Cara Therapeutics, Inc.
Form 10-Q
November 04, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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.)**

4 Stamford Plaza

107 Elm Street 9th Floor

Stamford, Connecticut	**06902**
(Address of registrant s principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (203) 406-3700

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
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 x No.

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of October 28, 2016 was: 27,282,863.

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FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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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, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 5,426	$ 15,101
Marketable securities	65,994	91,640
Income tax receivable	663	384
Other receivables	115	80
Prepaid expenses	4,820	1,729
Total current assets	77,018	108,934
Property and equipment, net	1,665	1,263
Restricted cash	1,469	700
Total assets	$ 80,152	$ 110,897
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,825	$ 5,268
Total current liabilities	6,825	5,268
Deferred lease obligation	1,525	585
Commitments and contingencies *(Note 14)*		
Stockholders equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized at September 30, 2016 and December 31, 2015, zero shares issued and outstanding at September 30, 2016 and December 31, 2015.		
Common stock; $0.001 par value; 100,000,000 shares authorized at September 30, 2016 and December 31, 2015, 27,282,863	27	27

shares and 27,254,863 shares issued and outstanding at
September 30, 2016 and December 31, 2015, respectively.

Additional paid-in capital		211,954		209,943
Accumulated deficit		(140,199)		(104,891)
Accumulated other comprehensive income (loss)		20		(35)
Total stockholders equity		71,802		105,044
Total liabilities and stockholders equity	$	80,152	$	110,897

See Notes to Condensed Financial Statements.

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CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

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

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenue:				
License and milestone fees	$	$ 1,710	$	$ 1,710
Collaborative revenue		730		2,093
Clinical compound revenue			86	
Total revenue		2,440	86	3,803
Operating expenses:				
Research and development	9,671	5,584	28,976	13,653
General and administrative	2,102	1,865	7,195	5,609
Total operating expenses	11,773	7,449	36,171	19,262
Operating loss	(11,773)	(5,009)	(36,085)	(15,459)
Other income	176	22	498	49
Loss before benefit from income taxes	(11,597)	(4,987)	(35,587)	(15,410)
Benefit from income taxes	55	200	279	250
Net loss	$ (11,542)	$ (4,787)	$ (35,308)	$ (15,160)
Net loss per share -Basic and Diluted	$ (0.42)	$ (0.19)	$ (1.29)	$ (0.64)
Weighted average shares:				
Basic and Diluted	27,282,863	25,545,164	27,275,133	23,737,443
Other comprehensive loss, net of tax of $0:				
Changes in unrealized gains (losses) on available-for-sale marketable securities	(21)		55	
Total comprehensive loss	$ (11,563)	$ (4,787)	$ (35,253)	$ (15,160)

See Notes to Condensed Financial Statements.

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CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS EQUITY

(amounts in thousands except share and per share data)

(unaudited)

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

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive Income	Total Stockholders
	Shares	Amount	Capital	Deficit	(Loss)	Equity
Balance at December 31, 2015	27,254,863	$ 27	$ 209,943	$ (104,891)	$ (35)	$ 105,044
Stock-based compensation expense			1,971			1,971
Shares issued upon exercise of stock options	28,000		40			40
Net loss				(35,308)		(35,308)
Other comprehensive income					55	55
Balance at September 30, 2016	27,282,863	$ 27	$ 211,954	$ (140,199)	$ 20	$ 71,802

See Notes to Condensed Financial Statements.

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CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(amounts in thousands)

(unaudited)

	Nine Months Ended	
	September 30, 2016	**September 30, 2015**
Operating activities		
Net loss	$ (35,308)	$ (15,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,971	1,807
Depreciation and amortization	1,346	580
Accretion/amortization on available-for-sale marketable securities	(183)	
Realized gain on sales of marketable securities	(12)	
Deferred rent costs	(158)	(214)
Changes in operating assets and liabilities:		
Income tax receivable	(279)	(250)
Other receivables	(35)	(2,143)
Prepaid expenses	(3,091)	(1,649)
Accounts payable and accrued expenses	1,556	1,171
Deferred revenue		(1,452)
Net cash used in operating activities	(34,193)	(17,310)
Investing activities		
Proceeds from maturities of available-for-sale marketable securities	59,650	
Proceeds from sale of available-for-sale marketable securities	23,368	
Purchases of available-for-sale marketable securities	(57,123)	
Change in restricted cash	(769)	
Purchases of property and equipment	(648)	(13)
Net cash provided by (used in) investing activities	24,478	(13)
Financing activities		
Proceeds from follow-on offering of common stock, net of issuance costs		75,453
Proceeds from the exercise of stock options	40	323
Net cash provided by financing activities	40	75,776
Net cash (decrease) increase for the period	(9,675)	58,453
Cash and cash equivalents at beginning of period	15,101	52,663
Cash and cash equivalents at end of period	$ 5,426	$ 111,116

Noncash investing and financing activities		
Tenant improvements paid by landlord	$ 1,094	$
Unpaid follow-on offering issuance costs		222

See Notes to Condensed Financial Statements.

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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 peripheral kappa opioid receptors. The Company s primary activities to date have been organizing and staffing the company, developing its product candidates, including conducting preclinical studies and clinical trials of CR845-based product candidates and raising capital.

As of September 30, 2016, the Company has raised aggregate net proceeds of approximately $204,800 from several rounds of equity financing, including its initial public offering, which closed in February 2014 and its follow-on offering, which closed in August 2015, and the issuance of debt. In addition, the Company received approximately $32,500 under its license agreements for CR845, primarily with Maruishi Pharmaceutical Co. Ltd., or Maruishi, and Chong Kun Dang Pharmaceutical Corp., or CKD, and an earlier product candidate for which development efforts ceased in 2007 (see Note 10, *Collaborations*).

As of September 30, 2016, the Company had unrestricted cash and cash equivalents and marketable securities of $71,420 and an accumulated deficit of $140,199. The Company has incurred substantial net losses and negative cash flows from operating activities in nearly every fiscal period since inception and expects this trend to continue for the foreseeable future. The Company recognized net losses of $35,308 and $15,160 and had net cash used in operating activities of $34,193 and $17,310 for the nine months ended September 30, 2016 and 2015, respectively. The Company expects that cash and cash equivalents and marketable securities as of September 30, 2016 will be sufficient to fund its operations beyond one year.

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, or FDA, and other government regulations. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

2. Basis of Presentation

The unaudited interim condensed financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission, or 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, or 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, 2015 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, 2015.

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 the fair value of marketable securities that are classified as level 2 of the fair value hierarchy, useful lives of fixed assets, the periods over which certain revenues will be recognized, including licensing and collaborative revenue recognized from non-refundable up-front and milestone payments, the determination of prepaid research and development, or R&D, clinical costs and accrued research projects, the amount of non-cash compensation costs related to share-based payments to employees and non-employees and the periods over which those costs are expensed and the likelihood of realization of deferred tax assets.

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CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in Note 2 to the Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2015.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-13, *Financial Instruments Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13, which replaces the incurred loss impairment methodology in current GAAP, that delays recognition of a credit loss until it is probable that such loss has been incurred, with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 modifies the other-than-temporary impairment model for available-for-sale debt securities by requiring (1) estimating expected credit losses only when the fair value is below the amortized cost of the asset; (2) recording a credit loss without regard to the length of time a security has been in an unrealized loss position; (3) limiting the measurement of the credit loss to the difference between the security s amortized cost basis and its fair value and (4) presenting credit losses as an allowance rather than as a write-down, which will allow the Company to record reversals of credit losses in current period net income, a practice that is currently prohibited. ASU 2016-13 will be effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently evaluating the effect that adoption of ASU 2016-13 will have on its results of operations, financial position and cash flows.

