliverable and $159 and $88, respectively, from the sale of CR845 clinical compound.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)
(unaudited)

The Company incurred R&D expense related to the Maruishi license agreement of $1,326 and $2,438 during the three and nine months ended September 30, 2014, respectively, and $1,043 and $1,396 during the three and nine months ended September 30, 2013, respectively.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2014	December 31, 2013
Accounts payable	$ 1,715	$ 676
Accrued research projects	1,476	405
Accrued professional fees	434	739
Accrued compensation and benefits	488	83
Accrued other	36	55
Total	$ 4,149	$ 1,958

7. Net Loss Per Share

The Company computes basic net (loss) income per share using the “two-class” method, which includes the weighted-average number of common stock outstanding during the period and other securities that participate in dividends (a participating security). Prior to the closing of the IPO, the Company’s shares of convertible preferred stock were participating securities as defined by ASC 260-10, *Earnings Per Share*. Under the two-class method, basic net (loss) income per share available to common stockholders is computed by dividing the net (loss) income available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net (loss) income per share is computed using the more dilutive of (1) the two-class method, or (2) the “if-converted” method. The Company allocates net earnings on a pari passu (equal) basis to both common and preferred stockholders. Net losses are not allocated to preferred stockholders as they have no obligation to share in the Company’s net losses.

Diluted net (loss) income per share gives effect to all potentially dilutive securities, including convertible preferred stock, convertible promissory notes and shares issuable upon the exercise of outstanding stock options and warrants, using the treasury stock method. For the three and nine months ended September 30, 2014 and 2013, the Company excluded the effects of potentially dilutive shares that were outstanding during those respective periods from the denominator as their inclusion would be ant-dilutive due to the Company’s net losses during those periods.

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(unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Basic:				
Weighted average common shares outstanding	22,713,040	4,288,243	20,351,005	4,080,869
Diluted:				
Weighted average common shares outstanding - Basic	22,713,040	4,288,243	20,351,005	4,080,869
Convertible preferred stock*	—	—	—	—
Common stock options*	—	—	—	—
Common stock warrants*	—	—	—	—
Convertible promissory notes (as if converted)*	—	—	—	—
Denominator for diluted net loss per share available to common stockholders	22,713,040	4,288,243	20,351,005	4,080,869

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

Basic and diluted net loss per share available to common stockholders are computed as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	$ (6,545)	$ (4,575)	$ (13,573)	$ (1,870)
Add back: extinguishment of preferred shares	—	—	—	891
Net loss available to common stockholders - Basic and Diluted	$ (6,545)	$ (4,575)	$ (13,573)	$ (979)
Net loss per share available to common stockholders:				
Basic and Diluted	$ (0.29)	$ (1.07)	$ (0.67)	$ (0.24)
Weighted-average common shares outstanding available to common stockholders:				
Basic and Diluted	22,713,040	4,288,243	20,351,005	4,080,869

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Securities outstanding at the end of the respective periods presented below, that could potentially dilute basic earnings per share in the future, that were not included in the computation of diluted net loss per share because to do so would have been antidilutive are as follows:

	September 30,	
	2014	2013
Convertible preferred stock	—	12,554,171
Common stock options	964,360	490,160
Common stock warrants	—	19,851
Total	964,360	13,064,182

All shares of the Company's convertible preferred stock were automatically converted to shares of the Company's common stock upon the closing of the IPO on February 5, 2014 (see Note 8). All convertible promissory notes were either converted into shares of the Company's Series D convertible preferred stock or repaid in cash by December 31, 2013.

8. Convertible Preferred Stock

As of December 31, 2013, the Company had authorized an aggregate of 29,402,200 shares of convertible preferred stock, par value $0.001 per share. Upon the closing of the Company's IPO on February 5, 2014, all 29,186,929 shares of the Company's convertible preferred stock that were issued and outstanding on that date were automatically converted into an aggregate of 12,554,171 shares of its common stock. As of September 30, 2014, there were no shares of convertible preferred stock authorized or outstanding.

