Cara Therapeutics, Inc.
Form 10-Q
August 03, 2017
Table of Contents

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 JUNE 30, 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 9th Floor

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. 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 July 28, 2017 was: 32,581,485.

Table of Contents

CARA THERAPEUTICS, INC.

INDEX TO FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

PART I FINANCIAL INFORMATION

PART II OTHER INFORMATION

Table of Contents

PART I

FINANCIAL INFORMATION

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

CARA THERAPEUTICS, INC.

CONDENSED BALANCE SHEETS

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

(unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 9,416	$ 12,092
Marketable securities	103,020	46,184
Income tax receivable	560	852
Other receivables	175	87
Prepaid expenses	1,934	1,530
Restricted cash, current	700	700
Total current assets	115,805	61,445
Property and equipment, net	1,399	1,614
Restricted cash	769	769
Total assets	$ 117,973	$ 63,828
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,190	$ 11,533
Total current liabilities	7,190	11,533
Deferred lease obligation	1,563	1,570
Commitments and contingencies *(Note 14)*		
Stockholders equity:		
Preferred stock; $0.001 par value; 5,000,000 shares authorized at June 30, 2017 and December 31, 2016, zero shares issued and outstanding at June 30, 2017 and December 31, 2016		
Common stock; $0.001 par value; 100,000,000 shares authorized at June 30, 2017 and December 31, 2016, 32,567,485 shares and 27,296,863 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	33	27
Additional paid-in capital	302,920	212,866

Accumulated deficit		(193,720)		(162,171)
Accumulated other comprehensive (loss) income		(13)		3
Total stockholders equity		109,220		50,725
Total liabilities and stockholders equity	$	117,973	$	63,828

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

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

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Revenue:				
License and milestone fees	$	$	$ 530	$
Collaborative revenue			313	
Clinical compound revenue		79	68	86
Total revenue		79	911	86
Operating expenses:				
Research and development	6,961	10,760	27,797	19,305
General and administrative	2,672	2,645	5,072	5,092
Total operating expenses	9,633	13,405	32,869	24,397
Operating loss	(9,633)	(13,326)	(31,958)	(24,311)
Other income	331	172	421	321
Loss before benefit from income taxes	(9,302)	(13,154)	(31,537)	(23,990)
Benefit from income taxes	2	79	33	224
Net loss	$ (9,300)	$ (13,075)	$ (31,504)	$ (23,766)
Net loss per share -Basic and Diluted	$ (0.29)	$ (0.48)	$ (1.06)	$ (0.87)
Weighted average shares:				
Basic and Diluted	32,239,877	27,282,863	29,783,424	27,271,226
Other comprehensive income, net of tax of $0:				
Unrealized gains (losses) on available-for-sale marketable securities	(37)	37	(16)	76
Total comprehensive loss	$ (9,337)	$ (13,038)	$ (31,520)	$ (23,690)

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS EQUITY

(amounts in thousands except share and per share data)

(unaudited)

	Common Stock		Additional Paid-In		Accumulated Other Comprehensive	Total Stockholders
	Shares	Amount	Capital	Accumulated Deficit	Income (Loss)	Equity
ance at cember 31, 15	27,254,863	$ 27	$ 209,943	$ (104,891)	$ (35)	$ 105,04
ck-based mpensation pense			1,194			1,19
res issued on exercise stock options	28,000		40			4
loss				(23,766)		(23,76
er mprehensive ome					76	7
ance at e 30, 2016	27,282,863	$ 27	$ 211,177	$ (128,657)	$ 41	$ 82,58

	Common Stock		Additional Paid-In		Other Comprehensive	Total Stockholders
	Shares	Amount	Capital	Accumulated Deficit	Income (Loss)	Equity
ance at cember 31, 16	27,296,863	$ 27	$ 212,866	$ (162,171)	$ 3	$ 50,72
e of mmon stock follow-on blic offering 8.00 per re), net of	5,117,500	5	86,219			86,22

derwriting counts and mmissions offering penses of 891						
ck-based mpensation pense			2,426			2,42
ares issued on exercise stock options	153,122	1	1,364			1,36
mulative ect ustment on adoption ASU 6-09			45	(45)		
loss				(31,504)		(31,50
her mprehensive s					(16)	(1
ance at e 30, 2017	32,567,485	$ 33	$ 302,920	$ (193,720)	$ (13)	$ 109,22

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(amounts in thousands)

(unaudited)

	Six Months Ended	
	June 30, 2017	**June 30, 2016**
Operating activities		
Net loss	$ (31,504)	$ (23,766)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,426	1,194
Depreciation and amortization	245	1,249
Accretion/amortization on available-for-sale marketable securities	(163)	(126)
Realized gain on sale of available-for-sale marketable securities	(3)	
Realized gain on sale of property and equipment	(13)	
Deferred rent costs	(7)	(395)
Changes in operating assets and liabilities:		
Income tax receivable	292	(224)
Other receivables	(88)	(171)
Prepaid expenses	(405)	(1,669)
Accounts payable and accrued expenses	(4,343)	2,616
Net cash used in operating activities	(33,563)	(21,292)
Investing activities		
Proceeds from maturities of available-for-sale marketable securities	35,906	42,400
Proceeds from sale of available-for-sale marketable securities	5,430	10,900
Purchases of available-for-sale marketable securities	(98,021)	(42,677)
Change in restricted cash		(769)
Purchases of property and equipment	(30)	(158)
Proceeds from sale of property and equipment	13	
Net cash (used in) provided by investing activities	(56,702)	9,696
Financing activities		
Proceeds from sale of common stock in a follow-on public offering, net of issuance costs	86,224	
Proceeds from the exercise of stock options	1,365	40
Net cash provided by financing activities	87,589	40
Net cash decrease for the period	(2,676)	(11,556)
Cash and cash equivalents at beginning of period	12,092	15,101