In May 2016, the FASB issued ASU No. 2016-12*, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, or ASU 2016-12, which amends guidance in the new revenue standard, ASU No. 2014-09 *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, on collectability, noncash consideration, presentation of sales tax and transition. The amendments in ASU 2016-12 are effective for annual reporting periods beginning after December 15, 2017 (i.e., January 1, 2018), including interim periods within those reporting periods, which is the same as for ASU 2014-09, as amended by ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, or ASU 2015-14. The Company is currently evaluating the effect that adoption of ASU 2016-12 will have on its financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606), Identifying Performance Obligations and Licensing*, or ASU 2016-10*,* which clarifies the principle for determining whether a good or service is separately identifiable from other promises in the contract and, therefore, should be accounted for as a separate performance obligation. In that regard, ASU 2016-10 requires that an entity determine whether its promise is to transfer individual goods or services to the customer, or a combined item (or items) to which the individual goods and services are inputs. In addition, ASU 2016-10 categorizes intellectual property, or IP, into two categories: functional and symbolic. Functional IP has significant standalone functionality. All other IP is considered symbolic

IP. Revenue from licenses of functional IP is generally recognized at a point in time, while revenue from licenses of symbolic IP is recognized over time. ASU 2016-10 has the same effective date and transition requirements as ASU 2014-09, as amended by ASU 2015-14. The Company is currently evaluating the effect that adoption of ASU 2016-10 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, or ASU 2016-08, which clarifies the implementation guidance on principal versus agent considerations contained in ASU 2014-09 by specifying that the determination as to whether an entity that is involved in providing a good or a service to a customer is a principal or an agent is based upon whether the entity controls the good or the service before it is transferred to the customer. ASU 2016-08 has the same effective date and transition requirements as ASU 2014-09, as amended by ASU 2015-14. The Company is currently evaluating the effect that adoption of ASU 2016-08 will have on its financial statements.

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CARA THERAPEUTICS, INC.

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In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09, which amends Accounting Standards Codification, or ASC, *Topic 718*, *Compensation Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the accounting for forfeitures, income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. Certain of the amendments will be applied using a modified retrospective transition method by means of a cumulative-effect adjustment to equity as of the beginning of the period in which ASU 2016-09 is adopted, while other amendments will be applied retrospectively, prospectively or using either a prospective or a retrospective transition method. Upon adoption on January 1, 2017, the Company will account for forfeitures as they occur rather than estimate a forfeiture rate and will record a cumulative-effect adjustment in equity on the date of initial adoption. In periods subsequent to adoption, a higher expense will be recognized related to stock-based awards that are not forfeited. The Company expects that the income tax amendments within ASU 2016-09 will have no impact on its results of operations or cash flows because it is in a net operating loss position with a full valuation allowance.

In May 2014, the FASB issued ASU 2014-09, which 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. ASU 2014-09, as amended by ASU 2015-14, is effective for annual reporting periods beginning after December 15, 2017 (i.e., January 1, 2018), including interim periods within those reporting periods. The standard allows for two transition methods: (1) retrospectively to each prior reporting period presented, or (2) using a modified retrospective approach, with the cumulative effect of initially applying ASU 2014-09 recognized as an adjustment to the opening balance of retained earnings at the date of initial adoption. The Company is currently in the process of deciding which method of transition it will use and the effect of adoption of ASU 2014-09 on its results of operations, financial position and cash flows. The Company currently recognizes revenue only from contracts with Maruishi and CKD, under both of which the Company may earn future milestone payments upon the achievement of defined clinical and regulatory events. The Company is continuing to monitor the timing of achievement of such milestones. To the extent that all defined milestones have not been achieved and the related revenue recognized under current GAAP prior to the adoption of ASU 2014-09, those contracts will be included within the scope of ASU 2014-09. However, since the current accounting for those contracts, as multiple element arrangements with milestone revenue recognized using the milestone method, is similar to ASU 2014-09, the Company does not expect a material effect on its financial statements from the adoption of ASU 2014-09.

3. Available-for-Sale Marketable Securities

As of September 30, 2016 and December 31, 2015, the Company s available-for-sale marketable securities consisted of money market mutual funds and debt securities issued by the U.S. government and government-sponsored entities and by investment grade institutions.

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

(unaudited)

The following tables summarize the Company s available-for-sale marketable securities by major type of security as of September 30, 2016 and December 31, 2015:

As of September 30, 2016

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market mutual funds	$ 18,858	$ 19	$	$ 18,877
U.S. Treasury securities	2,501	1		2,502
U.S. government agency obligations	8,886	4		8,890
Corporate bonds	15,054	2	(5)	15,051
Commercial paper	20,675	2	(3)	20,674
Total available-for-sale marketable securities	$ 65,974	$ 28	$ (8)	$ 65,994

As of December 31, 2015

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market mutual funds	$ 42,017	$	$ (31)	$ 41,986
U.S. Treasury securities	2,528			2,528
U.S. government agency obligations	13,492	4		13,496
Corporate bonds	14,194		(6)	14,188
Commercial paper	19,444	1	(3)	19,442
Total available-for-sale marketable securities	$ 91,675	$ 5	$ (40)	$ 91,640

All available-for-sale marketable securities are classified in the Company s Condensed Balance Sheets as Marketable securities.

The Company classifies its marketable debt securities based on their contractual maturity dates. As of September 30, 2016, the Company s marketable debt securities mature at various dates through June 2017. The fair values and

amortized cost of marketable debt securities by contractual maturity were as follows. The table does not include money market funds that are classified as available-for-sale marketable securities.

	As of September 30, 2016		As of December 31, 2015	
Contractual maturity	Fair Value	Amortized Cost	Fair Value	Amortized Cost
Less than one year	$ 47,117	$ 47,116	$ 49,653	$ 49,657

During the nine months ended September 30, 2016, the Company sold shares of money market mutual funds with a total fair value of $23,368 that were classified as available-for-sale marketable securities. The cost of the shares of money market mutual funds that were sold was determined by specific identification. Realized gains from those sales amounted to $12.

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CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

The following tables show the fair value of the Company s available-for-sale marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual investments have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
As of September 30, 2016	**Fair Value**	**Gross Unrealized Losses**	**Fair Value**	**Gross Unrealized Losses**	**Fair Value**	**Gross Unrealized Losses**
Corporate bonds	$ 9,528	$ (5)	$	$	$ 9,528	$ (5)
Commercial paper	9,443	(3)			9,443	(3)
Total	$ 18,970	$ (8)	$	$	$ 18,970	$ (8)

	Less than 12 Months		12 Months or Greater		Total	
As of December 31, 2015	**Fair Value**	**Gross Unrealized Losses**	**Fair Value**	**Gross Unrealized Losses**	**Fair Value**	**Gross Unrealized Losses**
Money market mutual funds	$ 30,985	$ (31)	$	$	$ 30,985	$ (31)
Corporate bonds	14,187	(6)			14,187	(6)
Commercial paper	11,960	(3)			11,960	(3)
Total	$ 57,132	$ (40)	$	$	$ 57,132	$ (40)

As of September 30, 2016 and December 31, 2015, the Company held a total of 20 out of 41 positions and 15 out of 23 positions, respectively, that were in an unrealized loss position, none of which had been in an unrealized loss position for 12 months or greater. Based on the Company s review of these securities, the Company believes that the cost basis of its available-for-sale marketable securities is recoverable and that, therefore, it had no other-than-temporary impairments on these securities as of September 30, 2016 and December 31, 2015. The Company does not intend to sell these debt securities and the Company believes it is not more likely than not that it will be required to sell these securities before the recovery of their amortized cost basis, which may be maturity.

4. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss), or AOCI, net of tax, from unrealized gains (losses) on available-for-sale marketable securities, the Company s only component of AOCI, for the nine months ended September 30, 2016. For the nine months ended September 30, 2015, all of the Company s funds were held in money market savings and checking accounts that were classified as cash equivalents and not as available-for-sale marketable securities.

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CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

	Total Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2015	$ (35)
Other comprehensive income before reclassifications	67
Amount reclassified out of accumulated other comprehensive income	(12)
Net current period other comprehensive income	55
Balance, September 30, 2016	$ 20

The reclassifications out of AOCI and into net loss were as follows:

	Amounts Reclassified out of AOCI		
Component of AOCI	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2016	Affected Line Item in the Condensed Statements of Comprehensive Loss
Unrealized gains (losses) on available-for-sale marketable securities			
Realized gains on sale of securities	$ 12	$ 12	Other income
			Income tax benefit
	$ 12	$ 12	Net of tax

The amount reclassified out of AOCI into net loss was determined by specific identification.

5. Fair Value Measurements

As of September 30, 2016 and December 31, 2015, the Company s financial instruments consist of cash and cash equivalents, available-for-sale marketable securities, restricted cash, accounts payable and accrued liabilities. The fair values of cash and cash equivalents, restricted cash, accounts payable and accrued liabilities approximate their

carrying values due to the short-term nature of these financial instruments. Marketable securities are reported on the Company s Condensed Balance Sheets at their fair values, based upon pricing of securities with the same or similar investment characteristics as provided by third-party pricing services, as described below.

Current accounting guidance defines fair value, establishes a framework for measuring fair value in accordance with 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 the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

The Company classifies its investments in a fair value hierarchy that is intended to increase consistency and comparability in fair value measurements and related disclosures. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

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.

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CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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.

Valuation Techniques - Level 2 Inputs

The Company estimates the fair values of its financial instruments categorized as level 2 in the fair value hierarchy, including U.S. Treasury securities, U.S. government agency obligations, corporate bonds, commercial paper and money market funds with similar underlying investments, by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, benchmark yields, issuer credit spreads, benchmark securities, and other observable inputs. The Company obtains a single price for each financial instrument and does not adjust the prices obtained from the pricing service.

The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods, obtaining market values from other pricing sources and comparing them to the share prices presented by the third-party pricing services. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its third-party pricing services as of September 30, 2016 or December 31, 2015.

The following tables summarize the Company s financial assets measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015.

Fair value measurement as of September 30, 2016

Financial assets	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Type of Instrument				
Cash and cash equivalents:				
Money market mutual funds, savings account and checking accounts	$ 5,426	$ 5,426	$	$
Available-for-sale marketable securities:				
Money market mutual funds	18,877		18,877	

U.S. Treasury securities	2,502		2,502	
U.S. government agency obligations	8,890		8,890	
Corporate bonds	15,051		15,051	
Commercial paper	20,674		20,674	
Restricted cash:				
Commercial money market account	1,469	1,469		
Total financial assets	$ 72,889	$ 6,895	$ 65,994	$

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Fair value measurement as of December 31, 2015:

Financial assets	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Type of Instrument				
Cash and cash equivalents:				
Money market mutual funds, savings account and checking accounts	$ 15,101	$ 15,101	$	$
Available-for-sale marketable securities:				
Money market mutual funds	41,986		41,986	
U.S. Treasury securities	2,528		2,528	
U.S. government agency obligations	13,496		13,496	
Corporate bonds	14,188		14,188	
Commercial paper	19,442		19,442	
Restricted cash:				
Bank Certificate of Deposit	700	700		
Total financial assets	$ 107,441	$ 15,801	$ 91,640	$

There were no purchases, sales or maturities of Level 3 financial assets and no unrealized gains or losses related to Level 3 available-for-sale marketable securities for the nine months ended September 30, 2016. There were no transfers of financial assets between Levels 1, 2, or 3 classifications during the nine months ended September 30, 2016.

6. Restricted Cash

The Company is required to maintain stand-by letters of credit as security deposits under each of its leases, one for its operating facility in Shelton, Connecticut and the other for its office space in Stamford, Connecticut (refer to Note 14, *Commitments and Contingencies*). The fair value of each letter of credit approximates its contract value. In each case, the Company s bank requires the Company to maintain restricted cash balances to serve as collateral for the letter of

credit issued to the respective landlords by the bank. As of September 30, 2016, the restricted cash balances for the Shelton lease and the Stamford lease were both invested in a commercial money market account.

The restricted cash balance for the Shelton lease remains at $700 through the end of the lease term in October 2017. For the Stamford lease, the letter of credit balance remains at $769 for the first three years following commencement of the Stamford lease and may, upon request from the Company, thereafter be reduced to $408 through the end of the lease term in 2023. The reduction in the balance of the letter of credit for the Stamford lease is contingent upon the Company not being in default of any provisions of that lease prior to request for the reduction. As of September 30, 2016 and December 31, 2015, the Company had $1,469 and $700 of restricted cash, respectively, in long-term assets.

7. Prepaid expenses

As of September 30, 2016, prepaid expenses were $4,820, consisting of $4,363 of prepaid R&D clinical costs, $327 of prepaid insurance and $130 of other prepaid costs. As of December 31, 2015, prepaid expenses were $1,729 consisting of $1,500 of prepaid R&D clinical costs, $98 of prepaid insurance, $96 of prepaid rent, and $35 of other prepaid costs.

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8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2016	December 31, 2015
Accounts payable	$ 2,387	$ 1,965
Accrued research projects	1,817	1,542
Accrued Shelton lease liability	998	
Accrued professional fees	373	371
Accrued compensation and benefits	1,177	1,204
Accrued other	73	186
Total	$ 6,825	$ 5,268

9. Stockholders Equity

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

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

10. Collaborations

Chong Kun Dang Pharmaceutical Corporation

In April, 2012, the Company entered into a license agreement with CKD (the CKD Agreement) that provides CKD with the exclusive rights to develop, manufacture and commercialize products containing CR845 in South Korea.

Under the CKD Agreement, the Company is eligible to receive milestone payments totaling $3,750, relating to pre-defined clinical development ($2,250) and regulatory events ($1,500), as well as royalties on sales of any marketed products containing CR845.

During the three months ended September 30, 2015, the Company met the milestone criteria, as set forth in the CKD Agreement, for the completion of both a Phase 1b trial of Oral CR845 in the United States and a Phase 2 trial of CR845 in uremic pruritus patients in the United States. Both milestones were considered to be substantive and, therefore, the full amount of each of the milestone payments earned, $626 (net of South Korean withholding tax of $124), was recognized as milestone revenue upon achievement of each milestone, of which $417 (net of South Korean withholding tax of $83) was due to the Company as of September 30, 2015.