9. Reverse Stock Split

The Company's Board of Directors and stockholders approved a 1-for-2.5 reverse stock split of the Company's common stock effective on January 16, 2014, which resulted in an adjustment to the preferred stock conversion price to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. All share and per share data in the unaudited interim condensed financial statements and accompanying notes thereto included in this Quarterly Report on Form 10-Q have been retroactively adjusted for all periods presented to give effect to this reverse stock split.

10. Stockholders' (Deficit) Equity

On January 16, 2014, the Company's Board of Directors approved an Amended and Restated Certificate of Incorporation, which, among other things, increased the authorized number of shares of the Company's common stock, par value $0.001 per share, from 50,000,000 to 100,000,000 and authorized 5,000,000 shares of undesignated preferred stock, par value $0.001 per share, that may be issued from time to time by the Board of Directors of the Company in one or more series. As of September 30, 2014, there were 22,778,597 shares of common stock and no shares of preferred stock issued and outstanding.

On July 31, 2014, Connecticut Innovations Inc. ("CII") exercised its outstanding warrants to purchase 19,851 shares of the Company's common stock, which the Company had issued in September 2007 in connection with a loan from CII, in a cashless exercise, resulting in the issuance of 6,383 shares of the Company's common stock.

11. Stock-Based Compensation

2014 Equity Incentive Plan

The Company's Board of Directors adopted, and its stockholders subsequently approved, its 2014 Equity Incentive Plan (the "2014 Plan") in January 2014. The 2014 Plan became effective immediately upon the signing of the underwriting agreement for the Company's initial public offering. 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,

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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. The Plan administrator determines the term of Stock Awards granted under the 2014 Plan up to a maximum of ten years.

Initially, the aggregate number of shares of the Company's common stock that may be issued pursuant to Stock Awards under the 2014 Plan is 1,600,000 shares. Additionally, the number of shares of the Company's common stock reserved for issuance under the 2014 Plan will automatically increase 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. 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.

2004 Stock Incentive Plan

Under the 2004 Stock Incentive Plan ("2004 Plan"), the Company granted stock options to selected officers, employees and consultants of the Company. As of December 31 2013, options to purchase 490,160 shares of common stock were outstanding under the 2004 Plan, with a weighted average exercise price per share of $1.34. Although as of December 31 2013, 757,799 shares remained available for future issuance pursuant to the grant of options or restricted share awards under the 2004 Plan, following the effectiveness of the 2014 Plan in January 2014, no additional options or restricted share awards were granted under the 2004 Plan. As of September 30, 2014, the 2004 Plan has expired and no further grants of stock options or restricted stock are allowed. The 2014 Plan and 2004 Plan are referred to collectively as the Stock Incentive Plans.

Under the Stock Incentive Plans, the Company granted 40,000 and 654,000 stock options during the three and nine months ended September 30, 2014, respectively, and no stock options during the three and nine months ended September 30, 2013. The fair values of stock options granted during the three and nine months ended September 30, 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, 2014	Nine Months Ended September 30, 2014
Risk-free interest rate	1.92%	1.80% - 2.72%
Expected volatility	65%	65% - 71%
Expected dividend yield	0%	0%
Expected life of employee options (in years)	6.25	6.25
Expected life of nonemployee options (in years)	10	10

The weighted average grant date fair value of options granted to employees and members of the Board of Directors for their Board service during the three and nine months ended September 30, 2014 was $8.01 and $7.58, respectively. As of September 30, 2014, the fair value of vested options that have been granted to nonemployee consultants, which is marked to market at each reporting date in accordance with ASC 505-50, was $5.87.

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During the three and nine months ended September 30, 2014 and 2013, the Company recognized compensation expense relating to stock options, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$ 38	$ 31	$ 269	$ 62
General and administrative	184	28	762	48
Total stock option expense	$ 222	$ 59	$ 1,031	$ 110

A summary of stock option award activity under the Company's Stock Incentive Plans as of and for the nine months ended September 30, 2014 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2013	490,160	$ 1.34
Granted	654,000	12.17
Exercised	(179,800)	0.66
Outstanding, September 30, 2014	964,360	8.81
Options exercisable, September 30, 2014	348,026	$ 3.10

12. Income Taxes

For the three months ended September 30, 2014 and 2013, pre-tax losses were $(6,577) and $(4,575), respectively, and for the nine months ended September 30, 2014 and 2013, pre-tax losses were $(13,632) and $(1,897), respectively. The Company recognized a full tax valuation allowance against net deferred tax assets at September 30, 2014 and December 31, 2013.