Cash and cash equivalents at end of period	$ 9,416	$ 3,545
Noncash investing and financing activities		
Tenant improvements paid by landlord	$	$ 1,094

See Notes to Condensed Financial Statements.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

1. Business

Cara Therapeutics, Inc. (the Company , we , our or us) is a clinical-stage biopharmaceutical corporation formed on July 2, 2004. The Company is focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting 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 June 30, 2017, the Company has raised aggregate net proceeds of approximately $291,100 from several rounds of equity financing, including its initial public offering, which closed in February 2014 and two follow-on public offerings of common stock, which closed in April 2017 and August 2015, respectively, 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 CKDP, 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 public offering, raising aggregate proceeds of approximately $86,224, net of underwriting discounts and commissions and offering expenses paid 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 June 30, 2017, the Company had unrestricted cash and cash equivalents and marketable securities of $112,436 and an accumulated deficit of $193,720. 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 $31,504 and $23,766 and had net cash used in operating activities of $33,563 and $21,292 for the six months ended June 30, 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.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

Use of Estimates

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

During the three months ended June 30, 2017, the Company recognized a reduction of the estimate of accrued clinical trial costs, within R&D expense, that had been recorded in the first quarter of 2017, by approximately $1,500.

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 forfeiture rates for stock option awards. As a result, the Company recorded a cumulative-effect adjustment to stockholders equity of $45 on the date of initial adoption for all stock option awards that were unvested as of that date. 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 May 2017, the Financial Accounting Standards Board, or FASB, issued ASU No. 2017-09, *Compensation Stock Compensation (Topic 718) - Scope of Modification Accounting*, or ASU 2017-09, which clarifies that a change to the terms or conditions of a share-based payment award should be accounted for as a modification only if the fair value, vesting conditions or classification (as equity or liability) of the award changes as a result of the change in terms or conditions. Modification of a share-based payment award may result in the Company recognizing additional compensation expense. ASU 2017-09 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company does not expect that the adoption of ASU 2017-09 will have a material effect on its financial position, results of operations or cash flows since it has not had a history of modifying, and does not expect to modify, the fair value, vesting conditions or classification of its share-based payment awards.

In January 2017, the FASB 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

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02, which amends the current guidance for the accounting and disclosure of leases (ASC 840) for both lessees and lessors. ASU 2016-02 requires a lessee to recognize in its balance sheet a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The lease liability will be equal to the present value of lease payments and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or capital leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while capital leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). Lessees and lessors will adopt ASU 2016-02 by using a modified retrospective transition approach. ASU 2016-02 also requires a lessee to disclose qualitative and quantitative information about its leasing arrangements. ASU 2016-02 is effective for interim and annual periods beginning after December 31, 2018, and may be adopted earlier. The Company is continuing to evaluate the impact that ASU 2016-02 will have on its financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, which changes the principle under which the Company will recognize revenue from contracts with customers from one which requires the Company to satisfy specific criteria before recognizing revenue to one which requires the Company to recognize revenue in an amount that reflects the consideration to which it expects to be entitled in exchange for the transfer of promised goods or services to customers. Topic 606 defines a five-step process to achieve this core principle: (1) identify the contract with the customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company currently recognizes revenue only from a license agreement with Maruishi, or the Maruishi Agreement, and a license agreement with CKDP, or the CKDP Agreement. Under each of these agreements, the Company has recognized revenue from upfront and milestone payments and may earn additional future milestone payments upon the achievement of defined clinical and regulatory events. The Company has also recognized revenue from a sub-license fee under the Maruishi Agreement. The Company is continuing to monitor the timing of achievement of the milestones under each agreement. To the extent that all defined milestones have not been achieved and the related revenue recognized under current GAAP prior to the adoption of ASU 2014-09, those contracts will be included within the scope of ASU 2014-09.

The Company is currently accounting for the Maruishi Agreement and the CKDP Agreement under ASC 605-25, *Multiple-Element Arrangements*, or ASC 605-25, and ASC 605-28, *Milestone Method*, or ASC 605-28. The Company

has analyzed the terms and conditions of each of these contracts in light of the guidance under ASC 606, including amendments under ASU 2016-08, 2016-10, 2016-12 and 2016-20, and has concluded that, due to the similarity of the application of the guidance under ASC 605-25 and ASC 605-28 and under ASC 606, as amended, as it relates to revenue recognition for licenses of intellectual property, or IP, as applied to each of these contracts, the distinct performance obligations, transaction prices, amount of the transaction price allocated to the performance obligations and timing and amount of revenue recognition under ASC 606, as amended, will be the same as under ASC 605-25 and ASC 605-28.

In particular, the following aspects of ASC 606, as amended, are the same as those under ASC 605-25 and ASC 605-28 in respect of the Maruishi Agreement and the CKDP Agreement. The Maruishi Agreement has two distinct performance obligations, granting of the license and the R&D services and the CKDP Agreement has one distinct performance obligation, granting of the license. The methodology for determining the relative standalone selling price of the performance obligations and the allocation of the transaction price to the performance obligations is the same under both standards. The licenses granted to the counterparties under these two contracts are deemed to be functional IP for which revenue is recognized at a point in time, which has been determined to be inception of the respective license agreements, the same as under ASC 605. The R&D services under the Maruishi Agreement were performed from inception of the agreement in 2013 through the third quarter of 2015. Accordingly, under ASC 606, as amended, revenue related to the R&D services under the Maruishi Agreement would be recognized proportionately as those services were performed, as it was under ASC 605-25.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