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Maruishi Pharmaceutical Co., Ltd.

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

At inception of the Maruishi Agreement, the Company identified two deliverables under ASC 605-25, *Revenue Recognition Multiple Element Arrangements*: (1) the license; and (2) the R&D services specific to the uremic pruritus field of use, both of which were determined to have standalone value and have been accounted for as separate units of accounting from the outset of the arrangement. Upon entering into the Maruishi Agreement, the Company received an upfront, non-refundable, non-creditable license fee of $15,000, a portion of which was assigned to each of the two identified deliverables based on their estimated selling prices. The amount assigned to the R&D services unit of accounting was initially recorded as deferred revenue, which was recognized as collaborative revenue as the services were provided through July 2015. Amortization of deferred revenue pursuant to the R&D services deliverable to collaborative revenue was $89 for the three months ended September 30, 2015 and $1,452 for the nine months ended September 30, 2015.

Under the terms of the Maruishi Agreement, the Company is also entitled to receive aggregate milestone payments of $8,000 for events performed by Maruishi in Japan and $2,500 for events performed by the Company in the United States. In September 2015, Maruishi initiated a Phase 2 clinical trial of CR845 in Japan for uremic pruritus, which triggered a $1,725 milestone payment (net of contractual foreign currency exchange adjustments of $275) to the Company. As of September 30, 2015, such payment was due to the Company. At the time of achievement of the milestone, the Company had delivered all deliverables under the Maruishi Agreement. Since the milestone was achieved in Japan, it was deemed not to be substantive. Accordingly, the Company recognized $1,084 as milestone revenue and $641 as collaborative revenue during both the three months and nine months ended September 30, 2015 in connection with achievement of this milestone.

The Company incurred R&D expense related to the Maruishi Agreement of $108 and $1,583 (both consisting of clinical trial costs related to the R&D services deliverable) during the three and nine months ended September 30, 2015, respectively.

11. Net Loss Per Share

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted average number of shares of common stock outstanding. Diluted net income per share includes the potential dilutive effect of common stock equivalents as if such securities were exercised during the period, when the effect is dilutive. Common stock equivalents may include outstanding stock options, which are included using the treasury stock method when dilutive. For the three and nine months ended September 30, 2016 and 2015, the Company excluded the effects of potentially dilutive shares that were outstanding during those respective periods from the denominator as their inclusion would be anti-dilutive due to the Company s net losses during those periods.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Basic:				
Weighted average common shares outstanding	27,282,863	25,545,164	27,275,133	23,737,443
Diluted:				
Weighted average common shares outstanding - Basic	27,282,863	25,545,164	27,275,133	23,737,443
Common stock options*				
Denominator for diluted net loss per share	27,282,863	25,545,164	27,275,133	23,737,443

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (11,542)	$ (4,787)	$ (35,308)	$ (15,160)
Weighted-average common shares outstanding:				
Basic and Diluted	27,282,863	25,545,164	27,275,133	23,737,443
Net loss per share, Basic and Diluted	$ (0.42)	$ (0.19)	$ (1.29)	$ (0.64)

As of September 30, 2016 and 2015, 2,299,117 and 1,541,772 stock options, respectively, were outstanding, which could potentially dilute basic earnings per share in the future, but were not included in the computation of diluted net

loss per share because to do so would have been anti-dilutive.

12. Stock-Based Compensation

2014 Equity Incentive Plan

The Company s 2014 Equity Incentive Plan, or the 2014 Plan, is administered by the Company s Board of Directors or a duly authorized committee thereof, referred to as the Plan administrator. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation, collectively referred to as Stock Awards. Additionally, the 2014 Plan provides for the grant of performance cash awards. Incentive stock options may be granted only to employees. All other awards may be granted to employees, including officers, non-employee directors, and consultants. No incentive stock options may be granted under the 2014 Plan after the tenth anniversary of the effective date of the 2014 Plan. Stock Awards granted under the 2014 Plan vest at the rate specified by the Plan administrator, which, for employees and non-employee consultants, has generally been 25% on the first anniversary of the date of grant and the balance ratably over the next 36 months. As of January 1, 2016, subsequent grants of Stock Awards made to employees and non-employee consultants vest monthly over a period of four years from the grant date. Stock options initially granted to members of the Company s Board of Directors vest on the date of the Annual Meeting of Stockholders at which their initial term expires based on the class of Director. Subsequent grants to Directors that are made automatically at Annual Meetings of Stockholders vest fully on the first anniversary of the date of grant. The Plan administrator determines the term of Stock Awards granted under the 2014 Plan up to a maximum of ten years.

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The aggregate 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. On January 1, 2016, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2014 Plan automatically increased from 2,284,061 to 3,101,707. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2014 Plan is 30,000,000 shares.

Under the 2014 Plan, the Company granted 75,000 and 797,000 stock options during the three and nine months ended September 30, 2016, respectively, and 25,000 and 629,000 stock options during the three and nine months ended September 30, 2015, respectively. The fair values of stock options granted during the three and nine months ended September 30, 2016 and 2015 were estimated as of the dates of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Risk-free interest rate	1.19%	1.77%	1.19% - 1.79%	1.43% - 1.89%
Expected volatility	71.9%	64.1%	67.8% - 72.6%	64.0% - 67.1%
Expected dividend yield	0%	0%	0%	0%
Expected life of employee options (in years)	6.25	6.25	6.25	6.25
Expected life of nonemployee options (in years)			10	10

The weighted average grant date fair value of options granted to employees and members of the Company s Board of Directors for their service during the three and nine months ended September 30, 2016 was $3.92 and $3.81, respectively, and during the three and nine months ended September 30, 2015 was $13.30 and $6.60, respectively.

The weighted average fair value of outstanding options that had been granted to nonemployee consultants, as re-measured during the vesting period of each tranche in accordance with ASC 505-50, was $5.75 and $4.16 during the three and nine months ended September 30, 2016, respectively, and $10.87 and $9.03 during the three and nine months ended September 30, 2015, respectively.

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During the three and nine months ended September 30, 2016 and 2015, the Company recognized compensation expense relating to stock options, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 375	$ 283	$ 867	$ 761
General and administrative	402	378	1,104	1,046
Total stock option expense	$ 777	$ 661	$ 1,971	$ 1,807

A summary of stock option award activity related to employees, non-employee members of the Company s Board of Directors and non-employee consultants as of and for the nine months ended September 30, 2016 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,658,408	$ 10.27
Granted	797,000	5.99
Exercised	(28,000)	1.41
Forfeited	(95,792)	12.15
Expired	(32,499)	11.03
Outstanding, September 30, 2016	2,299,117	8.80
Options exercisable, September 30, 2016	887,213	$ 8.98

The Company does not expect to realize any tax benefits from its stock option activity or the recognition of stock-based compensation expense because the Company currently has net operating losses and has a full valuation allowance against its deferred tax assets. Accordingly, no amounts related to excess tax benefits have been reported in cash flows from operations or cash flows from financing activities for the nine months ended September 30, 2016 and 2015.

13. Income Taxes

For the three months ended September 30, 2016 and 2015, pre-tax losses were $11,597 and $4,987, respectively, and for the nine months ended September 30, 2016 and 2015, pre-tax losses were $35,587 and $15,410, respectively. The Company recognized a full tax valuation allowance against its deferred tax assets as of September 30, 2016 and December 31, 2015.