The benefit from income taxes of $32 and $0 for the three months ended September 30, 2014 and 2013, respectively, and $59 and $27 for the nine months ended September 30, 2014 and 2013, 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.

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13. Commitments and Contingencies

Contractual obligations and commitments as of September 30, 2014 were as follows:

	Payment Due for the Year Ending December 31,						
	2014	2015	2016	2017	2018	Thereafter	Total
Operating lease (1)	$215	$ 886	$ 913	$ 740	$—	$ —	$2,754
Employment agreements (2)	238	952	952	952	952	—	4,046
Total	$453	$1,838	$1,865	$1,692	$952	$ —	$6,800

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

(2) Effective January 2014, the Company entered into employment agreements with three of its executive officers. Each such employment agreement has a term of four years and is renewable on the same terms for one additional year unless the executive officer party to such agreement notifies the Company in writing not to renew. Under these employment agreements, each executive officer is eligible for severance benefits in specified circumstances, including 6 to 12 months of salary.

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," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," and or the negative of these terms, 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;
- our plans to develop and commercialize I.V. CR845 and our other product candidates, including Oral CR845;
- 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, or 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 size and growth of the potential markets for pain management, including the postoperative and chronic pain markets, and our other product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any approved products;
- our expectations regarding the period during which we will be an emerging growth company under the JOBS Act;
- our use of the proceeds from our initial public 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 obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- the success of competing drugs that are or become available; 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, 2013 for a discussion of important factors that may cause our 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, 2013.

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 and have demonstrated efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available pain therapeutics.

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. We plan to request an End of Phase 2 meeting with the Food and Drug Administration ("FDA") before the end of 2014 to discuss the design of Phase 3 trials for I.V. CR845, in acute pain. Based on timelines for completion of Chemistry, Manufacturing and Controls ("CMC") requirements related to Active Pharmaceutical Ingredient ("API") synthesis and drug product manufacturing, we anticipate initiating Phase 3 trials early in 2015. In addition, in October 2014, we successfully completed a Human Abuse Liability ("HAL") trial of I.V. CR845. The top-line results from this HAL trial indicate that I.V. CR845 met the trial's primary endpoint by demonstrating highly statistically significant lower "drug liking" scores as measured by visual analog scale (VAS) Emax ($p < 0.0001$) when compared to I.V. pentazocine, a Schedule IV opioid receptor agonist. I.V. CR845 also demonstrated highly statistically significant lower "feeling high," "overall liking," and "take drug again" scores ($p < 0.0001$) as compared to pentazocine. Those scores represent standard subjective measures recommended by the FDA to assess a drug's abuse liability. The totality of results are supportive of the potential for CR845 to be the first Schedule V or non-scheduled peripheral opioid for acute pain.

We are also developing an oral version of CR845, or Oral CR845, for acute and chronic pain. We have successfully completed a Phase 1 trial of a capsule formulation of Oral CR845 that established oral bioavailability parameters. In June 2014, we initiated a Phase 1 trial of a tablet formulation of Oral CR845 for which we anticipate top-line data in the fourth quarter of 2014. CR845 has exhibited anti-pruritic (anti-itch) potency in standard preclinical models. In June 2014, we filed an IND and in August 2014 we initiated a proof-of-concept Phase 2 trial for 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 U.S. We expect to report top-line dose-ranging pharmacokinetic (PK) and safety data from this trial before the end of 2014 and top-line efficacy results in the first half of 2015.