Although the milestone method guidance under ASC 605-28 no longer applies under ASC 606, as amended, the guidance under ASC 606, as amended, for milestones and sales-based royalties related to licenses of IP is effectively the same as pertains to milestones achieved by the Company and those achieved by the counterparty to each license agreement. In addition, due to the probability, at inception of each of the two license agreements, that revenue recognized related to the achievement of milestones and sales-based royalty payments will be reversed in the future, the constraint on including those potential payments in the transaction price at that time applies under ASC 606, as amended. Under ASC 606, as amended, recognition of revenue for achievement of any milestone and sales-based royalty payment will occur at the time that it becomes probable that those events will be achieved. Application of the guidance under ASC 606, as amended, to the milestones achieved under the Maruishi Agreement and the CKDP Agreement prior to adoption of that standard will not change the amount or timing of revenue recognized under ASC 605 for any reporting period presented at or after the date of adoption of ASC 606, as amended. As a result of the foregoing considerations, the Company has concluded that upon adoption of ASC 606, as amended, there will be no impact on its results of operations, financial position or cash flows for any period presented.

ASU 2014-09, as amended by ASU 2015-14, is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those annual reporting periods. ASU 2014-09 allows for two transition methods: (1) retrospectively to each prior reporting period presented, or (2) using a modified retrospective approach, with the cumulative effect of initially applying ASU 2014-09 recognized as an adjustment to the opening balance of retained earnings at the date of initial adoption. The Company will adopt ASU 2014-09 using the full retrospective method on January 1, 2018.

3. Available-for-Sale Marketable Securities

As of June 30, 2017 and December 31, 2016, the Company s available-for-sale marketable securities consisted of a money market fund and debt securities issued by the U.S. government and government-sponsored entities and by investment grade institutions.

The following tables summarize the Company s available-for-sale marketable securities by major type of security as of June 30, 2017 and December 31, 2016:

As of June 30, 2017

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 42,976	$ 7	$	$ 42,983

U.S. government agency obligations	7,999		(1)	7,998
Corporate bonds	26,901		(12)	26,889
Commercial paper	25,157		(7)	25,150
Total available-for-sale marketable securities	$ 103,033	$ 7	$ (20)	$ 103,020

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 June 30, 2017, the Company s marketable debt securities mature at various dates through April 2018. The amortized cost and fair values 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 June 30, 2017		As of December 31, 2016	
Contractual maturity	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	$ 60,057	$ 60,037	$ 37,913	$ 37,908

During the six months ended June 30, 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 $5,430 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.

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 June 30, 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. government agency obligations	$ 4,004	$ (1)	$	$	$ 4,004	$ (1)
Corporate bonds	24,888	(12)			24,888	(12)
Commercial paper	22,152	(7)			22,152	(7)
Total	$ 51,044	$ (20)	$	$	$ 51,044	$ (20)

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 June 30, 2017 and December 31, 2016, the Company held a total of 28 out of 33 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 June 30, 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 six months ended June 30, 2017 and June 30, 2016.

	Total Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2016	$ 3
Other comprehensive income before reclassifications	(13)

Amount reclassified from accumulated other comprehensive income		(3)
Net current period other comprehensive income		(16)
Balance, June 30, 2017	$	(13)
Balance, December 31, 2015	$	(35)
Other comprehensive income before reclassifications		76
Amount reclassified from accumulated other comprehensive income		
Net current period other comprehensive income		76
Balance, June 30, 2016	$	41

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,		
Component of AOCI	**2017**	**2016**	**2017**	**2016**	**Affected Line Item in the Statements of Operations**
Unrealized gains (losses) on available-for-sale marketable securities	$	$	$ 3	$	Other income
					Benefit from income taxes
	$	$	$ 3	$	

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

5. Fair Value Measurements

As of June 30, 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.

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.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 June 30, 2017 or December 31, 2016.

The following tables summarize the Company s financial assets measured at fair value on a recurring basis as of June 30, 2017 and December 31, 2016.

Fair value measurement as of June 30, 2017

Financial assets		**Quoted prices in active markets for identical assets**	**Significant other observable inputs**	**Significant unobservable inputs**
Type of Instrument	**Total**	**(Level 1)**	**(Level 2)**	**(Level 3)**
Cash and cash equivalents:				
Money market fund and checking accounts	$ 9,416	$ 9,416	$	$
Available-for-sale marketable securities:				
Money market fund	42,983		42,983	
U.S. government agency obligations	7,998		7,998	
Corporate bonds	26,889		26,889	
Commercial paper	25,150		25,150	
Restricted cash:				
Commercial money market account	1,469	1,469		
Total financial assets	$ 113,905	$ 10,885	$ 103,020	$

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:				
Commercial money market account	1,469	1,469		
Total financial assets	$ 59,745	$ 13,561	$ 46,184	$

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 during the six months ended June 30, 2017 or 2016. There were no transfers of financial assets between Levels 1, 2, or 3 classifications during the six months ended June 30, 2017 or 2016.

6. Restricted Cash

The Company is required to maintain stand-by letters of credit as security deposits under each of its leases, one for its former 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 June 30, 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 on October 13, 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 June 30, 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 June 30, 2017, prepaid expenses were $1,934, consisting of $1,321 of prepaid R&D clinical costs, $465 of prepaid insurance and $148 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.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	June 30, 2017	December 31, 2016
Accounts payable	$ 1,865	$ 4,738
Accrued research projects	3,531	4,352

Accrued professional fees	323	163
Accrued compensation and benefits	1,119	1,514
Accrued other	352	766
Total	$ 7,190	$ 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.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 $86,224, after deducting the underwriting discounts and commissions and offering expenses paid by the Company of $294.

10. Collaborations

Maruishi Pharmaceutical Co., Ltd.

In April 2013, the Company entered into 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 in Maruishi s field of use.