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The benefit from income taxes of $55 and $200 for the three months ended September 30, 2016 and 2015, respectively, and $279 and $250 for the nine months ended September 30, 2016 and 2015, respectively, relates to state R&D tax credits exchanged for cash pursuant to the Connecticut R&D Tax Credit Exchange Program, which permits qualified small businesses engaged in R&D activities within Connecticut to exchange their unused R&D tax credits for a cash amount equal to 65% of the value of the exchanged credits.

14. Commitments and Contingencies

Contractual obligations and commitments as of September 30, 2016 were as follows:

	Payment Due for the Year Ending December 31,						
	2016	2017	2018	2019	2020	Thereafter	Total
Stamford operating lease	$ 192	$ 875	$ 1,093	$ 1,217	$ 1,241	$ 3,650	$ 8,268
Shelton operating lease	232	740					972
	$ 425	$ 1,615	$ 1,093	$ 1,217	$ 1,241	$ 3,650	$ 9,241

In May 2016, the Company moved its headquarters to Stamford, Connecticut, where it leases office space under an operating lease with a term through October 2023 (See Note 21 of Notes to Financial Statements, *Commitments and Contingencies*, in the Company s Annual Report on Form 10-K for the year ended December 31, 2015). As of September 30, 2016, the Stamford landlord had made tenant improvements of approximately $1,094 to the leased premises. Such amount is included in Property and equipment, net and in Deferred lease obligation on the Company s Condensed Balance Sheet. The portion of Deferred lease obligation that is related to tenant improvements is being amortized as a reduction to rent expense over the same term as rent expense. During the three and nine months ended September 30, 2016, the Company amortized $36 and $71, respectively, of Deferred lease obligation related to tenant improvements.

As of September 30, 2016, the Company continues to lease its former operating facility located in Shelton, Connecticut, which has a term through October 2017 (See Note 21 of Notes to Financial Statements, *Commitments and Contingencies*, in the Company s Annual Report on Form 10-K for the year ended December 31, 2015). The Company accelerated the amortization of the Shelton leasehold improvements through May 2016, the date the Company moved from the Shelton facility, or cease-use date, at which time the net book value of those leasehold improvements was zero. Acceleration of amortization of the Shelton leasehold improvements resulted in $899 of additional amortization expense (additional net loss per share of $0.03) for the nine months ended September 30,

2016.

In addition, in accordance with the accounting guidance in ASC 420-10-25-13 regarding exit or disposal cost obligations, as of May 2016, the Company recorded rent expense, within Research and development expense and General and administrative expense, and accrued a liability of $1,312, which represents the fair value of costs that will continue to be incurred during the remaining term of the Shelton operating lease without economic benefit to the Company. As of September 30, 2016, the carrying amount of the liability of $998, which includes the $972 of minimum rental payments in the table above, together with common area maintenance charges, was included in Accounts payable and accrued expenses on the Company s Condensed Balance Sheet. At the cease-use date, the Company also wrote off the balance of Deferred lease obligation of $429 related to the Shelton lease.

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A reconciliation of the balances of the accrued Shelton lease cease-use liability for the nine months ended September 30, 2016 is as follows:

Balance, January 1, 2016	$
Additional accruals	1,312
Rental payments	(314)
Balance, September 30, 2016	$ 998

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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, inter might, objective, ongoing, plan, predict, project, potential, should, will, or would, and or the nega or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

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

- the success and timing of our clinical trials, including our clinical trial programs for I.V. CR845 in acute pain and uremic pruritus and Oral CR845 in acute and chronic pain, and the reporting of clinical trial results;
- our plans to develop and commercialize I.V. CR845 and our other product candidates, including Oral CR845;
- the potential results of ongoing and planned preclinical studies and clinical trials and future regulatory and development milestones for our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, including I.V. 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 Pharmaceuticals Co. Ltd, or Maruishi, and Chong Kun Dang Pharmaceutical Corp., or CKD, and our ability to maintain such collaborations;
- our ability to establish additional collaborations for our product candidates;

the continued service of our key scientific or management personnel;

our ability to establish commercialization and marketing capabilities;

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

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

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

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

our ability to obtain funding for our operations;

our ability to 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; 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, 2015 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.

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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, 2015.

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 peripheral kappa opioid receptors. We are developing a novel and proprietary class of product candidates that target the body s peripheral nervous system.

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.

I.V. CR845 for Treatment of Acute Postoperative Pain

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

In April 2015, we completed an End-of-Phase 2 meeting with the FDA to discuss the design of our pivotal trials for our I.V. CR845 product candidate in acute pain. In September 2015, we initiated our Phase 3 clinical trial program for I.V. CR845 in postoperative pain with the dosing of the first subjects in an adaptive pivotal trial in patients undergoing a range of abdominal surgeries. This trial is a multi-center, randomized, double-blind, placebo-controlled, parallel-group adaptive design trial with repeated doses of I.V. CR845 or placebo administered both prior to and following abdominal surgery in male and female patients. The trial protocol initially included three dose levels of I.V. CR845 (1.0 ug/kg, 2.0 ug/kg and 5.0 ug/kg), which were compared to placebo with an interim conditional power assessment to identify optimal doses to be used to complete the enrollment of this trial.

In February 2016, the FDA advised us that our adaptive pivotal trial of I.V. CR845 for postoperative pain had been placed on IND clinical hold pending a safety review. The clinical hold was based on a pre-specified stopping rule related to elevated serum sodium levels of greater than 150 mmol/L that was included in the clinical trial protocol. A subsequent review of unblinded safety data from the first 90 patients dosed was completed by us, the trial s Independent Data Monitoring Committee and the FDA.

In April 2016, we received notice from the FDA that it had removed the clinical hold on our adaptive Phase 3 trial of I.V. CR845 for postoperative pain. Based on the safety review and our analysis of interim efficacy signals for pain, supplemental opioid use and opioid-related side effects that we observed in the unblinded data from the adaptive pivotal trial of I.V. CR845, we modified the trial protocol and, in June 2016, resumed the trial as a three-arm trial, testing two doses of CR845 (1.0 ug/kg and 0.5 ug/kg) versus placebo. The revised trial is enrolling up to 450 patients undergoing either hysterectomy, prostatectomy, hemi-colectomy or ventral hernia, all of which are associated with moderate-to-severe postoperative visceral pain, at approximately 30 clinical sites within the United States. The primary efficacy measure is the Change in Pain Intensity over the 24-hour postoperative period, or AUC, using the patient-reported Numeric Rating Scale, or NRS, score collected at pre-specified time points through 24 hours. Postoperative nausea and vomiting is also being evaluated as a secondary efficacy measure. The impact of I.V. CR845 treatment on inflammatory biomarkers is also being explored. An interim conditional power analysis of our adaptive Phase 3 trial of I.V. CR845 for postoperative pain is expected in the first half of 2017.

