CARA THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

Filed 05/04/17 for the Period Ending 03/31/17

Address	4 STAMFORD PLAZA 107 ELM STREET 9TH FLOOR STAMFORD, CT 06902
Telephone	203-406-3700
CIK	0001346830
Symbol	CARA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

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 9 th 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. ☒ Yes ☐ No.

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ Emerging growth company ☒	Smaller reporting company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of April 28, 2017 was: 32,507,487.

CARA THERAPEUTICS, INC.
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FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

PART I – FINANCIAL INFORMATION

PART II – OTHER INFORMATION

PART I
FINANCIAL INFORMATION

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

CARA THERAPEUTICS, INC.

CONDENSED BALANCE SHEETS
(amounts in thousands, excluding share and per share data)
(unaudited)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 5,306	$ 12,092
Marketable securities	31,504	46,184
Income tax receivable	558	852
Other receivables	984	87
Prepaid expenses	1,979	1,530
Restricted cash, current	700	700
Total current assets	41,031	61,445
Property and equipment, net	1,499	1,614
Restricted cash	769	769
Total assets	$ 43,299	$ 63,828
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,512	$ 11,533
Total current liabilities	12,512	11,533
Deferred lease obligation	1,518	1,570
Commitments and contingencies *(Note 14)*		
Stockholders' equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized at March 31, 2017 and December 31, 2016, zero shares issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock; $0.001 par value; 100,000,000 shares authorized at March 31, 2017 and December 31, 2016, 27,324,154 shares and 27,296,863 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	27	27
Common stock subscribed in follow-on offering; $0.001 par value; 5,117,500 shares at March 31, 2017	5	—
Additional paid-in capital	300,151	212,866
Subscriptions receivable	(86,518)	—
Accumulated deficit	(184,420)	(162,171)
Accumulated other comprehensive income	24	3
Total stockholders' equity	29,269	50,725
Total liabilities and stockholders' equity	$ 43,299	$ 63,828

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS
(amounts in thousands, excluding share and per share data)

(unaudited)

	Three Months Ended	
	March 31, 2017	March 31, 2016
Revenue:		
License and milestone fees	$ 530	$ —
Collaborative revenue	313	—
Clinical compound revenue	68	7
Total revenue	911	7
Operating expenses:		
Research and development	20,836	8,546
General and administrative	2,400	2,447
Total operating expenses	23,236	10,993
Operating loss	(22,325)	(10,986)
Other income	90	149
Loss before benefit from income taxes	(22,235)	(10,837)
Benefit from income taxes	31	145
Net loss	$ (22,204)	$ (10,692)
Net loss per share:		
Basic and Diluted	$ (0.81)	$ (0.39)
Weighted average shares:		
Basic and Diluted	27,299,678	27,259,589
Other comprehensive income (loss), net of tax of $0:		
Change in unrealized gains on available-for-sale marketable securities	21	39
Total comprehensive loss	$ (22,183)	$ (10,653)

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands except share and per share data)
(unaudited)

	Common Stock		Common Stock Subscribed in Follow On Offering		Additional Paid-In Capital	Subscriptions Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2015	27,254,863	$ 27	—	$ —	$ 209,943	$ —	$ (104,891)	$ (35)	$ 105,044
Stock-based compensation expense	—	—	—	—	496	—	—	—	496
Shares issued upon exercise of stock options	28,000	—	—	—	40	—	—	—	40
Net loss	—	—	—	—	—	—	(10,692)	—	(10,692)
Other comprehensive income	—	—	—	—	—	—	—	39	39
Balance at March 31, 2016	27,282,863	$ 27	—	$ —	$ 210,479	$ —	$ (115,583)	$ 4	$ 94,927

	Common Stock		Common Stock Subscribed in Follow On Offering		Additional Paid-In Capital	Subscriptions Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2016	27,296,863	$ 27	—	$ —	$ 212,866	$ —	$ (162,171)	$ 3	$ 50,725
Subscription of common stock in a follow-on offering ($18.00 per share), net of underwriting discounts and commissions and offering expenses of $6,127	—	—	5,117,500	5	85,983	(86,518)	—	—	(530)
Stock-based compensation expense	—	—	—	—	1,108	—	—	—	1,108
Shares issued upon exercise of stock options	27,291	—	—	—	149	—	—	—	149
Cumulative effect adjustment upon adoption of ASU 2016-09			—	—	45	—	(45)	—	—
Net loss	—	—	—	—	—	—	(22,204)	—	(22,204)
Other comprehensive income	—	—	—	—	—		—	21	21
Balance at March 31, 2017	27,324,154	$ 27	5,117,500	$ 5	$ 300,151	$ (86,518)	$ (184,420)	$ 24	$ 29,269

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

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

	Three Months Ended	
	March 31, 2017	March 31, 2016
Operating activities		
Net loss	$ (22,204)	$ (10,692)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,108	496
Depreciation and amortization	122	730
Amortization/accretion of available-for-sale marketable securities	(4)	(67)
Realized gain on sale of available-for-sale marketable securities	(3)	—
Deferred rent costs	(52)	(83)
Changes in operating assets and liabilities:		
Income tax receivable	294	(145)
Other receivables	(896)	(48)
Prepaid expenses	(449)	(844)
Accounts payable and accrued expenses	448	820
Net cash used in operating activities	(21,636)	(9,833)
Investing activities		
Proceeds from maturities of available-for-sale marketable securities	16,156	26,050
Proceeds from sale of available-for-sale marketable securities	5,030	—
Purchase of available-for-sale marketable securities	(6,477)	(22,625)
Change in restricted cash	—	(769)
Cash paid for construction in progress	—	(34)
Purchases of property and equipment	(8)	(8)
Net cash provided by investing activities	14,701	2,614
Financing activities		
Proceeds from the exercise of stock options	149	40
Net cash provided by financing activities	149	40
Net cash decrease for the period	(6,786)	(7,179)
Cash and cash equivalents at beginning of period	12,092	15,101
Cash and cash equivalents at end of period	$ 5,306	$ 7,922
Noncash investing and financing activities		
Tenant improvements paid by landlord	$ —	$ 495
Subscriptions receivable	530	—

See Notes to Condensed Financial Statements.