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, 2014, we have received net proceeds of $56.2 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, net proceeds of $65.9 million from the sale of various series of convertible preferred stock, $3.6 million from the issuance of 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 $29.4 million pursuant to license agreements related to CR845 and an earlier product candidate for which development efforts ceased in 2007. Included in those aforementioned payments pursuant to license agreements, in April 2013, we received $15.0 million as an upfront payment, and in August 2014, we received an additional $0.5 million related to achievement of a milestone in connection with the license of rights to CR845 in Japan to Maruishi Pharmaceutical Co., Ltd., ("Maruishi"). In 2012, we received aggregate upfront and milestone payments of $1.2 million pursuant to a license agreement with Chong Kun Dang Pharmaceutical Corporation ("CKD"), in connection with the license of rights to CR845 in South Korea.

Since inception, we have incurred significant operating and net losses. Our net losses were $6.5 million and $13.6 million for the three and nine months ended September 30, 2014, respectively. As of September 30, 2014, we had an accumulated deficit of $76.0 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:

- initiate our planned Phase 3 clinical trials of I.V. CR845;
- 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.

In addition, we have incurred and will continue to incur significant expenses as a result of our having become a public company, which subjects us to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act of 2002 and the rules and regulations of The NASDAQ Global Market. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. Commencing with our current fiscal year ending December 31, 2014, we are performing system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for this year, as required by Section 404. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

To achieve compliance with Section 404 within the prescribed period, we are engaged in a process of documenting and evaluating our internal control over financial reporting using the 2013 Internal Control – Integrated Framework established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). This process is both costly and challenging. In this regard, we are continuing to dedicate internal resources and have engaged outside consultants to assist us, under management's direction, in the design, documentation and testing of our internal controls and procedures. We have adopted a detailed work plan to assess whether each of the 17 principles underlying the five components of internal control is present and functioning and whether the five components are operating together to provide reasonable assurance that the relevant objectives are met.

As of September 30, 2014, we have identified and documented the controls, including key controls, within our significant classes of transactions as well as entity-level and information technology processes. Our outside consultants are in the process of testing our key controls to ensure that those controls are functioning as documented. Testing will continue through December 31, 2014 to ensure that our key controls over financial reporting are present and functioning as of that date. As a result of that testing, we have enhanced the documentation of some of our internal controls.

To fund future operations, we may need to raise additional capital. As of September 30, 2014, we had cash and cash equivalents of approximately $58.4 million. We may obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 18 months without giving effect to any potential milestone payments we may receive under our collaboration agreements. However, our ability to successfully transition to profitability will be dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

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 payments under 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. However, we have not received any significant clinical development or regulatory milestone payments, or 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 and the FDA approval process. 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.

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 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, potential commercialization of our product candidates and the increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, as well as expenses related to services associated with maintaining compliance with NASDAQ listing rules and SEC requirements, insurance, 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 (Expense), Net

Interest income (expense), net, consists of interest paid on debt instruments, amortized deferred financing costs and amortized debt discount, as offset by any interest income earned on our cash and cash equivalents. The debt discount primarily consisted of the intrinsic value of the beneficial conversion feature embedded in the convertible promissory notes we issued in December 2012 and February 2013. All convertible promissory notes were either converted to shares of series D convertible preferred stock or repaid prior to December 31, 2013.

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 Months Ended September 30, 2014 and 2013

The following table sets forth our results of operations for the three months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Period-to-Period Change
	2014	2013	
Revenue:			
Collaborative revenue	$ 1,125	$ 1,018	$ 107
Total revenue	1,125	1,018	107
Cost and expenses:			
Research and development	6,208	3,764	2,444
General and administrative	1,520	795	725
	7,728	4,559	3,169
Operating loss	(6,603)	(3,541)	(3,062)
Interest income (expense), net	26	(1,034)	1,060
Loss before benefit from income taxes	(6,577)	(4,575)	(2,002)
Benefit from income taxes	32	—	32
Net loss	$ (6,545)	$ (4,575)	$ (1,970)

Revenue

Collaborative revenue increased $0.1 million to $1.1 million for the three months ended September 30, 2014 compared to the same period of 2013. Collaborative revenue for the three months ended September 30, 2014 and 2013 included $1.1 million and $960 thousand, respectively, of revenue that had been deferred upon entry into the license agreement with Maruishi and $0 and $58 thousand, respectively, from the sale of clinical compound.