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

Oral CR845 for Treatment of Osteoarthritis

We are also developing an oral version of CR845, or Oral CR845, for acute and chronic pain. In August 2015, we advanced our tablet formulation of Oral CR845 into a Phase 2a clinical trial in patients with osteoarthritis, or OA, of the knee or hip. The Phase 2a trial was a single-blind, randomized, multiple ascending dose trial designed to evaluate the safety, pharmacokinetics, or PK, and effectiveness of oral CR845 tablets dosed over a two-week treatment period in OA patients experiencing moderate-to-severe pain, defined as >4 on an 11-point NRS at baseline. Patients discontinued current pain medications five days prior to baseline measurements. Four tablet strengths (0.25 mg, 0.5 mg, 1.0 mg and 5.0 mg) were administered twice a day over a two-week treatment period in a total of 80 OA patients enrolled at five sites in the United States. In addition to safety and PK observations, Oral CR845 s effectiveness was assessed by: change from baseline in joint pain using the NRS, which was measured daily, change from baseline in the Western Ontario and McMaster Osteoarthritis Index, or WOMAC, which was measured at the end of Weeks 1 and 2 of treatment, change from baseline in rescue medication use, measured daily, and Patient Global Assessment, which was measured on the last day of the trial. Acetaminophen was the only allowable rescue medication. PK analyses indicated dose-proportional exposure of CR845 after oral administration, with the 5.0 mg dose group exhibiting an approximately five-fold increased mean AUC value compared to the 1.0 mg dose group.

In December 2015, we announced positive top-line results from this Phase 2a trial. The results showed a dose-related reduction in mean baseline pain score up to 34% after two weeks, with statistically significant reduction in mean rescue medication for the top 5.0 mg dose group of approximately 80 percent (ANOVA: p= 0.02, for 5.0 mg vs lower dose groups). Fifty percent of the patients in the 5.0 mg dose group reported at least a 30% reduction in their pain score at the end of the treatment period. Fifty-nine percent of patients in the 5.0 mg dose group used no rescue medication in week two of the trial. The effectiveness of the 5.0 mg dose was further supported by statistically significant, dose-related increases in the proportion of patients whose OA was very much improved or much improved as indicated by patient global assessment (Cochran-Mantel-Haenszel test, p=0.02, 2-sided). In this trial, all four tablet strengths were observed to be safe and well tolerated.

The Phase 2a trial established therapeutic doses and a dosing regimen for a larger randomized, double-blind, placebo-controlled Phase 2b trial, which we initiated during the third quarter of 2016. The Phase 2b trial is a trial of three tablet strengths of CR845, 1.0 mg, 2.5 mg and 5.0 mg, dosed twice-daily over an eight-week treatment period in approximately 330 osteoarthritis patients experiencing moderate-to-severe pain at up to 35 sites across the United States. The primary efficacy endpoint is the change from baseline at week eight, with respect to the weekly mean of the daily pain intensity score using an NRS. Secondary endpoints include change from baseline in the WOMAC, the Patient Global Impression of Change, or PGIC, and amount of rescue medication used. We expect to report top-line data in the first half of 2017.

I.V. CR845 for Treatment of Uremic (Chronic Kidney Disease-Associated) Pruritus

CR845 has exhibited anti-pruritic, or anti-itch, potency in standard preclinical models. In July 2015, we reported positive top-line efficacy results from a Phase 2 proof-of-concept trial of I.V. CR845 for the treatment of uremic pruritus, a systemic condition with high prevalence in dialysis patients, for which there are no approved therapeutics in the United States. We observed that I.V. CR845 demonstrated statistically significant results on the primary endpoint of reducing worst itch intensity as well as the secondary endpoint of quality of life improvements**.** We also

observed I.V. CR845 to have a favorable safety and tolerability profile in the trial.

Based on the results of this trial, during the fourth quarter of 2015 we completed a guidance meeting with the FDA. We have incorporated the feedback we received from the FDA in this guidance meeting in the overall design of our Phase 3 clinical trial program for I.V. CR845 for the treatment of uremic pruritus.

In June 2016, we initiated a two-part Phase 2/3 adaptive design trial of I.V. CR845 in dialysis patients suffering from moderate-to-severe uremic pruritus, an intractable systemic itch condition in patients with chronic kidney disease. Part A of the trial, is a randomized, double-blind, placebo-controlled trial in 160 patients of three doses of I.V. CR845 (0.5ug/kg, 1.0 ug/kg and 1.5 ug/kg) administered three times per week after dialysis over an 8-week period. Part B will be a randomized double-blind placebo-controlled trial in up to 240 patients of one optimized dose of I.V. CR845 administered three times per week after dialysis over a 12-week treatment period. The primary endpoint will be reduction in worst itching scores from baseline values measured on a standard NRS alongside secondary quantitative quality of life endpoints. We expect to report top-line data from Part A of this trial in the first quarter of 2017.

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We have also initiated a pharmacokinetic safety trial of multiple doses of Oral CR845 in hemodialysis patients to define bioequivalent tablet strengths to inform our ability to develop an oral tablet formulation for moderate-to-severe uremic pruritus. We expect to report top-line data from this trial in the first quarter of 2017.

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. To date, we have earned a total of $3.5 million in clinical development or regulatory milestone payments, net of contractual foreign currency adjustments and South Korean withholding taxes, but have not received any royalties, under these collaborations.

Research and Development (R&D)

To date, our R&D expenses have related primarily to the development of CR845. R&D expenses consist of expenses incurred in performing R&D activities, including compensation and benefits for full-time R&D 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 R&D employees and non-employee consultants and other outside expenses. Our R&D 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.

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

R&D 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. Based on our current development plans, we presently expect that our R&D expenses will continue near their current level through 2018. 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.

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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 R&D expenses, legal fees, insurance costs, patent costs and fees for accounting and consulting services.

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

Other Income

Other income consists of interest and dividend income earned on our cash, cash equivalents, marketable securities and restricted cash and realized gains and losses on the sale of marketable securities.

Benefit from Income Taxes

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

Results of Operations

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

Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% change	2016	2015	% change
	Amounts in thousands			Amounts in thousands		
License and milestone fees revenue	$	$ 1,710	-100%	$	$ 1,710	-100%
Collaborative revenue		730	-100%		2,093	-100%
Clinical compound revenue			100%	86		100%
Total revenue	$	$ 2,440	-100%	$ 86	$ 3,803	-98%

License and milestone fees revenue

License and milestone fees revenue for the three and nine months ended September 30, 2015 of $1.7 million consists of (a) $1.1 million related to the portion of the $1.7 million milestone payment earned in September 2015 under our license agreement with Maruishi, which was deemed not to be a substantive milestone and which was attributable to the previously delivered license and (b) $626 thousand from the two milestone payments earned by us under our license agreement with CKD in July and September 2015 (see Note 10 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q).

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Collaborative revenue

Collaborative revenue for the three months ended September 30, 2015 of $730 thousand consists of (a) $641 thousand related to the portion of the $1.7 million milestone payment earned in September 2015 under our license agreement with Maruishi, which was deemed not to be a substantive milestone and which was attributable to the fully-delivered R&D services deliverable, and (b) $89 thousand of revenue that had been deferred upon entry into the license agreement with Maruishi (see Note 10 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q).

Collaborative revenue for the nine months ended September 30, 2015 of $2.1 million consists of (a) $641 thousand related to the portion of the $1.7 million milestone payment earned in September 2015 under our license agreement with Maruishi, which was deemed not to be a substantive milestone and which was attributable to the fully-delivered R&D services deliverable, and (b) $1.5 million of revenue that had been deferred upon entry into the license agreement with Maruishi.

Clinical compound revenue

Clinical compound revenue for the nine months ended September 30, 2016 of $86 thousand resulted from the sale of clinical compound to Maruishi.