CARA THERAPEUTICS, INC.

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

1. Business

Cara Therapeutics, Inc. (the "Company", "we", "our" or "us") is a clinical-stage biopharmaceutical corporation formed on July 2, 2004. The Company is focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting 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 March 31, 2017, 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 first follow-on offering of common stock, which closed in August 2015, and the issuance of debt. In addition, the Company received approximately $33,500 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*).

On April 5, 2017, the Company completed its second follow-on offering, raising aggregate net proceeds of approximately $86,518, net of underwriting discounts and commissions but before deducting estimated offering expenses payable by the Company. The offering was conducted pursuant to a shelf registration statement on Form S-3, which was filed on March 13, 2017 and declared effective by the Securities and Exchange Commission, or the SEC, on March 24, 2017 (see Note 9, *Stockholders' Equity*).

As of March 31, 2017, the Company had unrestricted cash and cash equivalents and marketable securities of $36,810 and an accumulated deficit of $184,420. 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 $22,204 and $10,692 and had net cash used in operating activities of $21,636 and $9,833 for the three months ended March 31, 2017 and 2016, respectively.

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 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, 2016 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, 2016.

CARA THERAPEUTICS, INC.

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, as of the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from the Company's estimates and assumptions. Significant estimates include 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.

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, 2016.

Accounting Pronouncements Recently Adopted

As of January 1, 2017, the Company adopted Accounting Standards Update, or 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. Certain of the amendments were applied using a modified retrospective transition method by means of a cumulative-effect adjustment to equity as of January 1, 2017, while other amendments were applied retrospectively, prospectively or using either a prospective or a retrospective transition method. Upon adoption, the Company began to account for forfeitures as they occur rather than estimate a forfeiture rate and has recorded a cumulative-effect adjustment in equity of $45 on the date of initial adoption. In periods subsequent to adoption, a higher expense will be recognized earlier during the respective vesting periods of 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 against its deferred tax assets.

Recent Accounting Pronouncements Not Yet Adopted

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business,* or ASU 2017-01 , that clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 requires an entity to evaluate if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single identifiable asset or a group of similar identifiable assets; if so, the set of transferred assets and activities is not a business. ASU 2017-01 also requires a business to include at least an input and one substantive process that together significantly contribute to the ability to create output and removes the evaluation of whether a market participant could replace missing elements. ASU 2017-01 will be applied prospectively and is effective for annual periods beginning after December 15, 2017 and interim periods within those annual periods. The Company does not expect that the adoption of ASU 2017-01 will have a material effect on its financial position, results of operations or cash flows since it has not and does not expect to acquire or dispose of assets for which the fair value is divided among diverse identifiable assets.

3. Available-for-Sale Marketable Securities

As of March 31, 2017 and December 31, 2016, the Company's available-for-sale marketable securities consisted of money market funds and debt securities issued by the U.S. government and government-sponsored entities and by investment grade institutions.

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(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 March 31, 2017 and December 31, 2016:

As of March 31, 2017

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 7,231	$ 28	$ —	$ 7,259
U.S. Treasury securities	2,512	—	(2)	2,510
U.S. government agency obligations	1,500	—	—	1,500
Corporate bonds	11,005	1	(3)	11,003
Commercial paper	9,232	—	—	9,232
Total available-for-sale marketable securities	$ 31,480	$ 29	$ (5)	$ 31,504

As of December 31, 2016

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 8,268	$ 8	$ —	$ 8,276
U.S. Treasury securities	2,523	—	(1)	2,522
U.S. government agency obligations	3,501	1	—	3,502
Corporate bonds	16,683	—	(6)	16,677
Commercial paper	15,206	3	(2)	15,207
Total available-for-sale marketable securities	$ 46,181	$ 12	$ (9)	$ 46,184

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 March 31, 2017, the Company's marketable debt securities mature at various dates through August 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 March 31, 2017		As of December 31, 2016	
Contractual maturity	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	$ 24,249	$ 24,245	$ 37,913	$ 37,908

During the three months ended March 31, 2017, the Company sold shares of two investments in commercial paper before their respective maturity dates and shares in a money market fund with a total fair value of $5,030 that were all classified as available-for-sale marketable securities. The cost of the shares of commercial paper and the money market fund that were sold was determined by specific identification. The sales of the investments in commercial paper as well as the sale of the shares of the money market fund each resulted in realized gains, totaling $3.

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.

As of March 31, 2017

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. Treasury securities	$ 2,510	$ (2)	$ —	$ —	$ 2,510	$ (2)
Corporate bonds	7,751	(3)	—	—	7,751	(3)
Total	$ 10,261	$ (5)	$ —	$ —	$ 10,261	$ (5)

As of December 31, 2016

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. Treasury securities	$ 2,522	$ (1)	$ —	$ —	$ 2,522	$ (1)
Corporate bonds	9,919	(6)	—	—	9,919	(6)
Commercial paper	5,227	(2)	—	—	5,227	(2)
Total	$ 17,668	$ (9)	$ —	$ —	$ 17,668	$ (9)

As of March 31, 2017 and December 31, 2016, the Company held a total of 16 out of 24 positions and 18 out of 34 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 March 31, 2017 and December 31, 2016. 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 three months ended March 31, 2017 and March 31, 2016.

