

Cara Therapeutics, Inc.
Form 10-Q
May 05, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2016

OR

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

COMMISSION FILE NUMBER 001-36279

CARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

75-3175693
(I.R.S. Employer
Identification No.)

1 Parrott Drive

Shelton, Connecticut 06484

(Address of registrant's principal executive offices)

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of April 29, 2016 was: 27,282,863.

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FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2016

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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)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,922	\$ 15,101
Marketable securities	88,322	91,640
Income tax receivable	529	384
Other receivables	128	80
Prepaid expenses	2,573	1,729
Total current assets	99,474	108,934
Property and equipment, net	1,070	1,263
Restricted cash	1,469	700
Total assets	\$ 102,013	\$ 110,897
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,089	\$ 5,268
Total current liabilities	6,089	5,268
Deferred lease obligation	997	585
Commitments and contingencies (Note 12)		
Stockholders equity:		
Preferred stock; \$0.001 par value; 5,000,000 shares authorized at March 31, 2016 and December 31, 2015, zero shares issued and outstanding at March 31, 2016 and December 31, 2015		
Common stock; \$0.001 par value; 100,000,000 shares authorized at March 31, 2016 and December 31, 2015, 27,282,863 shares and	27	27

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27,254,863 shares issued and outstanding at March 31, 2016 and
December 31, 2015, respectively

Additional paid-in capital	210,479	209,943
Accumulated deficit	(115,583)	(104,891)
Accumulated other comprehensive income (loss)	4	(35)
Total stockholders' equity	94,927	105,044
Total liabilities and stockholders' equity	\$ 102,013	\$ 110,897

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	
	March 31, 2016	March 31, 2015
Revenue:		
Collaborative revenue	\$	\$ 489
Clinical compound revenue	7	
Total revenue	7	489
Operating expenses:		
Research and development	8,546	3,385
General and administrative	2,447	1,822
Total operating expenses	10,993	5,207
Operating loss	(10,986)	(4,718)
Other income (expense), net	149	14
Loss before benefit from income taxes	(10,837)	(4,704)
Benefit from income taxes	145	15
Net loss	\$ (10,692)	\$ (4,689)
Net loss per share:		
Basic and Diluted	\$ (0.39)	\$ (0.21)
Weighted average shares:		
Basic and Diluted	27,259,589	22,808,479
Other comprehensive income (loss), net of tax of \$0:		
Unrealized gains on available-for-sale marketable securities	39	
Total comprehensive loss	\$ (10,653)	\$ (4,689)

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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount					
Balance at December 31, 2014	22,802,039	\$ 23	\$ 131,840	\$ (80,201)	\$	\$ 51,662	
Stock-based compensation expense			445			445	
Shares issued upon exercise of stock options	22,880		6			6	
Net loss				(4,689)		(4,689)	
Balance at March 31, 2015	22,824,919	\$ 23	\$ 132,291	\$ (84,890)	\$	\$ 47,424	

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

See Notes to Condensed Financial Statements.

Table of Contents**CARA THERAPEUTICS, INC.****CONDENSED STATEMENTS OF CASH FLOWS**

(amounts in thousands)

(unaudited)

	Three Months Ended	
	March 31, 2016	March 31, 2015
Operating activities		
Net loss	\$ (10,692)	\$ (4,689)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	496	445
Depreciation and amortization	730	193
Amortization/accretion of available-for-sale marketable securities	(67)	
Deferred rent costs	(83)	(71)
Changes in operating assets and liabilities:		
Income tax receivable	(145)	(15)
Other receivables	(48)	
Prepaid expenses	(844)	(733)
Accounts payable and accrued expenses	820	118
Deferred revenue		(489)
Net cash used in operating activities	(9,833)	(5,241)
Investing activities		
Proceeds from maturities of available-for-sale marketable securities	26,050	
Purchase of available-for-sale marketable securities	(22,625)	
Change in restricted cash	(769)	
Cash paid for construction in progress	(34)	
Purchases of property and equipment	(8)	(6)
Net cash provided by (used in) investing activities	2,614	(6)
Financing activities		
Proceeds from the exercise of stock options	40	6
Net cash provided by financing activities	40	6
Net cash decrease for the period	(7,179)	(5,241)
Cash and cash equivalents at beginning of period	15,101	52,663
Cash and cash equivalents at end of period	\$ 7,922	\$ 47,422

