
**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**

November 8, 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 November 8, 2017, Tocagen Inc. issued a press release announcing its financial results for the third quarter ended September 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 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.

Date: November 8, 2017

Tocagen Inc.

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



Tocagen Reports Third Quarter 2017 Financial and Business Results

SAN DIEGO – Nov. 8, 2017 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results for the third quarter ended September 30, 2017 and business highlights.

"Recent operational highlights include the acceleration of Toca 511 & Toca FC development into a pivotal Phase 3 trial and the presentation of updated Phase 1 data in patients with recurrent high-grade glioma at the recent AACR-NCI-EORTC meeting," said Marty Duvall, chief executive officer of Tocagen. "Advancing the development of Toca 511 & Toca FC with the prospect of helping more patients with brain cancer is core to Tocagen's mission and vision. The results we're seeing in our earlier trials encourage further development of our novel gene therapy approach with the goal of achieving transformative outcomes for patients with cancer."

Third Quarter 2017 and Recent Corporate Progress

- **Toca 5 trial accelerated into Phase 3:** On October 26, 2017, Tocagen announced that based on communications with the U.S. Food and Drug Administration (FDA) under Breakthrough Therapy Designation, Tocagen accelerated Toca 511 & Toca FC clinical development by modifying the original two-step trial design (Phase 2 followed by a Phase 3) into a seamless, pivotal trial, known as the Toca 5 trial.
- **Updated Phase 1 data presented:** Research collaborators presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on October 27, 2017, updated durable complete response data from the Phase 1 trial of Toca 511 & Toca FC in patients with high-grade glioma (HGG). Two previously announced partial responders converted to complete responses, bringing the total number of complete responses to six. The median duration of response has not been reached after nearly three years of follow up.
- **Grant to support development of products for orphan diseases awarded:** As previously announced, the FDA awarded Tocagen a \$2 million grant, payable over four years, to support the Toca 5 trial. More details on the grant awarded through the Orphan Products Clinical Trials Grants Program are available at FDA.gov.
- **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 HGG.

Third Quarter 2017 Financial Results

Research and Development (R&D) Expenses: R&D expenses were \$7.6 million for each of the quarters ended September 30, 2017 and 2016. The R&D expenses in both periods were primarily driven by costs to support the Toca 5 trial.

General and Administrative (G&A) Expenses: G&A expenses were \$2.2 million for the quarter ended September 30, 2017, compared to \$1.0 million for the quarter ended September 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 third quarter of 2017, including a \$0.7 million increase in stock-based compensation compared to the same period in the prior year.

Net Loss: Net loss was \$10.0 million, or \$0.50 per common share (basic and diluted), for the quarter ended September 30, 2017, compared to a net loss of \$9.0 million, or \$4.09 per common share (basic

and diluted), for the quarter ended September 30, 2016. The 2017 calculation is based on 19.8 million average common shares outstanding during the third quarter of 2017, compared to 2.2 million average common shares outstanding for the third quarter of 2016.

2017 Nine-Month Results

R&D Expenses: R&D expenses were \$20.8 million for the nine months ended September 30, 2017 compared to \$20.6 million for the nine months ended September 30, 2016. Similar to the third quarter results, the R&D expenses primarily reflect costs to support the Toca 5 clinical trial.

G&A Expenses: G&A expenses were \$6.2 million for the first nine months ended September 30, 2017 compared to \$3.2 million for the first nine months ended September 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 \$1.4 million increase in stock-based compensation compared to the same period in the prior year.

Net Loss: Net loss for the first nine months ended September 30, 2017 was \$28.1 million, or \$2.19 per common share (basic and diluted), compared to a net loss of \$25.0 million, or \$11.39 per common share (basic and diluted), for the first nine months ended September 30, 2016. This calculation is based on 12.8 million average common shares outstanding for the nine months ended September 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 \$99.6 million at September 30, 2017 compared to \$31.2 million at December 31, 2016. In April 2017, Tocagen raised \$97.8 million of gross proceeds in an initial public offering (IPO).

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. 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. Together, the Toca 511 & Toca FC combination directly kills cancer cells and immune-suppressive myeloid cells resulting in activation of the immune system against the 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. 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 the timing and success of our clinical trials and planned clinical trials. 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)

	September 30, 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 99,573	\$ 31,245
Prepaid expenses and other assets	2,597	4,106
Total assets	\$ 102,170	\$ 35,351
Current liabilities	16,738	14,382
Notes payable and other long-term liabilities	5,317	10,435
Convertible promissory notes payable and subscription liability	-	3,538
Convertible preferred stock	-	131,413
Total stockholders' equity (deficit)	80,115	(124,417)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 102,170	\$ 35,351

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
License revenue	\$ 10	\$ 11	\$ 31	\$ 38
Operating expenses:				
Research and development	7,563	7,586	20,819	20,585
General and administrative	2,184	956	6,154	3,170
Total operating expenses	<u>9,747</u>	<u>8,542</u>	<u>26,973</u>	<u>23,755</u>
Loss from operations	(9,737)	(8,531)	(26,942)	(23,717)
Other expense, net	(216)	(469)	(1,150)	(1,331)
Net loss	<u>\$ (9,953)</u>	<u>\$ (9,000)</u>	<u>\$ (28,092)</u>	<u>\$ (25,048)</u>
Net loss per common share, basic and diluted	<u>\$ (0.50)</u>	<u>\$ (4.09)</u>	<u>\$ (2.19)</u>	<u>\$ (11.39)</u>
Weighted-average number of common shares outstanding, basic and diluted	19,809,449	2,200,509	12,847,206	2,199,114

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