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, 2016	$ 3
Other comprehensive income before reclassifications	24
Amount reclassified from accumulated other comprehensive income	(3)
Net current period other comprehensive income	21
Balance, March 31, 2017	$ 24
Balance, December 31, 2015	$ (35)
Other comprehensive income before reclassifications	39
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive income	39
Balance, March 31, 2016	$ 4

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

Component of AOCI	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016	Affected Line Item in the Statements of Comprehensive Loss
Unrealized gains (losses) on available-for-sale marketable securities			
	$ 3	$ —	Other income
	—	—	Income tax benefit
	$ 3	$ —	Net of tax

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

5. Fair Value Measurements

As of March 31, 2017 and December 31, 2016, 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.

CARA THERAPEUTICS, INC.

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

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.
- 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 March 31, 2017 or December 31, 2016.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis as of March 31, 2017 and December 31, 2016.

Fair value measurement as of March 31, 2017:

Financial assets Type of Instrument	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents:				
Money market fund and checking accounts	$ 5,306	$ 5,306	$ —	$ —
Available-for-sale marketable securities:				
Money market funds	7,259	—	7,259	—
U.S. Treasury securities	2,510	—	2,510	—
U.S. government agency obligations	1,500	—	1,500	—
Corporate bonds	11,003	—	11,003	—
Commercial paper	9,232	—	9,232	—
Restricted cash:				
Commercial money market account	1,469	1,469	—	—
Total financial assets	$38,279	$ 6,775	$ 31,504	$ —

CARA THERAPEUTICS, INC.

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

Fair value measurement as of December 31, 2016:

Financial assets Type of Instrument	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents:				
Money market fund and checking accounts	$12,092	$ 12,092	$ —	$ —
Available-for-sale marketable securities:				
Money market fund	8,276	—	8,276	—
U.S. Treasury securities	2,522	—	2,522	—
U.S. government agency obligations	3,502	—	3,502	—
Corporate bonds	16,677	—	16,677	—
Commercial paper	15,207	—	15,207	—
Restricted cash:				
Money market fund	1,469	1,469	—	—
Total financial assets	$59,745	$ 13,561	$ 46,184	$ —

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 three months ended March 31, 2017. There were no transfers of financial assets between Levels 1, 2, or 3 classifications during the three months ended March 31, 2017.

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 March 31, 2017, 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 March 31, 2017 and December 31, 2016, the Company had $700 of restricted cash related to the Shelton lease in current assets and $769 of restricted cash related to the Stamford lease in long-term assets.

7. Prepaid expenses

As of March 31, 2017, prepaid expenses were $1,979, consisting of $1,109 of prepaid R&D clinical costs, $682 of prepaid insurance and $188 of other prepaid costs. As of December 31, 2016, prepaid expenses were $1,530 consisting of $1,256 of prepaid R&D clinical costs, $112 of prepaid insurance and $162 of other prepaid costs.

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8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2017	December 31, 2016
Accounts payable	$ 1,688	$ 4,738
Accrued research projects	8,861	4,352
Accrued professional fees	688	163
Accrued compensation and benefits	681	1,514
Accrued other	594	766
Total	$ 12,512	$ 11,533

9. Stockholders' Equity

On March 30, 2017, the Company entered into an underwriting agreement with Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated, as representatives of the several underwriters named therein, relating to the issuance and sale by the Company of up to 5,117,500 shares of its common stock, including 667,500 shares of common stock the underwriters had the option to purchase, at a public offering price of $18.00 per share (the "Offering"). The Offering was made pursuant to the Company's Registration Statement on Form S-3 (File No. 333-216657), filed with the SEC on March 13, 2017 and declared effective on March 24, 2017, and a related prospectus supplement dated March 30, 2017, which was filed with the SEC on March 31, 2017.

On April 5, 2017, the Company closed the Offering, including the full exercise of the underwriters' option to purchase 667,500 additional shares of common stock. The Company received net proceeds of approximately $86,518, after deducting the underwriting discounts and commissions but before deducting offering expenses payable by the Company, which the Company currently estimates to be approximately $530.

10. Collaborations

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. Maruishi has the right to grant sub-licenses in Japan, which entitle the Company to receive sub-license fees, net of prior payments made by Maruishi to the Company. 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.

In March 2017, Maruishi entered into a sub-license agreement with Kissei Pharmaceutical Co. Ltd. for the development and sales/marketing of CR845 (called MR13A9 by Maruishi) for the treatment of uremic pruritus in dialysis patients in Japan. Consequently, for the three months ended March 31, 2017, the Company recognized revenue of $843 related to the

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sub-license fee. The Company allocated the amount of the sub-license fee to each of the two identified deliverables in the same proportion as the upfront license fee that the Company received at inception of the Maruishi Agreement. Accordingly, $530 was recognized as license and milestone fees revenue and $313 was recognized as collaborative revenue. As of March 31, 2017, the Company was due the full amount of the sub-license fee, which was recorded in Other receivables on the Balance Sheet. Such amount was received in April 2017.

During the three months ended March 31, 2017 and 2016, the Company recognized clinical compound revenue of $68 and $7, respectively, from the sale of clinical compound to Maruishi.

The Company incurred R&D expense related to the Maruishi Agreement of $61, consisting of cost of clinical compound, during the three months ended March 31, 2017.

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 months ended March 31, 2017 and 2016, the Company excluded the effects of potentially dilutive shares that were outstanding during those respective periods from the denominator as their inclusion would be anti-dilutive due to the Company's net losses during those periods.

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

	Three Months Ended March 31,	
	2017	2016
Basic:		
Weighted average common shares outstanding	27,299,678	27,259,589
Diluted:		
Weighted average common shares outstanding -Basic	27,299,678	27,259,589
Common stock options*	—	—
Denominator for diluted net loss per share	27,299,678	27,259,589

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

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

	Three Months Ended March 31,	
	2017	2016
Net loss	$ (22,204)	$ (10,692)
Weighted-average common shares outstanding:		
Basic and Diluted	27,299,678	27,259,589
Net loss per share, Basic and Diluted	$ (0.81)	$ (0.39)

As of March 31, 2017 and 2016, 3,154,617 and 2,214,492 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. In addition, on April 5, 2017, the Company issued 5,117,500 shares of its common stock pursuant to the Offering (see Note 9, *Stockholders' Equity* , above), which will increase the denominator of net loss per share in future periods.