Noncash investing and financing activities

Tenant improvements paid by landlord	\$	495	\$
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See Notes to Condensed Financial Statements.

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CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

1. Business

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

As of March 31, 2016, the Company has raised aggregate net proceeds of approximately \$204,800 from several rounds of equity financing, including its initial public offering, which closed in February 2014 and its follow-on offering, which closed in August 2015, and the issuance of debt. In addition, the Company received approximately \$32,500 under its license agreements for CR845, primarily with Maruishi Pharmaceutical Co. Ltd., or Maruishi, and Chong Kun Dang Pharmaceutical Corp., or CKD, and an earlier product candidate for which development efforts ceased in 2007.

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

As of March 31, 2016, the Company had unrestricted cash and cash equivalents and marketable securities of \$96,244 and an accumulated deficit of \$115,583. 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 \$10,692 and \$4,689 and had net cash used in operating activities of \$9,833 and \$5,241 for the three months ended March 31, 2016 and 2015, respectively. The Company expects that cash and cash equivalents and marketable securities as of March 31, 2016 will be sufficient to fund its operations beyond one year.

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

2. Basis of Presentation

The unaudited interim condensed financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States of America, or GAAP. In the opinion of management, these unaudited interim financial statements reflect all adjustments, consisting primarily of normal recurring accruals, necessary for a fair presentation of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by SEC rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The condensed balance sheet data for the year ended December 31, 2015 were derived from audited financial statements, but do not include all disclosures required by GAAP. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and accompanying notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

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CARA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

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

(unaudited)

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, as of the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from the Company's estimates and assumptions. Significant estimates include the fair value of marketable securities that are classified as level 2 of the fair value hierarchy, useful lives of fixed assets, the periods over which certain revenues will be recognized, including licensing and collaborative revenue recognized from non-refundable up-front and milestone payments, the determination of prepaid research and development, or R&D, clinical costs and accrued research projects, the amount of non-cash compensation costs related to share-based payments to employees and non-employees and the periods over which those costs are expensed and the likelihood of realization of deferred tax assets.

Significant Accounting Policies

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

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-08, *Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, or ASU 2016-08, which clarifies the implementation guidance on principal versus agent considerations contained in ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* by specifying that the determination as to whether an entity that is involved in providing a good or a service to a customer is a principal or an agent is based upon whether the entity controls the good or the service before it is transferred to the customer. ASU 2016-08 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period (i.e., January 1, 2018), which is the same as for ASU 2014-09, as amended by ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*. The Company is currently evaluating the effect that adoption of ASU 2016-08 and ASU 2014-09 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09, which amends Accounting Standards Codification, or ASC, *Topic 718, Compensation - Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. Certain of the amendments will be applied using a modified retrospective transition method by means of a cumulative-effect adjustment to equity as of the beginning of

the period in which ASU 2016-09 is adopted, while other amendments will be applied retrospectively, prospectively or using either a prospective or a retrospective transition method. The Company is currently in the process of evaluating the impact of adoption of ASU 2016-09 on its financial statements.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606), Identifying Performance Obligations and Licensing*, or ASU 2016-10, which clarifies the principle for determining whether a good or service is separately identifiable from other promises in the contract and, therefore, should be accounted for as a separate performance obligation. In that regard, ASU 2016-10 requires that an entity determine whether its promise is to transfer individual goods or services to the customer, or a combined item (or items) to which the