

CASCADIAN THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	2601 FOURTH AVENUE SUITE 500 SEATTLE, WA, 98121
Telephone	(206) 801-2100
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 8, 2017

CASCADIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

**Delaware
(State or other jurisdiction of
incorporation)**

**001-33882
(Commission
File Number)**

**26-0868560
(IRS Employer
Identification No.)**

**2601 Fourth Avenue, Suite 500
Seattle, Washington 98121
(Address of principal executive offices, including zip code)**

**(206) 801-2100
(Registrant's telephone number, including area code)**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth 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.

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2017, Cascadian Therapeutics, Inc. (the “Company”) issued a press release regarding the Company’s financial results for the quarter ended September 30, 2017 and providing a corporate update. A copy of the Company’s press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

The information in this report, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be incorporated by reference into any other filing with the U.S. Securities and Exchange Commission, whether made before, on or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Cascadian Therapeutics, Inc. dated November 8, 2017.

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 hereunto duly authorized.

CASCADIAN THERAPEUTICS, INC.

By: /s/ Julia M. Eastland

Julia M. Eastland

Chief Financial Officer, Chief Business Officer and Secretary

Date: November 8, 2017



Cascadian Therapeutics Reports Third Quarter 2017 Financial Results

Conference Call Scheduled for Today at 4:30 p.m. ET

SEATTLE, November 8, 2017 – Cascadian Therapeutics, Inc. (NASDAQ:CASC), a clinical-stage biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2017, and provided an update on tucatinib, an investigational oral, small molecule kinase inhibitor that is highly selective for HER2 and the Company’s lead product in development for the treatment of HER2 overexpressing cancers.

Scott Myers, President and CEO of Cascadian Therapeutics, stated, “We had a productive third quarter. Tucatinib was granted orphan drug designation for a second indication, HER2+ colorectal cancer and enrollment began for an investigator-sponsored study of tucatinib in combination with trastuzumab in HER2 amplified metastatic colorectal cancer. Results from a pooled analysis of tucatinib combination studies were presented at ESMO that provide further support for the development of tucatinib in HER2+ metastatic breast cancer with brain metastases. Finally, enrollment of the HER2CLIMB pivotal trial continues to be robust, and we expect to end the year within our cash guidance.”

Mr. Myers added, “We look forward to sharing new follow up data from our tucatinib Phase 1b studies at the San Antonio Breast Cancer Symposium in early December.”

Third Quarter and Recent Highlights

- Tucatinib was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of HER2+ colorectal cancer. This is the second orphan designation for tucatinib, which also has orphan designation in breast cancer with brain metastases.
- Began enrollment in an investigator-initiated Phase 2 study of tucatinib in combination with trastuzumab for patients with HER2 amplified metastatic colorectal cancer. The study, known as MOUNTAINEER, is described on www.clinicaltrials.gov (NCT03043313).
- Presented at the European Society for Medical Oncology 2017 Congress in September results from a pooled analysis of Phase 1b combination studies supporting the potential utility of tucatinib for patients with HER2+ metastatic breast cancer with brain metastases, including untreated or progressive brain metastases after radiation therapy. Additional analyses of long-term patients in tucatinib studies will be presented at the 40th San Antonio Breast Cancer Symposium 2017 in early December. In addition, results of non-clinical studies were presented that support the MOUNTAINEER study, demonstrating tucatinib is active as a single agent in models of HER2+ colorectal cancer, as well as in other gastrointestinal cancers.
- Continued enrollment of HER2CLIMB pivotal trial, which is on track and enrolling in North America, Western Europe and Australia.
- Received positive regulatory feedback from the European Medicines Agency’s (EMA) Scientific Advice Working Group and Health Canada, validating the potential for the ongoing HER2CLIMB pivotal clinical trial and nonclinical programs to be sufficient for tucatinib registration, if data are supportive.

- Management is pursuing partnering opportunities for CASC-578, a Chk1 kinase inhibitor, and CASC-674, a TIGIT antibody program, and is closing internal laboratory operations to focus resources on tucatinib registration-enabling critical path activities.

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled \$113.0 million as of September 30, 2017, compared to \$62.8 million at December 31, 2016. The increase was primarily due to net proceeds of \$88.0 million from the Company's January 2017 financing, less cash used in operations of \$37.2 million.
- Net loss attributable to common stockholders for the three months ended September 30, 2017 was \$14.1 million, or \$0.28 per share, compared with a net loss attributable to common stockholders of \$11.8 million, or \$0.52 per share, for the comparable period in 2016. The \$2.3 million increase in net loss attributable to common stockholders for the quarter was primarily due to an increase in research and development expenses of \$3.6 million primarily due to greater activity related to the development of the Company's product candidates, offset by a non-cash deemed dividend of \$1.0 million related to the beneficial conversion feature on convertible preferred stock for the three months ended September 30, 2016.
- Net loss attributable to common stockholders for the nine months ended September 30, 2017 was \$41.2 million, or \$0.87 per share, compared to a net loss attributable to common stockholders of \$49.8 million, or \$2.74 per share, for the same period in 2016. The \$8.6 million decrease in net loss attributable to common stockholders for the nine months ended September 30, 2017 was primarily due to the non-cash intangible asset impairment charge of \$19.7 million offset by a \$6.9 million tax benefit related to the reversal of the deferred tax liability, each of which was recorded in connection with the termination of the STC.UNM license agreement in 2016. In addition, the decrease was due to lower general and administrative expenses of \$4.6 million primarily due to compensation-related expenses in connection with management changes in the first quarter of 2016 and lower non-cash expenses of \$1.6 million from the deemed dividend related to the beneficial conversion feature on convertible preferred stock. The decrease in net loss attributable to common stockholders were partially offset by increases in research and development expenses of \$11.0 million due to greater activity related to the development of the Company's product candidates.

