
**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**

March 8, 2018

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 March 8, 2018, Tocagen Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 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 March 8, 2018.](#)

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: March 8, 2018

Tocagen Inc.

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



Tocagen Reports Fourth Quarter and Full Year 2017 Financial and Business Results

SAN DIEGO – March 8, 2018 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2017.

"We had an excellent finish to the year with the acceleration of Toca 511 & Toca FC development into a pivotal Phase 3 trial and the presentation of updated data demonstrating continued favorable safety and long-term durable responses in patients with recurrent high-grade glioma," said Marty Duvall, chief executive officer of Tocagen. "With the closing of our upsized public offering in 2017 and enrollment in our Phase 3 trial remaining on track to complete in 2018, we believe we are well positioned to advance our lead program and platform technology in the year ahead."

Fourth Quarter 2017 and Recent Progress

- **Acceleration of Toca 511 & Toca FC into pivotal Phase 3 trial:** In October 2017, based on Tocagen's 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 Phase 3 trial, known as the Toca 5 trial.
- **Updated durable complete response data presented:** In October 2017, research collaborators presented updated durable complete response data from a Phase 1 trial of Toca 511 & Toca FC in patients with high-grade glioma (HGG), a type of brain tumor, at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. In addition to a continued favorable safety profile, six complete responses were reported for which the median duration of response had not been reached after nearly three years of follow up.
- **Orphan medicinal product designation granted from EMA:** In March 2018, Tocagen announced the European Medicines Agency granted orphan medicinal product designation to Toca 511 (vocimagene amiretroreprevec) & Toca FC (flucytosine) for the treatment of patients with glioma.
- **Publication of preclinical data:** In December 2017, data were published in Molecular Therapy — Oncolytics demonstrating the efficacy of intravenous (IV) administration of Toca 511 and 5-FC in a preclinical model of metastatic colorectal cancer, and in Human Gene Therapy demonstrating retroviral replicating vectors' ability to selectively deliver multiple genes to cancer cells.

2018 Milestones

- Complete enrollment of pivotal Phase 3 Toca 5 trial in recurrent HGG.
- Report Toca 6 activity and safety data in metastatic solid tumors.
- Update European regulatory path under PRIME (PRiority MEdicines) designation.
- Advance clinical development plan evaluating Toca 511 & Toca FC in newly diagnosed HGG.
- Advance Tocagen's retroviral replicating vector platform with anti-PD-L1 in investigational new drug (IND)-enabling studies.

Fourth Quarter 2017 Financial Results

Research and Development (R&D) Expenses: R&D expenses were \$8.3 million for the quarter ended December 31, 2017, compared to \$6.6 million for the quarter ended December 31, 2016. The R&D

expenses in both periods were primarily driven by costs to support the Toca 5 trial and to support the manufacturing of drug product. The increase in 2017 reflects primarily higher personnel costs as compared to the same period in 2016.

General and Administrative (G&A) Expenses: G&A expenses were \$2.4 million for the quarter ended December 31, 2017, compared to \$1.4 million for the quarter ended December 31, 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 fourth 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 \$10.8 million, or \$0.55 per common share (basic and diluted), for the quarter ended December 31, 2017, compared to a net loss of \$8.4 million, or \$3.83 per common share (basic and diluted), for the quarter ended December 31, 2016. The 2017 calculation is based on 19.8 million average common shares outstanding for the fourth quarter of 2017, compared to 2.2 million average common shares outstanding for the fourth quarter of 2016.

2017 Twelve-Month Results

R&D Expenses: R&D expenses were \$29.1 million for the 12 months ended December 31, 2017, compared to \$27.2 million for the 12 months ended December 31, 2016. The increase in R&D expenses primarily reflects increased personnel costs to support the Toca 5 clinical trial.

G&A Expenses: G&A expenses were \$8.6 million for the 12 months ended December 31, 2017, compared to \$4.5 million for the 12 months ended December 31, 2016, with the increase primarily driven by higher costs to support increased operations activity and costs associated with being a public company, including a \$1.9 million increase in stock-based compensation compared to the same period in the prior year.

Net Loss: Net loss was \$38.9 million, or \$2.66 per common share (basic and diluted), for the 12 months ended December 31, 2017, compared to a net loss of \$33.5 million, or \$15.22 per common share (basic and diluted), for the 12 months ended December 31, 2016. The 2017 calculation is based on 14.6 million average common shares outstanding for the 12 months ended December 31, 2017, compared to 2.2 million average shares outstanding for the same period in the prior year.

Cash Position and Guidance

Cash, cash equivalents and marketable securities were \$88.7 million at December 31, 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). Based on current operating plans, Tocagen estimates the total cash used in 2018 to fund operations, capital expenditures and debt amortization will not exceed \$50 million.

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. Toca FC is an orally administered prodrug, 5-fluorocytosine (5-FC), which is converted into 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's lead investigational product candidate, Toca 511 & Toca FC, is under evaluation in a pivotal Phase 3 trial for 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) for the treatment of HGG. For more information about Tocagen, visit www.tocagen.com.

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, activities related to development of our current and future product candidates in additional indications and our plan to update our regulatory plans. 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)

	December 31, 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 88,725	\$ 31,245
Prepaid expenses and other assets	3,348	4,106
Total assets	\$ 92,073	\$ 35,351
Current liabilities	17,330	14,382
Notes payable and other long-term liabilities	3,661	10,435
Convertible promissory notes payable and subscription liability	-	3,538
Convertible preferred stock	-	131,413
Total stockholders' equity (deficit)	71,082	(124,417)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 92,073	\$ 35,351

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

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
License revenue	\$ 10	\$ 11	\$ 41	\$ 49
Operating expenses:				
Research and development	8,294	6,633	29,113	27,218
General and administrative	2,403	1,352	8,557	4,522
Total operating expenses	<u>10,697</u>	<u>7,985</u>	<u>37,670</u>	<u>31,740</u>
Loss from operations	(10,687)	(7,974)	(37,629)	(31,691)
Other expense, net	(150)	(456)	(1,300)	(1,787)
Net loss	<u>\$ (10,837)</u>	<u>\$ (8,430)</u>	<u>\$ (38,929)</u>	<u>\$ (33,478)</u>
Net loss per common share, basic and diluted	<u>\$ (0.55)</u>	<u>\$ (3.83)</u>	<u>\$ (2.66)</u>	<u>\$ (15.22)</u>
Weighted-average number of common shares outstanding, basic and diluted	19,831,413	2,202,493	14,607,909	2,199,964

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