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.

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, 2017, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2014 Plan automatically increased from 3,101,707 to 3,920,613. 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 748,500 and 610,000 stock options during the three months ended March 31, 2017 and 2016, respectively. The fair values of stock options granted during the three months ended March 31, 2017 and 2016 were estimated as of the dates of grant using the Black-Scholes option pricing model with the following assumptions:

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	Three Months Ended March 31,	
	2017	2016
Risk-free interest rate	2.07% - 2.57%	1.40% -1.59%
Expected volatility	75.3% - 80.7%	67.8% - 69.7%
Expected dividend yield	0%	0%
Expected life of employee options (in years)	6.25	6.25
Expected life of nonemployee options (in years)	10	10

The weighted-average grant date fair value of options granted to employees during the three months ended March 31, 2017 and 2016 was $12.27 and $3.85, respectively.

As of March 31, 2017 and 2016, the Company used the Black-Scholes option valuation model with the following ranges of assumptions to re-measure the fair value of all outstanding options that had been granted to non-employee consultants during the vesting period of each tranche in accordance with ASC 505-50:

	March 31,	
	2017	2016
Risk-free interest rate	2.10% -2.39%	1.53%
Expected volatility	74.6% - 78.4%	72.30%
Expected dividend yield	0%	0%
Expected life of non-employee options (in years)	6.83 - 9.94	7.84

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 $12.14 and $3.82 as of March 31, 2017 and 2016, respectively.

On January 1, 2017, the Company adopted ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* , (see Note 2, *Basis of Presentation - Recently Adopted Accounting Pronouncements*). On the date of adoption of ASU 2016-09, the Company began to account for forfeitures of unvested stock options as they occur rather than estimate a forfeiture rate which was applied to all unvested options, as under the previous accounting guidance. Accordingly, on the date of adoption, the Company recorded a cumulative effect adjustment to stockholders' equity of $45 for all options that were unvested as of that date.

During the three months ended March 31, 2017 and 2016, the Company recognized compensation expense relating to stock options, as follows:

	Three Months Ended March 31,	
	2017	2016
Research and development	$ 563	$ 189
General and administrative	545	307
Total stock option expense	$ 1,108	$ 496

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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 three months ended March 31, 2017 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2016	2,548,408	$ 8.75
Granted	748,500	17.40
Exercised	(27,291)	5.47
Forfeited	(115,000)	7.74
Outstanding, March 31, 2017	3,154,617	$ 10.87
Options exercisable, March 31, 2017	1,097,711	

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 for the three months ended March 31, 2017 and 2016.

13. Income Taxes

For the three months ended March 31, 2017 and 2016, pre-tax losses were $22,235 and $10,837, respectively. The Company recognized a full tax valuation allowance against its deferred tax assets as of March 31, 2017 and December 31, 2016. Upon adoption of ASU 2016-09 on January 1, 2017, the tax benefit related to the exercise of stock options is recognized as a deferred tax asset that is offset by a corresponding valuation allowance.

The benefit from income taxes of $31 and $145 for the three months ended March 31, 2017 and 2016, 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 March 31, 2017, consisting of future minimum lease payments under the Company's Stamford and Shelton leases, were as follows:

	Payment Due for the Year Ending December 31,						
	2017	2018	2019	2020	2021	Thereafter	Total
Stamford operating lease	$ 587	$1,093	$1,217	$1,241	$1,266	$ 2,383	$7,787
Shelton operating lease	506	—	—	—	—	—	506
	$1,093	$1,093	$1,217	$1,241	$1,266	$ 2,383	$8,293

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Stamford Operating Lease

In December 2015, the Company entered into a lease agreement, or the Stamford Lease, with Four Stamford Plaza Owner LLC, or the Landlord, for office space in Stamford, Connecticut, or the Premises, for the purpose of relocating its headquarters. The initial term of the Stamford Lease commenced in May 2016, or the Commencement Date, and ends in November 2023. The Stamford Lease requires monthly lease payments, including rent escalations and rent holidays, during the initial lease term. The Company began to make rental payments from the Commencement Date. The Company records monthly rent expense on a straight-line basis from March 2016, upon taking possession of the Premises, through October 2023. As of March 31, 2017 and December 31, 2016, the balance of deferred lease obligation, representing the difference between cash rent paid and straight-line rent expense, was $567 and $583, respectively. The Stamford Lease is renewable for one five-year term.

As of the Commencement Date, the Stamford landlord had made tenant improvements of approximately $1,094 to the leased premises. Such amount was included in Property and equipment, net and in Deferred lease obligation on the Company's Balance Sheet on that date. 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. As of March 31, 2017 and December 31, 2016, the balance of Deferred lease obligation related to tenant improvements was $951 and $987, respectively.

In connection with the signing of the Stamford Lease, the Company entered into a standby letter of credit agreement for $769, which serves as a security deposit for the Premises. The standby letter of credit is automatically renewed annually through November 2023. This standby letter of credit is secured with restricted cash in a money market account (refer to Note 6, *Restricted Cash*).

Shelton Operating Lease

In May 2016, the Company relocated its headquarters to Stamford, Connecticut and vacated its former operating facility in Shelton, Connecticut, although the Company continues to lease its former Shelton operating facility under an operating lease, or the Shelton Lease, which commenced in 2007 and terminates on October 13, 2017.