Research and Development Expense

Research and development expenses increased by $2.4 million to $6.2 million for the three months ended September 30, 2014 compared to the same period of 2013. The increase was primarily the result of a $2.1 million net increase in direct preclinical studies and clinical trial costs and a $0.3 million increase in consultant services in support of preclinical studies and clinical trials. The net increase in clinical trial costs resulted from increases in costs incurred in connection with the Phase 1 Oral CR845 trial, which commenced in June 2014, the I.V. CR845 HAL trial, which commenced in July 2014, the Phase 2 I.V. CR845 uremic pruritus trial, which commenced in August 2014, and the costs of CR845 drug manufacturing. These costs were partially offset by decreases in costs incurred in connection with the Phase 2 I.V. CR845 bunionectomy trial, which was substantially completed in 2013 and the Phase 1 I.V. CR845 renal impairment trial and the costs of tablet formulation for the Phase 1 Oral CR845 trial. The cost of preclinical studies also declined.

The following table summarizes our research and development expenses by product candidate for the three months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,	
	2014	2013
External research and development expenses:		
I.V. CR845	$ 3,448	$ 2,129
Oral CR845	1,908	805
Internal research and development expenses	852	830
Total research and development expenses	$ 6,208	$ 3,764

General and Administrative Expenses

General and administrative expenses increased by $0.7 million to $1.5 million for the three months ended September 30, 2014 compared to the same period of 2013. The increase was primarily attributable to costs related to our becoming a public company in January 2014, including increases of $0.2 million in directors' and officers' insurance costs and $0.1 million in public/investor relations costs. There were also increases of $0.3 million in payroll and related costs, primarily due to increased headcount, and $0.1 million in stock-based compensation expense.

Interest Income (Expense), net

Interest income (expense), net, was $26 thousand of interest income earned on our cash and cash equivalents for the three months ended September 30, 2014 compared to $1.0 million of interest expense for the same period of 2013. The decrease in interest expense was due to the conversion of the outstanding convertible promissory notes in 2013, which had resulted in $1.0 million of non-cash expenses during the three months ended September 30, 2013, including the accretion of debt discount relating to the intrinsic value of the beneficial conversion feature embedded in the notes and amortization of deferred financing costs, and accrued interest expense.

Benefit from Income Taxes

For the three months ended September 30, 2014 and 2013, pre-tax losses were $(6.6 million) and $(4.6 million), respectively, and we recognized a benefit from income taxes of $32 thousand and $0, respectively. 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, as discussed above. We recognized a full valuation allowance against net deferred tax assets at September 30, 2014 and December 31, 2013.

Comparison of the Nine Months Ended September 30, 2014 and 2013

The following table sets forth our results of operations for the nine months ended September 30, 2014 and 2013 (in thousands):

	Nine Months Ended September 30, 2014	2013	Period-to-Period Change
Revenue:			
License fees	$ 302	$ 9,637	$ (9,335)
Collaborative revenue	1,961	1,354	607
Total revenue	2,263	10,991	(8,728)
Cost and expenses:			
Research and development	11,609	6,707	4,902
General and administrative	4,390	2,416	1,974
	15,999	9,123	6,876
Operating (loss) income	(13,736)	1,868	(15,604)
Interest income (expense), net	104	(3,765)	3,869
Loss before benefit from income taxes	(13,632)	(1,897)	(11,735)
Benefit from income taxes	59	27	32
Net loss	$ (13,573)	$ (1,870)	$ (11,703)

Revenue

License fee revenue decreased $9.3 million to $0.3 million for the nine months ended September 30, 2014 compared to the same period of 2013. The decrease was primarily the result of our recognition as license revenue of $0.3 million of the $0.5 million payment related to achievement of a milestone in June 2014 under the license agreement with Maruishi and $9.6 million of the upfront payment received from the execution of the license agreement with Maruishi in April 2013. Of the remaining $0.2 million of the milestone payment earned during June 2014, $0.1 million was recognized as collaborative revenue in June 2014 and $0.1 million was deferred and is being recognized as collaborative revenue through the period during which we provide R&D services to Maruishi.