At inception of the Maruishi Agreement, the Company identified two deliverables under ASC 605-25: (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, during the six months ended June 30, 2017, the Company recognized revenue of $843 related to the 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.

The Company recognized clinical compound revenue of $0 and $79, during the three months ended June 30, 2017 and 2016, respectively, and $68 and $86 during the six months ended June 30, 2017 and 2016, respectively, from the sale of clinical compound to Maruishi.

The Company incurred R&D expense related to the Maruishi Agreement of $0 and $72 during the three months ended June 30, 2017 and 2016, respectively, and $61 and $78 during the six months ended June 30, 2017 and 2016, respectively, consisting of cost of clinical compound.

11. Net Loss Per Share

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted-average number of shares of common stock outstanding. Diluted net income per share includes the potential dilutive effect of common stock equivalents as if such securities were exercised during the period, when the effect is dilutive. Common stock equivalents may include outstanding stock options, which are included using the treasury stock method when dilutive. For the three and six months ended June 30, 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 for the three and six months ended June 30, 2017 reflect the issuance of 5,117,500 common shares in the Offering on April 5, 2017, on a weighted-average basis (see Note 9, *Stockholders Equity*, above).

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Basic:				
Weighted average common shares outstanding	32,239,877	27,282,863	29,783,424	27,271,226
Diluted:				
Weighted average common shares outstanding -Basic	32,239,877	27,282,863	29,783,424	27,271,226
Common stock options*				
Denominator for diluted net loss per share	32,239,877	27,282,863	29,783,424	27,271,226

* No amounts were considered as their effects would be anti-dilutive.
Basic and diluted net loss per share are computed as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (9,300)	$ (13,075)	$ (31,504)	$ (23,766)
Weighted-average common shares outstanding:				
Basic and Diluted	32,239,877	27,282,863	29,783,424	27,271,226
Net loss per share, Basic and Diluted	$ (0.29)	$ (0.48)	$ (1.06)	$ (0.87)

As of June 30, 2017 and 2016, 3,118,786 and 2,256,700 stock options, respectively, were outstanding, which could potentially dilute basic earnings per share in the future, but were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive.

12. Stock-Based Compensation

2014 Equity Incentive Plan

The Company s 2014 Equity Incentive Plan, or the 2014 Plan, is administered by the Company s Board of Directors or a duly authorized committee thereof, referred to as the Plan administrator. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation, collectively referred to as Stock Awards. Additionally, the 2014 Plan provides for the grant of performance cash awards. Incentive stock options may be granted only to employees. All other awards may be granted to employees, including officers, non-employee directors, and consultants. No incentive stock options may be granted under the 2014 Plan after the tenth anniversary of the effective date of the 2014 Plan. Stock Awards granted under the 2014 Plan vest at the rate specified by the Plan administrator, which, for employees and non-

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 90,000 and 838,500 stock options during the three and six months ended June 30, 2017, respectively, and 112,000 and 722,000 stock options during the three and six months ended June 30, 2016, respectively. The fair values of stock options granted during the three and six months ended June 30, 2017 and 2016 were estimated as of the dates of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Risk-free interest rate	1.85% - 1.88%	1.23% - 1.79%	1.85% - 2.57%	1.23% - 1.79%
Expected volatility	83.3%	69.3% - 72.6%	75.3% - 83.3%	67.8% - 72.6%
Expected dividend yield	0%	0%	0%	0%
Expected life of employee options (in years)	6.25	6.25	6.25	6.25
Expected life of nonemployee options (in years)	10	10	10	10

The weighted-average grant date fair value of options granted to employees, non-employee members of the Company s Board of Directors for their Board service and non-employee consultants during the three and six months ended June 30, 2017 was $13.53 and $12.41, respectively, and during the three and six months ended June 30, 2016 was $3.55 and $3.80, respectively.

As of June 30, 2017 and 2016, the Company used the Black-Scholes option valuation model with the following 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:

	As of June 30,	
	2017	**2016**
Risk-free interest rate	2.02% - 2.28%	1.49%
Expected volatility	76.4% - 81.3%	70.80%
Expected dividend yield	0%	0%
Expected life of non-employee options (in years)	6.58 - 9.69	7.59

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 $12.18 and $2.82 as of June 30, 2017 and 2016, respectively.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

On January 1, 2017, the Company adopted ASU 2016-09 (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 forfeiture rates that were applied to unvested stock option awards, 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 stock option awards that were unvested as of that date.

During the three and six months ended June 30, 2017 and 2016, the Company recognized compensation expense relating to stock options, as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 603	$ 303	$ 1,166	$ 492
General and administrative	715	394	1,260	702
Total stock option expense	$ 1,318	$ 697	$ 2,426	$ 1,194

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 six months ended June 30, 2017 is presented below:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2016	2,548,408	$ 8.75
Granted	838,500	17.55
Exercised	(153,122)	8.91
Forfeited	(115,000)	7.74
Outstanding, June 30, 2017	3,118,786	11.14
Options exercisable, June 30, 2017	1,186,153	$ 9.43

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 six months ended June 30, 2017 and 2016.

13. Income Taxes

For the three months ended June 30, 2017 and 2016, pre-tax losses were $9,302 and $13,154, respectively, and for the six months ended June 30, 2017 and 2016, pre-tax losses were $31,537 and $23,990, respectively. The Company recognized a full tax valuation allowance against its deferred tax assets as of June 30, 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.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

The benefit from income taxes of $2 and $79 for the three months ended June 30, 2017 and 2016, respectively, and $33 and $224 for the six months ended June 30, 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 June 30, 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	$ 392	$ 1,093	$ 1,217	$ 1,241	$ 1,266	$ 2,348	$ 7,557
Shelton operating lease	272						272
	$ 664	$ 1,093	$ 1,217	$ 1,241	$ 1,266	$ 2,348	$ 7,829

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 June 30, 2017 and December 31, 2016, the balance of deferred lease obligation, representing the difference between cash rent paid and straight-line rent expense, was $648 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 June 30, 2017 and December 31, 2016, the balance of Deferred lease obligation related to tenant improvements was $915 and $987, respectively.

