
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

May 23, 2017

Date of Report (Date of earliest event reported)

Tocagen Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38052
(Commission File Number)

26-1243872
(IRS Employer Identification No.)

3030 Bunker Hill Street, Suite 230
San Diego, California
(Address of principal executive offices)

92109
(Zip Code)

Registrant's telephone number, including area code: (858) 412-8400

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- 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 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 May 23, 2017, Tocagen Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2017. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

**Exhibit
Number**

Description

99.1	Press Release dated May 23, 2017.
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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.

Tocagen Inc.

Date: May 23, 2017

By: /s/ Mark Foletta
Mark Foletta
Chief Financial Officer

INDEX TO EXHIBITS

**Exhibit
Number**
99.1

Description

[Press Release dated May 23, 2017.](#)



Tocagen Reports First Quarter 2017 Financial and Business Results

Upsized initial public offering completed, raising approximately \$97.8 million in gross proceeds

SAN DIEGO – May 23, 2017 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results for the first quarter ended March 31, 2017 and business highlights.

"Tocagen has made great strides in our mission to bring novel and effective cancer-selective immunotherapies to patients, with an initial focus on brain cancer. Key milestones achieved to date include observing durable objective responses, extended overall survival and a favorable safety profile for our lead product candidate in patients with recurrent high grade glioma. These milestones contributed to the completion of enrollment of the Phase 2 portion of our registrational trial and the FDA's granting of Breakthrough Therapy Designation," said Marty Duvall, chief executive officer of Tocagen. "Our upsized initial public offering substantially increased our financial strength, which will help support the advancement of our lead product, Toca 511 & Toca FC, our ongoing study in metastatic cancer and our planned initiation of a trial involving newly diagnosed patients with high grade glioma."

First Quarter 2017 and Recent Corporate Progress

- **Completed upsized initial public offering:** In April 2017, Tocagen completed its initial public offering (IPO), including the underwriters' exercise of their option to purchase an additional 1,275,000 shares at the public offering price of \$10.00 per share. The underwriters' option brought the total number of shares of common stock sold by Tocagen to 9,775,000 shares and increased the amount of gross proceeds raised in the offering to approximately \$97.8 million, prior to deducting the underwriting discount and estimated expenses of the offering.
 - **Breakthrough therapy designation granted from FDA:** In February 2017, the U.S. Food and Drug Administration (FDA) granted Toca 511 & Toca FC Breakthrough Therapy Designation for the treatment of patients with recurrent high grade glioma (HGG).
 - **Phase 2 trial fully enrolled:** In February 2017, Tocagen completed patient enrollment in the Phase 2 portion of Toca 5, a randomized, international Phase 2/3 clinical trial of Toca 511 & Toca FC, for the treatment of patients with recurrent brain cancer. Toca 5 is designed to serve as a potential registrational trial, and top-line results from the Phase 2 portion are anticipated in the first half of 2018. In the trial, patients with first or second recurrence of glioblastoma or anaplastic astrocytoma who are undergoing resection are randomized between a cancer-selective virus and oral prodrug, Toca 511 & Toca FC, or standard of care.
 - **Strengthened executive leadership team:** In March 2017, Asha Das, M.D., was promoted to senior vice president and chief medical officer and Mark Foletta joined Tocagen as executive vice president and chief financial officer. Mr. Foletta succeeded Tom Darcy, a company co-founder who retired in May 2017 and who continues to serve on Tocagen's board of directors. In November 2016, Marty Duvall joined Tocagen as chief executive officer and a member of Tocagen's board of directors while Harry Gruber, M.D., a company co-founder who previously served as Tocagen's chief executive officer, assumed the role of president, research and development, and remains a member of Tocagen's board of directors.
 - **Expanded Orphan-Drug Designation:** In May 2017, the FDA granted an expansion of the Orphan-Drug Designation for Toca 511 & Toca FC to include the treatment of malignant glioma, in addition to the previously granted orphan designation for the treatment of glioblastoma multiforme.
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- **Industry awards received:** In April 2017, Tocagen was selected by Informa as a winner of two Clinical and Research Excellence Awards (CARE), in the categories of “Most Successful Early Phase Trial (Preclinical & Phase I)” and “Excellence in Rare Disease Drug Development.”

Upcoming Milestones

- Update following interactions with FDA under Tocagen’s Breakthrough Therapy Designation expected in the second half of 2017.
- Initiation of Phase 1b trial, called Toca 7, evaluating Toca 511 & Toca FC in newly diagnosed high grade glioma expected in early 2018.
- Top-line results from the Phase 2 portion of the Phase 2/3 Toca 5 trial expected to be reported in the first half of 2018.
- Selection of second product candidate from Tocagen’s retroviral replicating vector platform expected in 2018.