Collaborative revenue increased $0.6 million to $2.0 million for the nine months ended September 30, 2014 compared to the same period of 2013. Collaborative revenue for the nine months ended September 30, 2014 and 2013 included $1.8 million and $1.3 million, respectively, of revenue that had been deferred upon entry into the license agreement with Maruishi and $159 thousand and $88 thousand, respectively, from the sale of clinical compound.

Research and Development Expense

Research and development expenses increased by $4.9 million to $11.6 million for the nine months ended September 30, 2014 compared to the same period of 2013. The increase was primarily the result of a $4.0 million net increase in direct preclinical studies and clinical trial costs, a $0.5 million increase in consultant services in support of preclinical studies and clinical trials, a $0.2 million increase in stock-based compensation expense and a $0.1 million increase in cost of compound sold to Maruishi. The net increase in clinical trial costs resulted from increases in the cost of CR845 drug manufacturing as well as increases in costs incurred in connection with the Phase 1 Oral CR845 trial, which commenced in June 2014, the Phase 2 I.V. CR845 uremic pruritus trial, which commenced in August 2014 and the I.V. CR845 HAL trial, which commenced in July 2014. These costs were partially offset by decreases in costs incurred in connection with the Phase 2 I.V. CR845 bunionectomy trial, which was substantially completed in 2013, tablet formulation costs for the Phase 1 Oral CR845 trial and the Phase 1 I.V. CR845 renal impairment trial. The cost of preclinical studies also declined.

The following table summarizes our research and development expenses by product candidate for the nine months ended September 30, 2014 and 2013 (in thousands):

	Nine Months Ended September 30,	
	2014	2013
External research and development expenses:		
I.V. CR845	$ 5,541	$ 3,352
Oral CR845	3,586	1,194
Internal research and development expenses	2,482	2,161
Total research and development expenses	$ 11,609	$ 6,707

General and Administrative Expenses

General and administrative expenses increased by $2.0 million to $4.4 million for the nine months ended September 30, 2014 compared to the same period of 2013. The increase was primarily attributable to costs related to our becoming a public company in January 2014, including increases of $0.3 million of professional fees, including accounting, legal and directors' fees, $0.4 million in directors' and officers' insurance costs and $0.3 million in public/investor relations costs. There were also increases of $0.7 million of stock-based compensation expense and $0.4 million of payroll and related costs, primarily due to increased headcount. Those costs were partially offset by a decrease of $0.3 million in consultant costs, primarily related to the success fee we incurred in connection with entering into the Maruishi license agreement in 2013.

Interest Income (Expense), net

Interest income (expense), net, was $104 thousand of interest income earned on our cash and cash equivalents for the nine months ended September 30, 2014 compared to $3.8 million of interest expense for the nine months ended September 30, 2013. The decrease in interest expense was due to the conversion of the outstanding convertible promissory notes during 2013, which had resulted in $3.8 million of non-cash expenses during the nine months ended September 30, 2013, including the accretion of debt discount relating to the intrinsic value of the beneficial conversion feature embedded in the notes and amortization of deferred financing costs, and accrued interest expense.

Benefit from Income Taxes

For the nine months ended September 30, 2014 and 2013, pre-tax losses were $13.6 million and $1.9 million, respectively, and we recognized a benefit from income taxes of $59 thousand and $27 thousand, respectively. 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, as discussed above. We recognized a full valuation allowance against net deferred tax assets at September 30, 2014 and December 31, 2013.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception and through September 30, 2014, we have raised an aggregate of approximately $159.2 million to fund our operations, including primarily proceeds of $56.2 million, net of underwriting discounts and commissions and offering expenses, from our IPO, which closed in February 2014, $29.4 million received under our license agreements, primarily with Maruishi and CKD, $65.9 million of proceeds from the sale of shares of our convertible preferred stock, including Junior A convertible preferred stock (see below), and $7.4 million of net proceeds from debt financings, including convertible promissory notes (see below). As of September 30, 2014, we had $58.4 million in cash and cash equivalents.