The Shelton Lease, requires monthly lease payments through its term. The Company recorded monthly rent expense associated with the Shelton Lease on a straight-line basis from inception of the Shelton Lease through May 2016. 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 R&D 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 Lease without economic benefit to the Company. As of March 31, 2017, the carrying amount of the liability of $515, which includes the $506 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 Balance Sheet.

A reconciliation of the balances of the accrued Shelton Lease cease-use liability for the three months ended March 31, 2017 is as follows:

Balance, December 31, 2016	$ 756
Rental payments	(247)
Interest accretion	6
Balance, March 31, 2017	$ 515

In conjunction with the signing of the Shelton Lease, the Company entered into a standby letter of credit agreement, which expires on May 31, 2017, as a security deposit for the premises. As of March 31, 2017 and December 31, 2016, the balance of the letter of credit was $700, which is secured with restricted cash (refer to Note 6, *Restricted Cash*).

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The Company accelerated the amortization of the Shelton leasehold improvements from the date of signing of the Stamford Lease in December 2015 through the date that the Company vacated the Shelton facility in May 2016. Additional amortization expense as a result of such acceleration amounted to $539 (additional net loss per share of $0.02) for the three months ended March 31, 2016.

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

Cautionary Note Regarding Forward-Looking Statements

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

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

- the success and timing of our 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;
- the potential regulatory development pathway for I.V. CR845 in uremic pruritus;
- our plans to develop and commercialize I.V. CR845, Oral CR845 and our other product candidates;
- 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. and Chong Kun Dang Pharmaceutical Corp. 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 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, 2016 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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

The following *Management’s Discussion and Analysis of Financial Condition and Results of Operations* should be read in conjunction with: (i) the Condensed Financial Statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our Annual Report on Form 10-K for the year ended December 31, 2016.

Introduction

We are a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. We are developing a novel and proprietary class of product candidates, led by CR845, that target the body’s peripheral nervous system and have demonstrated efficacy in clinical trials of patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available pain therapeutics.

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.

Product Development Pipeline

The current status of the development of our product candidates is as follows:

I.V. CR845 for Treatment of Acute Postoperative Pain

Our most advanced product candidate, CR845, is a new chemical entity that is designed to produce pain relief by specifically stimulating kappa, rather than mu, opioid receptors outside of the central nervous system. Intravenous, or I.V., CR845, has demonstrated significant pain relief and a favorable safety and tolerability profile in three Phase 2 clinical trials in patients with acute postoperative pain. 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 trial’s primary endpoint by demonstrating highly statistically significant lower “drug liking” scores as measured by visual analog scale (VAS) Emax ($p<0.0001$) when compared to the approved Schedule IV opioid, pentazocine. We believe that the totality of the results from the HAL trial are supportive of the potential for CR845 to be the first non-scheduled or low (Schedule V) scheduled peripheral opioid for acute pain.

In 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 June 2016, we modified the trial protocol and resumed the trial as a three-arm trial, testing two doses of I.V. CR845 (1.0 ug/kg and 0.5 ug/kg) versus placebo, based on a safety review by us, the trial's Independent Data Monitoring Committee and the U.S. Food and Drug Administration, or FDA, of unblinded safety data from the first 90 patients dosed. The safety review was conducted in response to a clinical hold that the FDA placed on the trial in February 2016 and removed in April 2016 following the 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.

The revised trial is enrolling up to 450 patients undergoing a range of abdominal surgeries, all of which are associated with moderate-to-severe postoperative pain, within the United States. The primary efficacy measure is the Change in Pain Intensity over the 24-hour postoperative period using a common measurement method known as area under the curve, 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. An interim conditional power analysis of our adaptive Phase 3 trial of I.V. CR845 for postoperative pain is expected in the second quarter of 2017.

In addition, in April 2017, we announced summary results from our quantitative Phase 1 trial measuring respiratory safety of I.V. CR845, in which it was observed that I.V. CR845 did not significantly differ from placebo across three quantitative measures of respiratory drive in healthy individuals. Respiratory depression remains the most life-threatening side effect of traditional, centrally acting, opioid analgesics, the most commonly used drug class for current treatment of postoperative pain in the United States. The Phase 1 trial was a randomized, double-blind, placebo-controlled, three-way crossover trial of two doses of I.V. CR845 versus placebo on three measures of respiratory drive in 15 healthy volunteers. Each subject was randomized to one of three treatment sequences and was administered I.V. bolus placebo, I.V. CR845 (1.0 ug/kg) and I.V. CR845 (5.0 ug/kg) on sequential 24-hour periods, with I.V. CR845 (5.0 ug/kg) representing a projected five-fold supra-therapeutic dose. After each administration, and continuing through four hours post-dosing, end-tidal CO2 (ETCO2), oxygen saturation (SpO2) and respiratory rate were continuously monitored. The primary safety endpoints were: a >10 mmHg sustained ($\geq$ 30 seconds duration) increase in ETCO2 above baseline or to >50 mmHg, and a sustained reduction in SpO2 to <92 percent.

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 ongoing and 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 four tablet strengths (0.25 mg, 0.5 mg, 1.0 mg and 5.0 mg) of Oral CR845 tablets dosed over a two-week treatment period in 80 OA patients in the United States 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. 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, and a post-hoc analysis of the data revealed a statistically significant reduction in mean rescue medication for the top 5.0 mg dose group, as compared to the other dose groups, of approximately 80%. In this trial, all four tablet strengths were observed to be safe and well tolerated.

The results of 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 Oral CR845 (1.0 mg, 2.5 mg and 5.0 mg), dosed twice-daily over an eight-week treatment period in more than 450 OA patients (increased from the initial target of 330 patients) experiencing moderate-to-severe pain 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. We expect to report top-line data from this trial in the second quarter 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. Uremic pruritus is an intractable systemic itch condition with high prevalence in dialysis patients with chronic kidney disease, for which there are no approved therapeutics in the United States. Pruritus is also associated with diseases such as atopic dermatitis, eczema, cholestatic liver disease and psoriasis, with the largest number of patients treated for pruritus being those suffering from atopic dermatitis or eczema, chronic kidney disease and cholestatic liver disease.