First Quarter 2017 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were \$28.9 million at March 31, 2017, compared with \$31.2 million at December 31, 2016. In April 2017, Tocagen raised approximately \$97.8 million of gross proceeds in the IPO.

Research and Development (R&D) Expenses: R&D expenses were \$6.6 million for the quarter ended March 31, 2017, compared to \$6.5 million for the quarter ended March 31, 2016. The R&D expenses were primarily driven by continued increases in clinical costs to support our ongoing Phase 2/3 clinical trial, mostly offset by lower manufacturing costs in the first quarter of 2017.

General and Administrative (G&A) Expenses: G&A expenses were \$1.9 million for the quarter ended March 31, 2017, compared to \$1.1 million for the quarter ended March 31, 2016. The increase in G&A expenses was primarily due to higher costs to support the increased level of clinical and finance activities during the first quarter of 2017. Stock-based compensation also increased by \$0.2 million in the first quarter of 2017 compared to the same period in the prior year.

Net Loss: Net loss was \$9.1 million, or \$4.11 per common share (basic and diluted), for the quarter ended March 31, 2017, compared to a net loss of \$8.0 million, or \$3.64 per common share (basic and diluted), for the quarter ended March 31, 2016. This calculation is based on 2.2 million common shares outstanding during each period.

About Toca 511 & Toca FC

Tocagen’s lead product candidate is a cancer-selective immunotherapy comprised of an investigational biologic, Toca 511, and an investigational small molecule, Toca FC, that are designed to be used together. Toca 511 is an injectable retroviral replicating vector (RRV) that encodes a prodrug activator enzyme, cytosine deaminase (CD). CD is derived from yeast, and humans do not naturally have this gene. Its selective delivery to cancer cells means that the infected cancer cells selectively carry the CD gene and produce CD protein. Toca FC is an investigational orally administered prodrug, 5-fluorocytosine (5-FC) that is inactive as an anti-cancer drug. In animal models, Tocagen has shown that 5-FC is converted into the anticancer drug, 5-FU, at high concentrations in Toca 511-infected cancer cells that are producing CD protein. Together, the Toca 511 & Toca FC combination directly kills cancer cells and immune-suppressive myeloid cells resulting in activation of the immune system against cancer.

About Tocagen

Tocagen is a clinical-stage, cancer-selective gene therapy company developing first-in-class, broadly applicable product candidates designed to activate a patient’s immune system against their own cancer. Tocagen is developing its lead investigational product candidate, Toca 511 & Toca FC, initially for

the treatment of recurrent high grade glioma (HGG), a disease with significant unmet medical need. Toca 511 & Toca FC was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of recurrent HGG. Tocagen has received grant support from leading brain cancer foundations, including [Accelerate Brain Cancer Cure \(ABC2\)](#), [National Brain Tumor Society \(NBTS\)](#), American Brain Tumor Association (ABTA), [Musella Foundation](#) and [Voices Against Brain Cancer \(VABC\)](#).

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding our business plans and objectives, expectations regarding our cash position, timing and success of our clinical trials and planned clinical trials, timing of results from our clinical trials and updates from communications with the FDA and selection of additional product candidates. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost and timing of our product candidate development activities and planned clinical trials; our ability to execute on our strategy; regulatory developments in the United States and foreign countries; and our estimates regarding expenses, future revenue and capital requirements. These and other risks and uncertainties are described more fully under the caption "Risk Factors" and elsewhere in Tocagen's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Tocagen undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

TOCAGEN INC.
CONDENSED BALANCE SHEETS
(in thousands)

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 28,885	\$ 31,245
Prepaid expenses and other assets	5,409	4,106
Total assets	<u>\$ 34,294</u>	<u>\$ 35,351</u>
Current liabilities	16,075	14,382
Notes payable and other long-term liabilities	8,711	10,435
Convertible promissory notes payable and subscription liability	11,016	3,538
Convertible preferred stock	131,413	131,413
Total stockholders' deficit	<u>(132,921)</u>	<u>(124,417)</u>
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 34,294</u>	<u>\$ 35,351</u>

TOCAGEN INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2017	2016
	<u>(unaudited)</u>	
License revenue	\$ 11	\$ 14
Operating expenses:		
Research and development	6,624	6,469
General and administrative	1,940	1,111
Total operating expenses	<u>8,564</u>	<u>7,580</u>
Loss from operations	(8,553)	(7,566)
Other expense, net	(520)	(440)
Net loss	<u>\$ (9,073)</u>	<u>\$ (8,006)</u>
Net loss per common share, basic and diluted	<u>\$ (4.11)</u>	<u>\$ (3.64)</u>
Weighted-average number of common shares outstanding, basic and diluted	2,207,747	2,198,080

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