

CASCADIAN THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/08/17 for the Period Ending 08/08/17

Address	2601 FOURTH AVENUE SUITE 500 SEATTLE, WA 98121
Telephone	(206) 801-2100
CIK	0001412067
Symbol	CASC
SIC Code	8731 - Commercial Physical and Biological Research
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): August 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 August 8, 2017, Cascadian Therapeutics, Inc. (the “Company”) issued a press release regarding the Company’s financial results for the quarter ended June 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 August 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: August 8, 2017

EXHIBIT INDEX

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



Cascadian Therapeutics Reports Second Quarter 2017 Financial Results

First Patients Randomized in Western Europe and Australia in Ongoing Global HER2CLIMB Registrational Trial of Tucatinib

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

SEATTLE, August 8, 2017 – Cascadian Therapeutics, Inc. (NASDAQ:CASC), a clinical-stage biopharmaceutical company, today reported financial results for the second quarter ended June 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.

"During the second quarter, we were pleased to receive confirmation from the European Medicines Agency (EMA) that HER2CLIMB, if positive, could serve as a single registrational trial for submission to the European regulators for potential marketing approval, and that tucatinib was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of breast cancer patients with brain metastases," said Scott Myers, President and CEO of Cascadian Therapeutics. "We are now enrolling patients in HER2CLIMB on three continents. We are pleased with site activations and patient enrollment, which are currently ahead of our projections in North America."

Second Quarter and Recent Highlights

- In July 2017, the Company announced that it received confirmation from the EMA that positive results from its ongoing pivotal trial of tucatinib, known as HER2CLIMB, could serve as a single registrational trial for submission of a Marketing Authorization Application to the EMA and potential marketing approval. The Company had received similar confirmation from the FDA in 2016.
- In June 2017, the Company announced that tucatinib was granted orphan drug designation by the FDA for the treatment of breast cancer patients with brain metastases.

Second Quarter Financial Results

- Cash, cash equivalents and investments totaled \$125.4 million as of June 30, 2017, compared to \$62.8 million at December 31, 2016. The increase was primarily due to the result of net proceeds of \$88.0 million from the Company's January 2017 financing, less cash used in operations of \$24.8 million.
 - Net loss attributable to common stockholders for the three months ended June 30, 2017 was \$14.7 million, or \$0.30 per share, compared with a net loss attributable to common stockholders of \$25.1 million, or \$1.57 per share, for the comparable period in 2016. The \$10.4 million decrease in net loss attributable to common stockholders for the quarter 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. Both amounts were recorded in connection with the termination of the STC.UNM license agreement in 2016. The decrease was offset by an increase in research and development expenses of \$5.1 million primarily due to greater activity related to the development of the Company's product candidates.
-

- Net loss attributable to common stockholders for the six months ended June 30, 2017 was \$27.1 million, or \$0.60 per share, compared to a net loss attributable to common stockholders of \$38.0 million, or \$2.39 per share, for the same period in 2016. The \$10.9 million decrease in net loss attributable to common stockholders for the six months ended June 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. Both of these amounts were 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 \$4.5 million primarily due to compensation-related expenses in connection with management changes in the first quarter of 2016 and lower non-cash expense 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 \$7.4 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 provided 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 second quarter financial results and provide an update on business activities today at 1:30 p.m. PT / 4:30 p.m. ET. 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-positive breast cancer with and without brain metastases, who have previously been treated with a taxane, 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.

###

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 June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	\$ 11,514	\$ 6,380	\$ 20,101	\$ 12,717
General and administrative	3,507	4,365	6,482	10,998
Intangible asset impairment	—	19,738	—	19,738
Total operating expenses	15,021	30,483	26,583	43,453
Loss from operations	(15,021)	(30,483)	(26,583)	(43,453)
Other income (expense)				
Investment and other income (expense), net	312	42	472	125
Total other income (expense), net	312	42	472	125
Net loss before income taxes	\$ (14,709)	\$ (30,441)	\$ (26,111)	\$ (43,328)
Income tax (benefit) provision	—	(6,908)	—	(6,908)
Net loss	(14,709)	(23,533)	(26,111)	(36,420)
Deemed dividend related to beneficial conversion feature on convertible preferred stock	—	(1,599)	(982)	(1,599)
Net loss attributable to common stockholders	(14,709)	(25,132)	(27,093)	(38,019)
Net loss per share – basic and diluted	\$ (0.30)	\$ (1.57)	\$ (0.60)	\$ (2.39)
Shares used to compute basic and diluted net loss per share	49,244,348	16,051,836	45,405,430	15,939,412

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

	As of	
	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Cash, cash equivalents and investments	\$ 125,415	\$ 62,805
Total assets	\$ 145,512	\$ 83,265
Long term liabilities	\$ 70	\$ 135
Stockholders' equity	\$ 137,908	\$ 74,357
Common shares outstanding	49,303,172	22,562,640
