
**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**

August 9, 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 August 9, 2017, Tocagen Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 9, 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: August 9, 2017

By: /s/ Mark Foletta

Mark Foletta
Chief Financial Officer

INDEX TO EXHIBITS

**Exhibit
Number**

Description

99.1

[Press Release dated August 9, 2017.](#)



Tocagen Reports Second Quarter 2017 Financial and Business Results

SAN DIEGO – Aug. 9, 2017 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results for the second quarter ended June 30, 2017 and business highlights.

"Tocagen is committed to bringing new treatment options to cancer patients, with an initial focus on recurrent high grade glioma," said Marty Duvall, chief executive officer of Tocagen. "During the second quarter, we completed our initial public offering and were granted PRIME designation from the European Medicines Agency, both positioning us well to advance the clinical development of Toca 511 and Toca FC."

Second Quarter 2017 and Recent Corporate Progress

- **Completed upsized initial public offering:** In April 2017, Tocagen completed its initial public offering (IPO), raising approximately \$97.8 million in gross proceeds.
- **Complementary preclinical studies published in Neuro-Oncology:** In July 2017, preclinical data from two independent research programs published, which together showed that Toca 511 & Toca FC treatment resulted in increased immune infiltrates in tumors and that long-term survival and anti-tumor immune effects were T-cell dependent and correlated with depletion of immune-suppressive myeloid cells. The papers were published in the July issue of Neuro-Oncology, featured on the cover of the journal and highlighted in an editorial.
- **PRIME designation granted from EMA:** In July 2017, the European Medicines Agency (EMA) granted Toca 511 PRIME (PRiority MEDicines) designation for the treatment of patients with high grade glioma (HGG), a type of brain tumor with significant unmet medical need.

Upcoming Milestones

- Toca 511 & Toca FC program 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 patients with newly diagnosed high grade glioma expected in the first half of 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.

Second Quarter 2017 Financial Results

Research and Development (R&D) Expenses: R&D expenses were \$6.6 million for the quarter ended June 30, 2017, compared to \$6.5 million for the quarter ended June 30, 2016. The R&D expenses were primarily driven by continued increases in costs to support the company's ongoing Phase 2/3 clinical trial.

General and Administrative (G&A) Expenses: G&A expenses were \$2.0 million for the quarter ended June 30, 2017, compared to \$1.1 million for the quarter ended June 30, 2016. The increase in G&A expenses was primarily due to higher costs to support increased operations activity and costs associated with being a public company during the second quarter of 2017, including a \$0.5 million increase in stock-based compensation compared to the same period in the prior year.

Net Loss: Net loss was \$9.1 million, or \$0.56 per common share (basic and diluted), for the quarter ended June 30, 2017, compared to a net loss of \$8.0 million, or \$3.66 per common share (basic and diluted), for the quarter ended June 30, 2016. The 2017 calculation is based on 16.3 million average common shares outstanding during the second quarter of 2017, compared to 2.2 million average common shares outstanding for the second quarter of 2016. The average common shares outstanding for the second quarter of 2017 includes the issuance of 9.8 million common shares, as well as the conversion of the convertible preferred stock and convertible promissory notes into 7.8 million common shares, upon the IPO in April 2017.

2017 Six-Month Results

R&D Expenses: R&D expenses were \$13.3 million for the six months ended June 30, 2017 compared to \$13.0 million for the six months ended June 30, 2016. Similar to the second quarter results, the R&D expenses primarily reflect increased costs to support the ongoing Phase 2/3 clinical trial.

G&A Expenses: G&A expenses were \$4.0 million for the first six months ended June 30, 2017 compared to \$2.2 million for the first six months ended June 30, 2016, with the increase primarily driven by higher costs to support increased operations activity and costs associated with being a public company, including a \$0.7 million increase in stock-based compensation compared to the same period in the prior year.

Net Loss: Net loss for the first six months ended June 30, 2017 was \$18.1 million, or \$1.95 per common share (basic and diluted), compared to a net loss of \$16.0 million, or \$7.30 per common share (basic and diluted), for the first six months ended June 30, 2016. This calculation is based on 9.3 million average common shares outstanding for the six months ended June 30, 2017, compared to 2.2 million average shares outstanding for the same period in 2016.

Cash Position

Cash, cash equivalents and marketable securities were \$108.6 million at June 30, 2017 compared to \$31.2 million at December 31, 2016. In April 2017, Tocagen raised \$97.8 million of gross proceeds in the IPO.

About Toca 511 & Toca FC

Tocagen's lead product candidate is a two-part cancer-selective immunotherapy comprised of an investigational biologic, Toca 511, and an investigational small molecule, Toca FC. Toca 511 is a retroviral replicating vector (RRV) that selectively infects cancer cells and delivers a gene for the enzyme, cytosine deaminase (CD). Through this targeted delivery, only infected cancer cells carry the CD gene and produce CD protein. Toca FC is an orally administered prodrug, 5-fluorocytosine (5-FC), which is converted into high concentrations of an anti-cancer drug, 5-fluorouracil (5-FU), when it encounters CD. 5-FU kills cancer cells and immune-suppressive myeloid cells resulting in anti-cancer immune activation and subsequent tumor killing.

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. The U.S. Food and Drug Administration (FDA) has granted Toca 511 & Toca FC Breakthrough Therapy Designation for the treatment of recurrent HGG and the European Medicines Agency (EMA) has granted Toca 511 PRIME (PRiority MEDicines) designation for the treatment of HGG.

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, timing of updates from communications with the FDA and our plans regarding 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)

	June 30 , 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 108,642	\$ 31,245
Prepaid expenses and other assets	2,128	4,106
Total assets	<u>\$ 110,770</u>	<u>\$ 35,351</u>
Current liabilities	15,224	14,382
Notes payable and other long-term liabilities	6,979	10,435
Convertible promissory notes payable and subscription liability	-	3,538
Convertible preferred stock	-	131,413
Total stockholders' equity (deficit)	88,567	(124,417)
Total liabilities, convertible preferred stock and stockholders' equity	<u>\$ 110,770</u>	<u>\$ 35,351</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
License revenue	\$ 10	\$ 13	\$ 21	\$ 27
Operating expenses:				
Research and development	6,632	6,530	13,256	12,999
General and administrative	2,030	1,103	3,970	2,214
Total operating expenses	8,662	7,633	17,226	15,213
Loss from operations	(8,652)	(7,620)	(17,205)	(15,186)
Other expense, net	(414)	(422)	(934)	(862)
Net loss	<u>\$ (9,066)</u>	<u>\$ (8,042)</u>	<u>\$ (18,139)</u>	<u>\$ (16,048)</u>
Net loss per common share, basic and diluted	<u>\$ (0.56)</u>	<u>\$ (3.66)</u>	<u>\$ (1.95)</u>	<u>\$ (7.30)</u>
Weighted-average number of common shares outstanding, basic and diluted	16,330,996	2,198,739	9,308,386	2,198,409

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Media Contact:
Monica May
Canale Communications
(619) 849-5383
monica@canalecomm.com

Investor Contact:
Elizabeth Broder
The Trout Group
(646) 378-2945
ebroder@troutgroup.com