In connection with the signing of the Stamford Lease, the Company entered into a standby letter of credit agreement, 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.

Table of Contents

CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

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 June 30, 2017, the carrying amount of the liability of $276, which includes the $272 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 and six months ended June 30, 2017 and 2016 is as follows:

Three Months Ended June 30,			
2017		**2016**	
Balance April 1, 2017	$ 515	Balance, April 1, 2016	$
Charges		Charges	1,312
Rental payments	(247)	Rental payments	(80)
Interest accretion	8	Interest accretion	
Balance June 30, 2017	$ 276	Balance June 30, 2016	$ 1,232

Six Months Ended June 30,			
2017		**2016**	
Balance, January 1, 2017	$ 756	Balance January 1, 2016	$
Charges		Charges	1,312
Rental payments	(494)	Rental payments	(80)
Interest accretion	14	Interest accretion	
Balance June 30, 2017	$ 276	Balance June 30, 2016	$ 1,232

In conjunction with the signing of the Shelton Lease, the Company entered into a standby letter of credit agreement, which expires on October 13, 2017, as a security deposit for the premises. As of June 30, 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*).

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 $359 and $899 (additional net loss per share of $0.01 and $0.03) for the three and six months ended June 30, 2016, respectively.

Table of Contents

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

Cautionary Note Regarding Forward-Looking Statements

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

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

- the success and timing of, and the reporting of results from, 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;
- 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.

Table of Contents

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: (1) the Condensed Financial Statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (2) 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 and uremic (chronic kidney disease-associated) pruritus 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.

Table of Contents

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, or IDMC, 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.

In June 2017, we announced the completion of a prespecified interim conditional power analysis of our adaptive Phase 3 trial of I.V. CR845. Based on the guidance of the IDMC, the trial will continue in accordance with its current protocol, testing two doses of I.V. CR845 (1.0 ug/kg and 0.5 μg/kg I.V.) versus placebo in up to 450 patients undergoing abdominal surgery. The IDMC also reviewed the available safety information, including serum sodium levels, and confirmed that both doses of I.V. CR845 were observed to be well tolerated with no significant changes in the monitored safety parameters. We expect to complete enrollment for this trial in the fourth 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, or ETCO2, oxygen saturation, or SpO2, and respiratory rate were continuously monitored. The primary safety endpoints were: a >10 mmHg sustained (≥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 476 patients (increased from the initial target of 330 patients) with OA of the knee or hip experiencing moderate-to-severe pain across the United States. The primary efficacy endpoint was the change from baseline at week eight, with respect to the weekly mean of the daily pain intensity score using an NRS. Secondary endpoints included overall Patient Global Assessment, or PGA, score, and overall improvement in Western Ontario and McMaster Osteoarthritis Index, or WOMAC, scores, two commonly used patient-reported outcome measures, as well as mean reduction in rescue medication.

Table of Contents

In June 2017, we announced top-line results from the Phase 2b trial. The results of the primary efficacy analysis comparing Oral CR845 (all doses) vs. placebo were not statistically significant across all patients (OA of the knee or hip). However, patients with OA of the hip maintained on the 5.0 mg dose to the end of the eight-week treatment period exhibited a statistically significant 39% reduction in mean joint pain score (p=0.043 vs. placebo); all patients (OA of the knee or hip) maintained on the 5.0 mg dose to the end of the eight-week treatment period exhibited a 35% reduction in mean joint pain score, which did not reach statistical significance (p=0.111 vs. placebo). For patients maintained on the 5.0 mg dose, there was a statistically significant increase in the proportion of patients whose OA was very much improved or much improved as indicated by PGA score in both the total patient group (p <0.005 vs. placebo) and in patients with primary OA of the hip (p<0.006 vs. placebo). The reduction in pain score in the 5.0 mg dose group in hip patients was accompanied by a reduction in mean rescue medication of 41% at week eight versus placebo. Patients maintained on the 1.0 mg and 2.5 mg tablet strengths did not exhibit significant reductions in mean joint pain scores compared to placebo. All tablet strengths were generally well tolerated with no drug-related serious adverse events. For the 5.0 mg dose, the most common adverse events reported at the >5 percent incidence level were dry mouth (6%) and constipation (12%). There were no clinically significant changes in serum sodium levels observed during the eight-week treatment period for any dose group.

I.V. CR845 for Treatment of 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, or CKD, 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, CKD 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. In March 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.

Table of Contents

In June 2017, the FDA granted breakthrough therapy designation for I.V. CR845 for the treatment of moderate-to-severe uremic pruritus in CKD patients undergoing hemodialysis. This regulatory decision was supported primarily by positive top-line results from Part A of the Phase 2/3 clinical trial of I.V. CR845 in patients with uremic pruritus. Breakthrough therapy designation is granted to expedite the development and review process for new therapies addressing serious or life-threatening conditions, where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

We plan to meet with the FDA for an end-of-Phase 2 meeting in the third quarter of 2017 to finalize the pivotal program for I.V. CR845 for the treatment of moderate-to-severe uremic pruritus in CKD patients undergoing hemodialysis. Pending discussions with the FDA, in the fourth quarter of 2017, we expect to initiate a pivotal randomized, double-blind, placebo-controlled Phase 3 trial of I.V. CR845 administered over a 12-week treatment period in patients with moderate-to-severe uremic pruritus.