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. During June 2014, Maruishi completed a Phase 1 clinical trial in Japan related to CR845 in acute post-operative pain for which, as of September 30, 2014, we received a clinical development milestone payment of $0.5 million. 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. 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.

We believe that, as of September 30, 2014, cash and cash equivalents on hand will be sufficient to fund our operations for the next 18 months without giving effect to any potential milestone payments we may receive under our collaboration agreements.

Convertible Promissory Notes

During February 2013, we issued $1.5 million principal amount of convertible promissory notes, due August 28, 2013, in addition to the $2.5 million principal amount of convertible promissory notes due August 28, 2013 that were issued in December 2012 (total aggregate amount of convertible promissory notes issued was $4.0 million). The notes bore interest at 8% per annum and included both optional and mandatory conversion features. The optional conversion feature allowed each note holder, at any time prior to maturity, to elect to convert the balance of the note plus accrued interest into shares of our Series D convertible preferred stock at a conversion price of approximately $1.44 per share. The mandatory conversion feature of the notes provided that, if we issued or sold equity securities of not less than $10.0 million on or before the maturity date, the notes plus all accrued interest thereon would automatically convert into shares of the issued class of equity securities at a price per share equal to 90% of the cash price paid by the investors in the new equity securities.

We did not need to complete an equity financing prior to August 28, 2013, which would have triggered the mandatory conversion of the notes. In August 2013, certain holders of notes elected to convert their notes in the aggregate amount of $3.9 million in principal plus accrued interest thereon into 2,692,291 shares of our Series D convertible preferred stock. In October 2013, we repaid the remaining notes in the aggregate amount of $311 thousand in principal and accrued interest thereon.

Junior A Convertible Preferred Stock

Under the terms of the Maruishi agreement, during April 2013, Maruishi purchased 2,105,263 shares of our Junior A convertible preferred stock pursuant to a stock purchase agreement for a purchase price of $8.0 million. These shares have been recorded at their fair value of $7.7 million. As a result, the premium of $0.3 million was allocated to the arrangement consideration and was, therefore, recognized as license fee revenue in accordance with our revenue recognition policies.

Funding Requirements

Our primary uses of capital have been, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs. See Part II Item 2, *Unregistered Sales of Equity Securities and Use of Proceeds*, below, regarding the use of the net proceeds from our IPO.

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 payors 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 the early stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may 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.

In addition, we have incurred and will continue to incur significant expenses as a result of our having become a public company in January 2014, which subjects us to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 and the rules and regulations of The NASDAQ Global Market (see *Overview*, above).

We may require additional capital beyond our currently anticipated amounts and this additional capital may not be available when needed, on reasonable terms, or at all. 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 research and development 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, 2014 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 18 months, without giving effect to any potential milestone payments we may receive under our collaboration agreements. 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, 2014 and 2013 (in thousands):

	Nine Months Ended September 30,	
	2014	2013
Net cash (used in) provided by operating activities	$ (11,818)	$ 7,893
Net cash (used in) investing activities	(27)	(4)
Net cash provided by financing activities	57,881	8,727
Net increase in cash and cash equivalents	$ 46,036	$ 16,616

Net cash (used in) provided by operating activities

For the nine months ended September 30, 2014, net cash used in operating activities was $11.8 million compared to net cash provided by operating activities of $7.9 million for the nine months ended September 30, 2013. The $19.7 million increase in net cash used in operating activities was due to an increase in net loss, net of non-cash charges, in addition to a decrease in inflows related to changes in operating assets and liabilities.

For the nine months ended September 30, 2014, 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. The net change in operating assets and liabilities primarily consisted of cash outflows from a $1.5 million decrease in deferred revenue from the Maruishi license transaction, partially offset by cash inflows from a $0.2 million decrease in prepaid expenses, primarily related to prepaid insurance and prepaid clinical costs and a $1.6 million increase in accounts payable and accrued expenses.