In the fourth quarter of 2014, we reported positive top-line dose-ranging PK and safety data from a Phase 1b clinical trial, which was Part A of a Phase 2 proof-of-concept trial of I.V. CR845 for the treatment of uremic pruritus. In July 2015, we reported positive top-line efficacy results from Part B of this Phase 2 proof-of-concept trial, in which 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 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. On March 28, 2017, we announced top-line data from Part A of this trial, which was a randomized, double-blind, placebo-controlled trial 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 eight-week treatment period in 174 patients with moderate-to-severe uremic pruritus.

The primary endpoint of Part A of this trial was the change from baseline of the mean worst itching score for week eight (days 51-57) measured on a standard NRS. Patients receiving I.V. CR845 experienced a 68% greater reduction from baseline in worst itch scores than those receiving placebo ($p<0.0019$). The secondary endpoint of Part A of this trial focused on quality of life measures associated with pruritus using the Skindex-10 score, a validated self-assessment scale with higher scores indicating worse quality of life. Patients receiving I.V. CR845 experienced a 100% greater reduction from baseline in the average total Skindex-10 score at week eight than those receiving placebo ($p<0.0007$). The total average Skindex-10 score reflected statistically significant reductions in each of the three Skindex-10 domains: disease ($p<=0.0001$), mood/emotional distress ($p=0.01$) and social functioning ($p=0.009$).

Overall, I.V. CR845 was observed to be well tolerated over the eight-week treatment period and the unblinded Drug Safety Monitoring Board did not report any significant drug-related events during the course of the trial. The most common adverse events were transient paresthesia (i.e., primarily mid-facial tingling or numbness), somnolence and dizziness, as reported in previous clinical studies of I.V. CR845.

We plan to meet with the FDA for an end-of-Phase 2 meeting to review the results of Part A of this trial to determine an optimal dose to take into Part B of this Phase 2/3 adaptive design trial, and define the broader path towards potential approval. Pending discussions with the FDA, Part B of this trial is intended to be a randomized, double-blind, placebo-controlled trial of I.V. CR845 administered three times per week after dialysis over a 12-week treatment period in up to 240 patients with moderate-to-severe uremic pruritus.

We also initiated a PK 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 second 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 $4.3 million in clinical development or regulatory milestone payments and sub-license fees, 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)

Our R&D expenses relate 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 overhead expenses, 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 included expenses related to preclinical activities, such as drug discovery, target validation and lead optimization for CR845 and our other, earlier stage programs in prior periods and may include such expenses in the future.

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.

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 continue near their current level through 2018 to support our continued R&D activities and potential commercialization of our product candidates. These expenses will likely include 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 Months Ended March 31, 2017 and 2016

Revenue

	Three Months Ended March 31,		
	2017	2016	% change
	Dollar amounts in thousands		
License and milestone fees revenue	$ 530	$ —	100%
Collaborative revenue	313	—	100%
Clinical compound revenue	68	7	871%
Total revenue	$ 911	$ 7	12914%

License and milestone fees revenue

License and milestone fees revenue for the three months ended March 31, 2017 included $530 thousand of the $843 thousand sub-license fee earned by us in connection with Maruishi's sub-license agreement with Kissei Pharmaceuticals, Co. Ltd. that was allocated to the license fee deliverable under the Maruishi Agreement. (see Note 10 of Notes to Condensed Financial Statements, *Collaborations* , in this Quarterly Report on Form 10-Q).

Collaborative revenue

Collaborative revenue for the three months ended March 31, 2017 included $313 thousand of the $843 thousand sub-license fee earned by us in connection with Maruishi's sub-license agreement with Kissei Pharmaceuticals, Co. Ltd. that was allocated to the R&D services deliverable under the Maruishi Agreement.

Clinical compound revenue

Clinical compound revenue for the three months ended March 31, 2017 and 2016 included $68 thousand and $7 thousand, respectively, from the sale of clinical compound to Maruishi.

Research and Development Expense

	Three Months Ended March 31,		
	2017	2016	% change
	Dollar amounts in thousands		
Direct clinical trial costs	$ 17,202	$ 5,702	202%
Consultant services in support of clinical trials	372	625	-40%
Stock-based compensation	563	189	198%
Depreciation and amortization	103	384	-73%
Other R&D operating expenses	2,597	1,646	58%
Total R&D expense	$ 20,836	$ 8,546	144%

For the three months ended March 31, 2017 compared to the three months ended March 31, 2016, the net increase in direct clinical trial costs and related consultant costs primarily resulted from increases totaling $13.9 million, mainly from the Phase 3 I.V. CR845 adaptive pivotal clinical trial in postoperative pain, 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. Those costs were partially offset by a decrease of $1.7 million of CR845 drug manufacturing costs and a net decrease of $0.6 million for the cost of toxicology studies. The increase in stock-based compensation expense relates primarily to stock option awards granted to non-employee consultants, which are marked to market each quarter, and resulted from an increase in the market price of our common stock and an increase in the number of options outstanding as a result of increased employee headcount. The decrease 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 to Stamford, Connecticut in May 2016, as well as a lower balance of property and equipment at our Stamford, Connecticut headquarters. 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 costs of travel and conferences related to our clinical trial activities.