We are also conducting a 52-week Phase 3 safety trial of I.V. CR845 in hemodialysis patients. The trial is enrolling up to 240 hemodialysis patients with CKD-associated pruritus, or CKD-aP who completed one of our prior Phase 2/3 trials of I.V. CR845 (CR845-CLIN2101 Part A or CR845-CLIN2005 Part B). This open-label trial will evaluate the long-term safety of I.V. CR845 at the dose of 0.5ug/kg, a dose that met both primary and secondary efficacy endpoints (reduction of itch and improved quality of life, respectively) in patients with moderate-to-severe uremic pruritus in our prior Phase 2/3 trials.

Oral CR845 for Treatment of Chronic Kidney and Liver Disease-Associated Pruritus

Based on dual anti-pruritic and anti-inflammatory properties exhibited in preclinical data, we believe CR845 has the potential to treat pruritus across multiple medical conditions. We initially plan to develop Oral CR845 to treat chronic pruritus in both CKD and Chronic Liver Disease, or CLD, patients.

We recently completed a Phase 1 safety and PK trial of multiple doses of Oral CR845 in CKD patients undergoing hemodialysis to define bioequivalent tablet strengths to inform our ability to develop an oral tablet formulation for moderate-to-severe uremic pruritus. In July 2017, we announced summary results from this trial. The Phase 1 results showed that all four tablet strengths of Oral CR845 (0.25, 0.5, 1.0 and 2.5 mg) were generally well-tolerated when administered either daily or after dialysis three times per week. Top-line pharmacokinetic analysis indicated that plasma levels of CR845 attained after oral administration of doses up to 2.5 mg were comparable to or exceeded those attained with clinically efficacious doses of I.V. CR845 for the treatment of moderate-to-severe CKD-aP, in hemodialysis patients. The plasma levels of CR845 attained after oral administration of the 1.0 mg tablet strength approximated those attained with the 1.0 ug/kg I.V. CR845 dose, which demonstrated significant clinical benefit in Part A of our Phase 2/3 trial in hemodialysis patients with CKD-aP.

The Phase 1 trial was a three-part, randomized, placebo-controlled study to evaluate the safety and pharmacokinetics of Oral CR845 tablets in 90 hemodialysis patients. In Part A, ascending repeated oral doses of 0.25, 0.5, 1.0 and 2.5 mg were given to four cohorts of patients (n=47) after each dialysis (i.e., three times) over a one-week treatment period. In Part B, ascending repeated oral doses of 0.25, 0.5 and 1.0 mg were given daily to three cohorts of hemodialysis patients (n=36). In Part C, the final crossover phase of the study, patients were administered a single 1.0 mg oral dose of CR845 or a single 1.0 ug/kg I.V. dose of CR845 (n=7) given after hemodialysis with a one-week washout period between treatments to determine the absolute bioavailability of Oral CR845. Parts A and B randomized up to 12 patients per dose group (nine active and three placebo). Part C was conducted as an open-label phase with seven patients receiving active drug.

Overall, the frequency of treatment emergent adverse events, or TEAEs, in Oral CR845-treated patients was similar to the group administered placebo. All TEAEs were generally mild and comparable to those reported in our Phase 2/3 trial after I.V. CR845 administration in CKD-aP patients undergoing hemodialysis. Absolute oral bioavailability of the 1.0 mg tablet strength was determined to be similar in hemodialysis patients to that obtained in non-CKD patients.

We expect to initiate a Phase 1 trial of Oral CR845 in CKD-aP non-hemodialysis patients in the fourth quarter of 2017.

CLD-associated pruritus, or CLD-aP, manifests as cholestasis symptoms causing severe whole-body itch. It is an intense, intractable, debilitating condition that significantly disrupts patients daily activities and sleep, and consequently impairs their quality of life. Although the pathophysiology is not well understood, it is likely multi-factorial, involving immune system dysregulation (including elevated pro-inflammatory activity) and imbalance in the endogenous opioid system. Consequently, the use of selective kappa-opioid receptor agonists has been suggested for the treatment of pruritus in patients with CLD.

Table of Contents

We plan to submit an Investigational New Drug Application for Oral CR845 for the treatment of CLD-aP in the fourth 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, milestone and sub-license payments under the Maruishi Agreement and the CKD Agreement 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.

Table of Contents

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, legal, business development and human resources functions. Other significant costs include facility costs not otherwise included in R&D expenses, legal fees, insurance costs, investor relations 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, Oral 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 and property and equipment.

Benefit from Income Taxes

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

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2017 and 2016

Revenue

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	% change	2017	2016	% change
	Amounts in thousands			Amounts in thousands		
License & milestone fees	$	$	0%	$ 530	$	100%
Collaborative revenue			0%	313		100%
Clinical compound revenue		79	-100%	68	86	-21%
Total revenue	$	$ 79	-100%	$ 911	$ 86	959%

License and milestone fees revenue

License and milestone fees revenue for the six months ended June 30, 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).

26

Table of Contents

Collaborative revenue

Collaborative revenue for the six months ended June 30, 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 and six months ended June 30, 2017 and 2016 resulted from the sale of clinical compound to Maruishi.