For the nine months ended September 30, 2013, non-cash charges primarily consisted of aggregate non-cash interest and amortization of beneficial conversion feature on our convertible promissory notes of $3.6 million and depreciation and amortization expense of $0.6 million, partially offset by deferred rent costs of $0.2 million. The net change in operating assets and liabilities primarily consisted of cash inflows from a $4.4 million increase in deferred revenue related to the Maruishi license agreement and a $1.3 million increase in accounts payable and accrued expenses.

Net cash used in investing activities

Net cash used in investing activities was $27 thousand and $4 thousand for the nine months ended September 30, 2014 and 2013, respectively, related to the purchase of office equipment and furniture.

Net cash provided by financing activities

Net cash provided by financing activities was $57.9 million for the nine months ended September 30, 2014, which consisted primarily of gross proceeds of $63.2 million from our initial public offering, partially offset by $5.5 million of underwriting discounts and commissions and offering expenses paid in the nine months ended September 30, 2014, and proceeds of $0.1 million received from stock option exercises.

Net cash provided by financing activities was $8.7 million for the nine months ended September 30, 2013, which consisted primarily of $7.6 million of proceeds received from the sale of Junior A convertible preferred stock and $1.4 million of net proceeds received from the issuance of convertible promissory notes, partially offset by the repayment of long-term debt (Connecticut Innovations Inc. loan) of $0.3 million.

Significant Contractual Obligations and Commitments

Contractual obligations and commitments as of September 30, 2014 included those related to employment agreements with executive officers that were entered into in January 2014, in addition to operating lease obligations related to our operating facility in Shelton, Connecticut. See Note 13 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

Discussion of Critical Accounting Policies

The preparation of financial statements in conformity with 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, 2014, 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, 2013.

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, 2014 and December 31, 2013, we had cash and cash equivalents of $58.4 million and $12.4 million, respectively. We generally hold our cash equivalents in interest-bearing money market 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, 2014. 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, 2014, our disclosure controls and procedures were effective.

(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, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. ***Legal Proceedings***

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, 2013, filed with the SEC on March 28, 2014, 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, 2014, 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, 2013.

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

Recent Sales of Unregistered Equity Securities

On July 31, 2014, Connecticut Innovations Inc. exercised its outstanding warrant to purchase 19,851 shares of the Company's common stock, which the Company had issued in September 2007 in connection with a loan from CII, in a cashless exercise, resulting in the issuance of 6,383 shares of the Company's common stock.

No underwriters were used in the foregoing transaction. The issuance of securities described above was deemed to be exempt from registration pursuant to an exemption from registration under the Securities Act in reliance upon Section 3(a)(9) of the Securities Act. Such holder received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. The foregoing securities are deemed restricted securities for the purposes of the Securities Act.

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 from the sale of 5,750,000 shares of common stock, after deducting approximately $4.4 million of underwriting discounts and commissions but before giving effect to any offering expenses borne by us. In addition, as of September 30, 2014, we have paid or accrued approximately an additional $2.6 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, 2014, we have used approximately $6.8 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.

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 10, 2014

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

Date: November 10, 2014

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

EXHIBIT 31.1

Certification of Chief Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Derek Chalmers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cara Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

By: /s/ Derek Chalmers, Ph.D.
DEREK CHALMERS
CHIEF EXECUTIVE OFFICER

EXHIBIT 31.2

Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Josef Schoell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cara Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

By: /s/ Josef Schoell
JOSEF SCHOELL
CHIEF FINANCIAL OFFICER

EXHIBIT 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

In connection with the Quarterly Report on Form 10-Q of Cara Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Derek Chalmers, Ph.D., as Chief Executive Officer of the Company, and Josef Schoell, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, based upon a review of the Report:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DEREK CHALMERS

Name: Derek Chalmers, Ph.D.
Title: Chief Executive Officer
Date: November 10, 2014

/s/ JOSEF SCHOELL

Name: Josef Schoell
Title: Chief Financial Officer
Date: November 10, 2014