Research and Development Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% change	2016	2015	% change
	Amounts in thousands			Amounts in thousands		
Direct clinical trial costs	$ 6,974	$ 3,554	96%	$ 19,970	$ 8,362	139%
Consultant services in support of clinical trials	423	270	57%	1,557	625	149%
Stock-based compensation	375	283	33%	867	761	14%
Depreciation and amortization	76	104	-27%	739	311	137%
Other R&D operating expenses	1,823	1,373	33%	5,843	3,594	63%
Total R&D expense	$ 9,671	$ 5,584	73%	$ 28,976	$ 13,653	112%

For the three months ended September 30, 2016 compared to the three months ended September 30, 2015, the net increase in direct clinical trial costs and related consultant costs primarily resulted from increases totaling $3.6 million, primarily for the Phase 2b clinical trial of Oral CR845 in osteoarthritis patients and the Phase 2/3 I.V. CR845 clinical trial in patients with uremic pruritus, coupled with a net increase of $0.8 million of CR845 drug manufacturing costs and a net increase of $0.9 million for toxicology studies. Those costs were partially offset by decreases totaling $1.7 million in clinical trial costs primarily in connection with the Phase 2a I.V. CR845 proof-of-concept trial in patients with uremic pruritus, which was completed in the third quarter of 2015, and the Phase 2a Oral CR845 clinical trial in patients with OA, which was completed in the fourth quarter of 2015. The increase in stock-based compensation expense relates primarily to increased employee headcount. The decrease in depreciation and amortization expense reflects a lower balance of property and equipment in connection with the relocation of our headquarters from Shelton, Connecticut to Stamford, Connecticut. The increase in other R&D

operating expenses was primarily the result of an increase in payroll and related costs associated with R&D personnel, partially offset by a decrease in costs associated with non-clinical R&D consultants.

For the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, the net increase in direct clinical trial costs and related consultant costs primarily resulted from increases totaling $7.5 million for the Phase 3 I.V. CR845 adaptive pivotal clinical trial, the Phase 2/3 I.V. CR845 clinical trial in patients with uremic pruritus and the Phase 2b clinical trial of Oral CR845 in osteoarthritis patients, coupled with a net increase of $4.9 million of CR845 drug manufacturing costs and a net increase of $3.8 million for toxicology studies. Those costs were partially offset by decreases totaling $3.7 million in clinical trial costs primarily in connection with the Phase 2a I.V. CR845 proof-of-concept trial in patients with uremic pruritus, which was completed in the third quarter of 2015, and the Phase 2a Oral CR845 clinical trial in patients with OA, which was completed in the

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fourth quarter of 2015. The increase in stock-based compensation expense relates primarily to increased employee headcount, partially offset by a decrease in expense related to stock option awards granted to non-employee consultants, which are marked to market each quarter, due to the decrease in the market price of our common stock. The increase in depreciation and amortization expense reflects the acceleration of amortization of the leasehold improvements at our Shelton, Connecticut facility related to research and development activities prior to the relocation of our corporate headquarters (See Note 14 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q). The increase in other R&D operating expenses was primarily the result of an increase in payroll and related costs associated with R&D personnel and rent, which includes recognition of all of the remaining rent expense allocable to research and development activities due during the remaining term of the Shelton operating lease (See Note 14 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q).

The following table summarizes our R&D expenses by product candidate for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	Amounts in thousands		Amounts in thousands	
External research and development expenses:				
I.V. CR845	$ 3,519	$ 1,970	$ 12,246	$ 6,292
Oral CR845	3,878	1,854	9,281	2,695
Internal research and development expenses	2,274	1,760	7,449	4,666
Total research and development expenses	$ 9,671	$ 5,584	$ 28,976	$ 13,653

General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% change	2016	2015	% change
	Amounts in thousands			Amounts in thousands		
Professional fees and public/investor relations	$ 509	$ 486	5%	$ 1,584	$ 1,455	9%
Stock-based compensation	402	378	6%	1,104	1,046	5%
Depreciation and amortization	21	89	-77%	607	268	126%
Other G&A operating expenses	1,170	912	28%	3,900	2,840	37%
Total G&A expense	$ 2,102	$ 1,865	13%	$ 7,195	$ 5,609	28%

For the three months ended September 30, 2016 compared to the three months ended September 30, 2015, the decrease in depreciation and amortization expense reflects a lower balance of property and equipment in connection with the relocation of our headquarters from Shelton, Connecticut to Stamford, Connecticut. The increase in other G&A operating expenses included increases in payroll and related costs and in franchise taxes.

For the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, the increase in professional fees and public/investor relations costs primarily included increases in public/investor relations costs and in accounting and auditing fees. The increase in depreciation and amortization expense reflects the acceleration of amortization of our leasehold improvements at our Shelton, Connecticut facility related to general and administrative activities prior to the relocation of our corporate headquarters (See Note 14 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q). The increase in other G&A operating expenses included increases in payroll and related costs and in franchise taxes and rent, which includes recognition of all of the remaining rent expense allocable to general and administrative activities due during the remaining term of the Shelton operating lease (See Note 14 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q).

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Other Income

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	% change	2016	2015	% change
	Amounts in thousands			Amounts in thousands		
Other Income	$ 176	$ 22	700%	$ 498	$ 49	916%

During the three months ended September 30, 2016 compared to the three months ended September 30, 2015, and during the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, the respective increases in other income were primarily due to an increase in interest income and dividends earned on our portfolio of investments, which included marketable securities during the 2016 periods but not during the 2015 periods. The increase in the amount of other income also reflects higher interest rates in the 2016 periods and a higher average balance of cash and cash equivalents and marketable securities in the nine month 2016 period as a result of our follow-on offering of common stock, which closed in August 2015. For the three and nine months ended September 30, 2016, the increase in other income also included $12 thousand of realized gains on sales of marketable securities.

Benefit from Income Taxes

For the three months ended September 30, 2016 and 2015, pre-tax losses were $11.6 million and $5.0 million, respectively, and we recognized a benefit from income taxes of $55 thousand and $200 thousand, respectively.

For the nine months ended September 30, 2016 and 2015, pre-tax losses were $35.6 million and $15.4 million, respectively, and we recognized a benefit from income taxes of $279 thousand and $250 thousand, respectively.

The benefit from income taxes relates to state R&D tax credits exchanged for cash pursuant to the Connecticut R&D Tax Credit Exchange Program, as discussed above. We recognized a full valuation allowance against deferred tax assets at September 30, 2016 and December 31, 2015.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception and through September 30, 2016, we have raised an aggregate of approximately $237.5 million to fund our operations, including (1) proceeds of $75.2 million, net of underwriting discounts and commissions and offering expenses paid by us, from our follow-on offering of our common stock, which closed in August 2015; (2) proceeds of $56.3 million, net of underwriting discounts and commissions and offering expenses paid by us, from our initial public offering, or IPO, which closed in February 2014; (3) $32.5 million under our license agreements, primarily with Maruishi and CKD, and an earlier product candidate for which development efforts ceased in 2007; (4) $65.9 million of proceeds from the sale of shares of our convertible preferred stock prior to our IPO and (5) $7.4 million of net proceeds from debt financings. As of September 30, 2016, we had $71.4 million in unrestricted cash and cash equivalents and available-for-sale marketable securities, which we believe will be sufficient to fund our planned operating expenses and capital expenditure requirements through the end of the first quarter of 2018, without giving effect to any potential milestone payments we may receive under our collaboration agreements with Maruishi and CKD.