Research and Development Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	% change	2017	2016	% change
	Amounts in thousands			Amounts in thousands		
Direct clinical trial costs	$ 3,544	$ 7,294	-51%	$ 20,746	$ 12,996	60%
Consultant services in support of clinical trials	539	523	3%	911	1,148	-21%
Stock-based compensation	603	303	99%	1,166	492	137%
Depreciation and amortization	104	279	-63%	207	663	-69%
Other R&D operating expenses	2,171	2,361	-8%	4,767	4,006	19%
Total R&D expense	$ 6,961	$ 10,760	-35%	$ 27,797	$ 19,305	44%

For the three months ended June 30, 2017 compared to the three months ended June 30, 2016, the net decrease in direct clinical trial costs and related consultant costs primarily resulted from decreases totaling $7.0 million, including a decrease of $2.7 million, mainly from the Phase 2/3 I.V. CR845 adaptive pivotal clinical trial in postoperative pain and the Phase 2/3 I.V. CR845 clinical trial in patients with uremic pruritus, a decrease of $2.8 million of CR845 drug manufacturing costs and a decrease of $1.5 million for the cost of toxicology studies. The decrease in the cost of the Phase 2/3 I.V. CR845 adaptive pivotal clinical trial in postoperative pain includes a reduction in cost of approximately $1.5 million related to a change in estimate that had been recorded in the first quarter of 2017. Those decreases were partially offset by increases totaling $3.2 million, mainly from the Phase 2b clinical trial of Oral CR845 in osteoarthritis patients, the 52-week safety trial of I.V. CR845 in hemodialysis patients with uremic pruritus and the Phase 1 safety and pharmacokinetic trial of multiple doses of Oral CR845 in CKD patients undergoing hemodialysis. The increase in stock-based compensation expense relates primarily to 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. The decrease in other R&D operating expenses was primarily the result of a decrease in rent expense, partially offset by an increase in payroll and related costs associated with R&D personnel.

For the six months ended June 30, 2017 compared to the six months ended June 30, 2016, the net increase in direct clinical trial costs and related consultant costs primarily resulted from increases totaling $14.4 million, mainly from the Phase 2b clinical trial of Oral CR845 in osteoarthritis patients, the Phase 2/3 I.V. CR845 adaptive pivotal clinical trial in postoperative pain, the Phase 2/3 I.V. CR845 clinical trial in patients with uremic pruritus, the Phase 1 safety

and pharmacokinetic trial of multiple doses of Oral CR845 in CKD patients undergoing hemodialysis, the 52-week trial of I.V. CR845 in hemodialysis patients with uremic pruritus and the Phase 1 trial measuring respiratory safety of I.V. CR845. Those costs were partially offset by a decrease of $4.4 million of CR845 drug manufacturing costs and a decrease of $2.0 million for the cost of toxicology studies. The increase in stock-based compensation expense relates primarily to an increase in the number of options outstanding as a result of increased employee headcount and 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

Table of Contents

stock. 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. 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, partially offset by a decrease in rent expense.

The following table summarizes our R&D expenses by product candidate for the three and six months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	Amounts in thousands		Amounts in thousands	
External research and development expenses:				
I.V. CR845 - Pain	$ 86	$ 3,279	$ 8,730	$ 6,377
I.V. CR845 - Pruritus	990	667	4,366	2,356
Oral CR845 - Pain	1,865	3,871	5,955	5,411
Oral CR845 - Pruritus	1,142		2,606	
Internal research and development expenses	2,878	2,943	6,140	5,161
Total research and development expenses	$ 6,961	$ 10,760	$ 27,797	$ 19,305

During the three months ended June 30, 2017, we recognized a reduction, by approximately $1.5 million, of the estimate of accrued clinical trial costs for I.V. CR845 - Pain that had been recorded in the first quarter of 2017.

General and Administrative Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	% change	2017	2016	% change
	Amounts in thousands			Amounts in thousands		
Professional fees and public/investor relations	$ 568	$ 503	13%	$ 1,102	$ 1,075	2%
Stock-based compensation	715	394	81%	1,260	702	80%
Depreciation and amortization	19	240	-92%	38	586	-93%
Other G&A operating expenses	1,370	1,508	-9%	2,672	2,729	-2%
Total G&A expense	$ 2,672	$ 2,645	1%	$ 5,072	$ 5,092	0%

For the three months ended June 30, 2017 compared to the three months ended June 30, 2016, the increase in professional fees and public/investor relations costs was primarily related to an increase in investor relations expense, partially offset by a decrease in legal fees. The increase in stock-based compensation resulted from additional stock option grants to employees. 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 decrease in other G&A operating expenses was primarily the result of a decrease in rent expense, partially offset by an increase in payroll and related

costs associated with G&A personnel.

For the six months ended June 30, 2017 compared to the six months ended June 30, 2016, professional fees and public/investor relations costs were basically unchanged, primarily reflecting an increase in investor relations expense, offset by decreases in legal, accounting and audit fees. The increase in stock-based compensation primarily resulted from additional stock option grants to employees. 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. Other G&A operating expenses were substantially unchanged, reflecting the offset of an increase in payroll and related costs associated with G&A personnel and a decrease in rent expense.

Table of Contents

Other Income

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	% change	2017	2016	% change
	Amounts in thousands			Amounts in thousands		
Other Income	$ 331	$ 172	92%	$ 421	$ 321	31%

During the three months ended June 30, 2017 compared to the three months ended June 30, 2016, the increase in other income was primarily due to an increase in dividend and interest income resulting from higher interest rates on a higher average balance of our portfolio of investments in the 2017 period.

During the six months ended June 30, 2017 compared to the six months ended June 30, 2016, the increase in other income was primarily due to an increase in dividend and interest income resulting from higher interest rates on a lower average balance of our portfolio of investments in the 2017 period.

Benefit from Income Taxes

For the three months ended June 30, 2017 and 2016, pre-tax losses were $9.3 million and $13.2 million, respectively, and we recognized a benefit from income taxes of $2 thousand and $79 thousand, respectively.