The following table summarizes our R&D expenses by product candidate for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
	2017	2016
	Dollar amounts in thousands	
External research and development expenses:		
I.V. CR845 - Pain	$ 8,643	$ 3,097
I.V. CR845 - Pruritus	3,376	1,690
Oral CR845	5,555	1,540
Internal research and development expenses	3,262	2,219
Total research and development expenses	$ 20,836	$ 8,546

General and Administrative Expenses

	Three Months Ended March 31,		
	2017	2016	% change
	Dollar amounts in thousands		
Professional fees and public/investor relations	$ 534	$ 572	-7%
Stock-based compensation	545	307	77%
Depreciation and amortization	19	347	-95%
Other G&A operating expenses	1,302	1,221	7%
Total G&A expense	$ 2,400	$ 2,447	-2%

For the three months ended March 31, 2017 compared to the three months ended March 31, 2016, the decrease in professional fees and public/investor relations costs was primarily related to decreases in legal, accounting and audit fees. The increase in stock-based compensation resulted from additional stock option grants to employees and stock option awards granted to non-employee consultants, which are marked to market each quarter, due to the increase in the market price of our common stock. The decrease 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 in May 2016. The increase in other G&A operating expenses was primarily the result of an increase in payroll and related costs associated with G&A personnel.

Other Income

	Three Months Ended March 31,		
	2017	2016	% change
	Dollar amounts in thousands		
Other Income	$ 90	$ 149	-39%

During the three months ended March 31, 2017 compared to the three months ended March 31, 2016, the decrease in other income was primarily due to a decrease in dividend income earned on the lower average balance of our portfolio of investments.

Benefit from Income Taxes

For the three months ended March 31, 2017 and 2016, pre-tax losses were $22.2 million and $10.8 million, respectively, and we recognized a benefit from income taxes of $31 thousand and $145 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 March 31, 2017 and December 31, 2016.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception and through March 31, 2017, we have raised an aggregate of approximately $238.3 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 the sale of approximately 4.33 million shares of our common stock in our first 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 the sale of 5.75 million shares of our common stock in our initial public offering, or IPO, which closed in February 2014; (3) proceeds of $65.9 million from the sale of shares of our convertible preferred stock prior to our IPO; (4) $7.4 million of net proceeds from debt financings; and (5) $33.5 million under our license agreements, primarily with Maruishi and CKD, and an earlier product candidate for which development efforts ceased in 2007.

In addition, in order to fund future operations, including our planned clinical trials, we filed a shelf registration statement on Form S-3 (File No. 333-216657), which the Securities and Exchange Commission, or SEC, declared effective on March 24, 2017. The shelf registration statement provides for aggregate offerings of up to $250 million of common stock, preferred stock, debt securities, warrants or any combination thereof. The shares registered under this shelf registration statement include unsold shares that had been registered under our previous shelf registration statement (File No. 333-203072) that was declared effective on May 13, 2015.

On April 5, 2017, we completed a second follow-on public offering of 5,117,500 shares of our common stock, including 667,500 shares sold upon the full exercise by the underwriters of their option to buy additional shares. The offering was conducted pursuant to the shelf registration statement on Form S-3, which was filed on March 13, 2017 and declared effective by the SEC on March 24, 2017, and a related prospectus supplement dated March 30, 2017, filed with the SEC on March 31, 2017. We received gross proceeds from the offering of approximately $92.1 million, or net proceeds of $86.5 million after deducting the underwriting discounts and commissions but before deducting estimated offering expenses payable by us. We expect that the offering expenses related to this offering payable by us will be approximately $530 thousand. The proceeds of the offering are expected to be used to fund our clinical and research development activities, including the completion of the Phase 3 program for I.V. CR845 in uremic pruritus, two Phase 3 trials of I.V. CR845 in acute pain and additional trials of Oral CR845 in other diseases associated with pruritus as well as for working capital and general corporate purposes.

We may offer additional securities under our 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 the use of a shelf registration statement provides us with the flexibility to raise additional capital to finance our operations as needed.

As of March 31, 2017, we had $36.8 million in unrestricted cash and cash equivalents and available-for-sale marketable securities, which, together with the $86.5 million of net proceeds from our recently-completed follow-on offering of common stock, that closed on April 5, 2017, we believe will be sufficient to fund our currently anticipated operating expenses and capital expenditures into 2019, without giving effect to any potential milestone payments we may receive under our collaboration agreements with Maruishi and CKD.

In addition, under the 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 the listing in the South Korean National Health Insurance Program of I.V. CR845 for pain. If achieved, this milestone will result in a payment $500 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, clinical costs, legal and other regulatory expenses and general overhead costs. In the past, we have also previously used capital for laboratory and related supplies.

Since inception, we have incurred significant operating and net losses. Our net losses were $22.2 million and $10.7 million for the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, we had an accumulated deficit of $184.4 million. We expect to continue to incur significant expenses and operating and net losses over at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, the receipt of additional milestone payments, if any, under our collaborations with Maruishi and CKD, the receipt of payments under any future collaborations we may enter into, and our expenditures on other R&D activities.

We anticipate that our expenses will increase as we:

- continue our I.V. CR845 pivotal clinical trial program in acute pain;
- continue the development of I.V. CR845 for uremic pruritus;
- continue the development of Oral CR845 for acute and chronic pain;
- continue the R&D of CR701 and any potential future 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.

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, 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 completing required trials for I.V. CR845 in postoperative pain to enable an NDA submission; completing the Phase 3 program for I.V. CR845 in uremic pruritus and completing additional trials of Oral CR845 in other diseases associated with pruritus, we expect that our existing cash and cash equivalents and available-for-sale marketable securities as of March 31, 2017, together with the proceeds from our second follow-on offering, which closed on April 5, 2017, will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2019, without giving effect to any potential milestone payments we may receive under our collaboration agreements with Maruishi and CKD. Because the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain, it is possible that the assumptions upon which we have based this estimate may prove to be wrong, and we could use our capital resources sooner than we presently expect.