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

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In addition, under the Maruishi License Agreement, or Maruishi Agreement, 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, before any foreign exchange adjustment, 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 2014 and 2015, we earned a total of $2.2 million, net of contractual foreign currency exchange adjustments of $0.3 million, related to two milestones involving clinical trials in Japan of CR845 in acute post-operative pain and for the treatment of uremic pruritus.

The next potential milestone payment that we could be entitled to receive under the Maruishi Agreement will be for a clinical development milestone for completion by us in the United States of the first Phase 3 pivotal trial of CR845 in acute pain. If achieved, this milestone will result in a payment of $1.0 million, before any foreign exchange adjustment, being due to us.

Under the CKD License Agreement, or CKD Agreement, we are potentially eligible to earn up to an aggregate of $2.25 million in clinical development milestones and $1.5 million in regulatory milestones, before South Korean withholding tax, 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. During 2012 and 2015, we earned a total of $1.25 million, net of South Korean withholding tax of $0.25 million, related to three milestones involving clinical trials in the United States of CR845 in acute post-operative pain and for the treatment of uremic pruritus.

The next potential milestone payment that we could be entitled to receive under the CKD Agreement will be for a clinical development milestone for completion of a Phase 3 trial of CR845 in the United States for the treatment of uremic pruritus. If achieved, this milestone will result in a payment $750 thousand, before South Korean withholding tax, being due to us.

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

Funding Requirements

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

Since inception, we have incurred significant operating and net losses. Our net losses were $35.3 million and $15.2 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $140.2 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 R&D activities.

We anticipate that our expenses may increase as we:

continue our I.V. CR845 pivotal clinical trial program in acute pain;

continue the development of our I.V. CR845 uremic pruritus product candidate;

continue the R&D 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.

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

- successful enrollment in, and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- achieving meaningful penetration in the markets which we seek to serve; and
- obtaining adequate coverage or reimbursement by third parties, such as commercial payers and government healthcare programs, including Medicare and Medicaid.

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

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

We will require additional capital beyond our current balances of cash and cash equivalents and available-for-sale marketable securities and anticipated amounts as described above, and this additional capital may not be available when needed, on reasonable terms, or at all. In particular, because we do not have sufficient financial resources to meet all of our development objectives, especially the completion of our planned development of Oral CR845 and I.V. CR845 in uremic pruritus, we will need to raise additional capital. If we are not able to do so, we could be required to postpone, scale back or eliminate some, or all, of these objectives. To the extent that we raise additional capital through the future sale of equity or convertible debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing

common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Outlook

Based on timing expectations and projected costs for our current clinical development plans, which include:

(1) completing required trials for I.V. CR845 in postoperative pain to enable an NDA submission;

(2) completing a Phase 2b trial of Oral CR845 in chronic pain; and

(3) advancing our CR845 uremic pruritus program through a Phase 2/3 adaptive pivotal trial

we expect that our existing cash and cash equivalents and available-for-sale marketable securities as of September 30, 2016 will be sufficient for us to fund our operating expenses and capital expenditure requirements through the end of the first quarter of 2018, without giving effect to any potential milestone payments we may receive under our collaboration agreements with Maruishi and CKD. Because the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain, it is possible that the assumptions upon which we have based this estimate may prove to be wrong, and we could use our capital resources sooner than we presently expect.

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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, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	Amounts in thousands	
Net cash used in operating activities	$ (34,193)	$ (17,310)
Net cash provided by (used in) investing activities	24,478	(13)
Net cash provided by financing activities	40	75,776
Net (decrease) increase in cash and cash equivalents	$ (9,675)	$ 58,453

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2016 consisted primarily of a net loss of $35.3 million and a $1.8 million cash outflow from net changes in operating assets and liabilities, partially offset by a $2.9 million cash inflow from net non-cash charges. The net change in operating assets and liabilities primarily consisted of a cash outflow of $3.1 million from an increase in prepaid expense, primarily related to increases in prepaid clinical costs and prepaid insurance and a cash outflow of $0.3 million due to an increase in income tax receivable from the State of Connecticut under the Connecticut R&D Tax Credit Exchange Program. Those cash outflows were partially offset by a cash inflow of $1.6 million from an increase in accounts payable and accrued expenses. Net non-cash charges primarily consisted of depreciation and amortization expense of $1.3 million and stock-based compensation expense of $2.0 million, partially offset by deferred rent costs of $0.2 million and accretion/amortization on available-for-sale marketable securities of $0.2 million.

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

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $24.5 million for the nine months ended September 30, 2016, which primarily included cash inflows of $59.6 million from maturities of available-for-sale marketable securities and $23.4 million from the sale of available-for-sale marketable securities. Those cash inflows were partially offset by cash outflows of $57.1 million from the purchase of available-for-sale marketable securities, $0.6 million of cash paid for purchase of property and equipment at our new corporate headquarters in Stamford, Connecticut and $0.8 million of additional restricted cash related to our Stamford lease.

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

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2016 consisted primarily of proceeds of $40 thousand received from the exercise of stock options.

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

Significant Contractual Obligations and Commitments

Contractual obligations and commitments as of September 30, 2016 consisted of operating lease obligations in connection with our facilities in Shelton, Connecticut and Stamford, Connecticut. See Note 14 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q.

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

Discussion of Critical Accounting Policies

The preparation of financial statements in conformity with 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, 2016, 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, 2015.

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

Interest Rate Risk

As of September 30, 2016, we invested a majority of our cash reserves in a variety of available-for-sale marketable securities, including money market funds and investment-grade debt instruments, principally corporate notes, commercial paper and direct obligations of the U.S. government and government-sponsored entities, and in cash equivalents. See Note 3 of Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q for details about our available-for-sale marketable securities.

Information about our market risks are disclosed in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk,* of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have been no material changes to our market risks as of September 30, 2016.

We maintain an investment portfolio in accordance with our investment policy, which includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The primary objectives of our investment policy are to preserve principal and to maintain proper liquidity to meet operating needs. Our investments are subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. As of September 30, 2016, if interest rates were to increase or decrease by 10%, the decrease (increase) in the fair value of our investment portfolio would be immaterial. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes.

Credit Quality Risk

Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Nonetheless,

deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security.

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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, 2016. 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, 2016, 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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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, 2015, filed with the SEC on March 10, 2016, 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, 2016, 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, 2015.

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

Use of IPO Proceeds

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

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

There has been no material change in the planned use of proceeds from our initial public offering from that described in the final prospectus related to the offering, which we filed with the SEC on February 3, 2014. As of September 30, 2016, we have used approximately $48.7 million of the funds received from our IPO for clinical trials and payments to R&D consultants.

Item 3. ***Defaults upon Senior Securities.***

None.

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

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

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

Exhibit

No.	**Description of Exhibit**
3.1	Amended and Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
10.1 +	Twelfth Amendment to Services Agreement dated July 2, 2004 between the Registrant and Bio Diligence Partners, Inc. (3)
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.

\+ Indicates management contract or compensatory plan.

(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.

(3) The Services Agreement, as previously amended, was filed as exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q (File No. 001-36279) filed with the Securities and Exchange Commission on May 5, 2016 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.

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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 3, 2016

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

Date: November 3, 2016

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