For the six months ended June 30, 2017 and 2016, pre-tax losses were $31.5 million and $24.0 million, respectively, and we recognized a benefit from income taxes of $33 thousand and $224 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 June 30, 2017 and December 31, 2016.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception and through June 30, 2017, we have raised an aggregate of approximately $324.5 million to fund our operations, including (1) net proceeds of $217.7 million from the sale of shares of our common stock in three public offerings, including our initial public offering; (2) proceeds of $73.3 million from the sale of shares of our convertible preferred stock and from debt financings prior to our initial public offering; and (3) payments of $33.5 million under our license agreements, primarily with Maruishi and CKDP, and an earlier product candidate for which development efforts ceased in 2007.

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 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 $86.2 million after deducting the underwriting discounts and commissions and offering expenses paid by us. The proceeds of the offering are expected to be

Table of Contents

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 June 30, 2017, we had $112.4 million in unrestricted cash and cash equivalents and available-for-sale marketable securities, which 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 CKDP.

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 CKDP 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 four 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 CKDP 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 $31.5 million and $23.8 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had an accumulated deficit of $193.7 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 CKDP, the receipt of payments under any future collaborations we may enter into, and our expenditures on other R&D activities.

Table of Contents

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 development of Oral CR845 for uremic pruritus and other diseases associated with pruritus;
- 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 CKDP.

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.

Table of Contents

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 uremic pruritus and other diseases associated with pruritus, we expect that our existing cash and cash equivalents and available-for-sale marketable securities as of June 30, 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 CKDP. 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 six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,	
	2017	**2016**
Net cash used in operating activities	$ (33,563)	$ (21,292)
Net cash (used in) provided by investing activities	(56,702)	9,696
Net cash provided by financing activities	87,589	40
Net decrease in cash and cash equivalents	$ (2,676)	$ (11,556)

Net cash used in operating activities

Net cash used in operating activities for the six months ended June 30, 2017 consisted primarily of a net loss of $31.5 million, and a $4.5 million outflow from net changes in operating assets and liabilities, partially offset by a $2.5 million cash inflow from net non-cash charges. The net change in operating assets and liabilities primarily consisted of a cash outflow of $4.3 million from a decrease in accounts payable and accrued expenses 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 $0.3 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 $2.4 million of stock-based compensation expense and $0.2 million of depreciation and amortization expense.

Net cash used in operating activities for the six months ended June 30, 2016 consisted primarily of a net loss of $23.8 million partially offset by a $0.6 million cash inflow from net changes in operating assets and liabilities and a $1.9 million cash inflow from net non-cash charges. The net change in operating assets and liabilities primarily consisted of a cash inflow of $2.6 million from an increase in accounts payable and accrued expenses, partially offset by cash outflows of (a) $1.7 million from an increase in prepaid expense, primarily related to increases in prepaid clinical costs and prepaid insurance, (b) $0.2 million due to an increase in income tax receivable from the State of Connecticut under the Connecticut R&D Tax Credit Exchange Program, and (c) $0.2 million from an increase in a receivable from the Stamford landlord for leasehold improvements and an increase in interest receivable on our

portfolio of marketable securities. Net non-cash charges primarily consisted of $1.2 million of stock-based compensation expense and $1.2 million of depreciation and amortization expense, partially offset by $0.4 million of deferred rent costs.

Net cash (used in) provided by investing activities

Net cash used in investing activities for the six months ended June 30, 2017, primarily included cash outflows of $98.0 million for the purchase of available-for-sale marketable securities, partially offset by cash inflows of $35.9 million from maturities of available-for-sale marketable securities and $5.4 million from the sale of available-for-sale marketable securities.

Table of Contents

Net cash provided by investing activities for the six months ended June 30, 2016, primarily included cash inflows of $42.4 million from maturities of available-for-sale marketable securities and $10.9 million from the sale of available-for-sale marketable securities. Those cash inflows were partially offset by cash outflows of $42.7 million from the purchase of available-for-sale marketable securities, $0.2 million of cash paid for purchase of property and equipment at our corporate headquarters in Stamford, Connecticut and $0.8 million of additional restricted cash related to the Stamford Lease.

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended June 30, 2017 consisted of proceeds, net of issuance costs, of $86.2 million from our public offering of common stock completed in April 2017 and $1.4 million received from the exercise of stock options.

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

Significant Contractual Obligations and Commitments

Contractual obligations and commitments as of June 30, 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 six months ended June 30, 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 June 30, 2017, we invested a majority of our cash reserves in a variety of available-for-sale marketable securities, including a money market fund and investment-grade debt instruments, principally corporate notes, commercial paper 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 June 30, 2017.

Table of Contents

As of June 30, 2017, we had invested $103.0 million of our cash reserves in such marketable securities. Those marketable securities include $60.0 million of investment grade debt instruments with an average interest rate of approximately 1.0% and maturities through April 2018 and $43.0 million of money market funds with an average interest rate of 1.28%. 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 June 30, 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*.

Evaluation of 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 June 30, 2017. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2017, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

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 June 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls and Procedures

Management, including our Chief Executive Officer and Chief Financial Officer, 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. Because of the inherent limitations in all control systems, no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within Cara have been detected.

Table of Contents

PART II

OTHER INFORMATION

Item 1. ***Legal Proceedings***

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

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

Please refer to *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the year ended December 31, 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 six months ended June 30, 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, other than as set forth below.

We have been granted breakthrough therapy designation for I.V. CR845, however, it may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that I.V. CR845 will receive marketing approval.

In June 2017, the FDA granted breakthrough therapy designation for I.V. CR845 for the treatment of moderate-to-severe uremic pruritus in CKD patients undergoing hemodialysis. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

The receipt of a breakthrough therapy designation for I.V. CR845 for the treatment of moderate-to-severe uremic pruritus in CKD patients undergoing hemodialysis may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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.

Table of Contents

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

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

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

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

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

Table of Contents

SIGNATURES

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

CARA THERAPEUTICS, INC.

Date: August 3, 2017

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

Date: August 3, 2017

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