2017 Financial Outlook

Cascadian Therapeutics expects operating expenses in 2017 to be slightly higher than in 2016, primarily due to an increase in activities related to the ongoing worldwide HER2CLIMB pivotal trial. Cash used in operations for 2017 is expected to be approximately \$50.0 million to \$54.0 million.

Cascadian Therapeutics believes the above financial guidance to be correct as of the date hereof and is providing the guidance as a convenience to investors and assumes no obligation to update it.

Conference Call Information

Cascadian Therapeutics management will host a conference call and live audio webcast to review its third quarter financial results and provide an update on business activities today at 4:30 p.m. ET / 1:30 p.m. PT. Participants can access the call at +1 (877) 280-7291 (domestic) or +1 (707) 287-9361 (international). To access the live audio webcast or the subsequent archived recording, visit the Events & Presentations page of the News & Events section of the Cascadian Therapeutics' website at www.cascadianrx.com.

About Cascadian Therapeutics

Cascadian Therapeutics is a clinical-stage biopharmaceutical company dedicated to developing innovative product candidates for the treatment of cancer. Its lead product candidate, tucatinib, is an investigational oral, selective small molecule HER2 inhibitor. Cascadian Therapeutics is conducting a randomized, double-blind, controlled pivotal clinical trial called HER2CLIMB, which is comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab, in patients with locally advanced or metastatic HER2+ breast cancer with and without brain metastases, who have previously been treated with trastuzumab, pertuzumab and T-DM1. Additional details on HER2CLIMB can be found at www.HER2CLIMB.com or www.clinicaltrials.gov. For more information, please visit www.cascadianrx.com.

Forward-Looking Statements

In order to provide Cascadian Therapeutics' investors with an understanding of its current results and future prospects, this release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include Cascadian Therapeutics' expectations regarding clinical development activities, HER2CLIMB enrollment, timing of additional data, potential benefits of its product candidates, timing of submission of marketing applications, potential regulatory approvals, and its use and adequacy of cash reserves and future financial results.

Forward-looking statements involve risks and uncertainties related to Cascadian Therapeutics' business and the general economic environment, many of which are beyond its control. These risks, uncertainties and other factors could cause Cascadian Therapeutics' actual results to differ materially from those projected in forward-looking statements, including the risks associated with the costs and expenses of developing its product candidates, the adequacy of financing and cash, cash equivalents and investments, changes in general accounting policies, general economic factors, achievement of the results it anticipates from its preclinical development and clinical trials of its product candidates, the receipt of regulatory approvals, and its ability to adequately obtain and protect its intellectual property rights. Although Cascadian Therapeutics believes that the forward-looking statements contained herein are reasonable as of the date hereof, it can give no assurance that its expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For a detailed description of Cascadian Therapeutics' risks and uncertainties, you should review the documents filed by Cascadian Therapeutics with the securities regulators in the United States on EDGAR and in Canada on SEDAR. Cascadian Therapeutics does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof, except to the extent required by law.

Additional Information

Additional information relating to Cascadian Therapeutics can be found on EDGAR at www.sec.gov and on SEDAR at www.sedar.com.

Source: Cascadian Therapeutics, Inc.

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Investor and Media Contact:

Monique Greer
Cascadian Therapeutics
206-801-2107
mgreer@cascadianrx.com

CASCADIAN THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	\$ 10,910	\$ 7,281	\$ 31,011	\$ 19,998
General and administrative	3,448	3,511	9,930	14,509
Intangible asset impairment	—	—	—	19,738
Total operating expenses	14,358	10,792	40,941	54,245
Loss from operations	(14,358)	(10,792)	(40,941)	(54,245)
Other income				
Investment and other income, net	297	19	769	144
Total other income, net	297	19	769	144
Net loss before income taxes	\$ (14,061)	\$ (10,773)	\$ (40,172)	\$ (54,101)
Income tax benefit	—	—	—	(6,908)
Net loss	(14,061)	(10,773)	(40,172)	(47,193)
Deemed dividend related to beneficial conversion feature on convertible preferred stock	—	(989)	(982)	(2,588)
Net loss attributable to common stockholders	(14,061)	(11,762)	(41,154)	(49,781)
Net loss per share – basic and diluted	\$ (0.28)	\$ (0.52)	\$ (0.87)	\$ (2.74)
Shares used to compute basic and diluted net loss per share	50,404,201	22,551,740	47,089,996	18,159,603

CASCADIAN THERAPEUTICS, INC.
Consolidated Balance Sheet Data
(In thousands except share amounts)
(Unaudited)

	<i>As of</i>	
	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Cash, cash equivalents and investments	\$ 112,979	\$ 62,805
Total assets	\$ 133,387	\$ 83,265
Long term liabilities	\$ 38	\$ 135
Stockholders' equity	\$ 124,616	\$ 74,357
Common shares outstanding	50,560,320	22,562,640