Cash Flows

The following is a summary of the net cash flows provided by (used in) our operating, investing and financing activities for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
	2017	2016
	Dollar amounts in thousands	
Net cash used in operating activities	$ (21,636)	$ (9,833)
Net cash provided by investing activities	14,701	2,614
Net cash provided by financing activities	149	40
Decrease in cash and cash equivalents	$ (6,786)	$ (7,179)

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2017 consisted primarily of a net loss of $22.2 million, and a $0.6 million outflow from net changes in operating assets and liabilities, partially offset by a $1.2 million cash inflow from net non-cash charges. The net change in operating assets and liabilities primarily consisted of a cash outflow of $0.9 million from an increase in other receivables, principally related to the sub-license fee due from Maruishi and a cash outflow of $0.4 million from an increase in prepaid expense, primarily related to an increase in prepaid clinical costs. Those cash outflows were partially offset by a cash inflow of $0.4 million from an increase in accounts payable and accrued expenses and a cash inflow of $0.3 million due to a decrease in income tax receivable from the State of Connecticut under the Connecticut R&D Tax Credit Exchange Program. Net non-cash charges primarily consisted of $1.1 million of stock-based compensation expense and $0.1 million of depreciation and amortization expense.

Net cash used in operating activities for the three months ended March 31, 2016 consisted primarily of a net loss of $10.7 million and a $0.2 million outflow from net changes in operating assets and liabilities, partially offset by a $1.1 million cash inflow from net non-cash charges. The net change in operating assets and liabilities primarily consisted of cash outflows of $0.8 million from an increase in prepaid expense, primarily related to increases in prepaid clinical costs and prepaid insurance, and of $0.1 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 $0.8 million from an increase in accounts payable and accrued expenses. Net non-cash charges primarily consisted of depreciation and amortization expense of $0.7 million and stock-based compensation expense of $0.5 million, partially offset by deferred rent costs of $0.1 million.

Net cash provided by investing activities

Net cash provided by investing activities was $14.7 million for the three months ended March 31, 2017, which primarily included cash inflows of $16.2 million from maturities of available-for-sale marketable securities and $5.0 million from the sale of available-for-sale marketable securities, partially offset by cash outflows of $6.5 million for the purchase of available-for-sale marketable securities.

Net cash provided by investing activities was $2.6 million for the three months ended March 31, 2016, which primarily included cash inflows of $26.0 million from maturities of available-for-sale marketable securities. Those cash inflows were partially offset by cash outflows of $22.6 million for the purchase of available-for-sale marketable securities, $0.8 million of additional restricted cash related to our Stamford Lease and $42 thousand of cash paid for ongoing construction at our corporate headquarters in Stamford, Connecticut and purchase of office equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2017 and 2016, consisted of proceeds of $149 thousand and $40 thousand, respectively, received from the exercise of stock options.

Significant Contractual Obligations and Commitments

Contractual obligations and commitments as of March 31, 2017 consisted of operating lease obligations in connection with our operating facilities in Shelton, Connecticut and Stamford, Connecticut. See Note 14 of Notes to Condensed Financial Statements, *Commitments and Contingencies* , in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

Please refer to Note 2 of Notes to Condensed Financial Statements, *Basis of Presentation* , 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 three months ended March 31, 2017, 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, 2016.

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

Interest Rate Risk

As of March 31, 2017, 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, *Available-for-Sale Marketable Securities* , 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, 2016. There have been no material changes to our market risks as of March 31, 2017.

As of March 31, 2017, we had invested $31.5 million of our cash reserves in such marketable securities. Those marketable securities include $24.2 million of investment grade debt instruments with an average interest rate of approximately 0.96% and maturities through August 2017 and $7.3 million of money market funds with an average interest rate of 1.17%. As of December 31, 2016, we had invested $46.2 million of our cash reserves in such marketable securities. Those marketable securities include $37.9 million of investment grade debt instruments with an average interest rate of approximately 1.0% and maturities through August 2017 and $8.3 million of money market funds with an average interest rate of 0.92%.

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.

Duration is a sensitivity measure that can be used to approximate the change in the fair value of a security that will result from a change in interest rates. Applying the duration model, a hypothetical 10% increase in interest rates as of March 31, 2017 and December 31, 2016 would have resulted in immaterial decreases in the fair values of our portfolio of marketable securities at those dates. 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.

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 March 31, 2017. 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 March 31, 2017, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

(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 March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. ***Legal Proceedings***

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

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

Please refer to *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 10, 2017, for a description of certain significant risks and uncertainties to which our business, operations and financial condition are subject. During the three months ended March 31, 2017, 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, 2016.

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

None.

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

None.

Item 4. ***Mine Safety Disclosures.***

Not applicable.

Item 5. ***Other Information.***

None.

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

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

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

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

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

SIGNATURES

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

CARA THERAPEUTICS, INC.

Date: May 4, 2017

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

Date: May 4, 2017

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

EXHIBIT 31.1

Certification of Chief Executive Officer Pursuant to

Rule 13a-14(a) under the Securities Exchange Act

of 1934, as Adopted Pursuant to

Section 302 of the Sarbanes-Oxley Act of 2002

I, Derek Chalmers, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 4, 2017

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

EXHIBIT 31.2

Certification of Chief Financial Officer Pursuant to

Rule 13a-14(a) under the Securities Exchange Act

of 1934, as Adopted Pursuant to

Section 302 of the Sarbanes-Oxley Act of 2002

I, Josef Schoell, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 4, 2017

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

EXHIBIT 32.1

CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
OF CARA THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Cara Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Derek Chalmers, Ph.D., D.Sc., as Chief Executive Officer of the Company, and Josef Schoell, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge, based upon a review of the Report:

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

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

/s/ DEREK CHALMERS

Name: Derek Chalmers, Ph.D., D.Sc.
Title: Chief Executive Officer
Date: May 4, 2017

/s/ JOSEF SCHOELL

Name: Josef Schoell
Title: Chief Financial Officer
Date: May 4, 2017