
**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 10, 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 May 10, 2018, Tocagen Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2018 . 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 10, 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: May 10, 2018

Tocagen Inc.

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



Tocagen Reports First Quarter 2018 Financial and Business Results

SAN DIEGO – May 10, 2018 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results and business highlights for the first quarter ended March 31, 2018.

“We are off to a strong start this year and are well positioned to execute on our key priorities, including completing enrollment in our Phase 3 trial in recurrent brain cancer by year end,” said Marty Duvall, chief executive officer of Tocagen. “In parallel, we are working to expand Toca 511 & Toca FC into newly diagnosed brain cancer while exploring its potential in other tumor types.”

First Quarter 2018 and Recent Highlights

- **Entered into a license agreement with ApolloBio:** In April 2018, Tocagen and ApolloBio entered a license agreement to develop and commercialize Toca 511 & Toca FC within the greater China region. Tocagen is eligible to receive up to \$127 million in upfront payment, development and commercial milestones, plus additional double-digit tiered sales royalties. Upfront and near-term development milestone payments total up to \$20 million. More details are available in the corresponding Form 8-K filed with the U.S. Securities and Exchange Commission (SEC).
- **Updated durable response data from Phase 1 recurrent high grade glioma (rHGG) resection study:** Updated durable response data from the Phase 1 study involving patients with rHGG who received Toca 511 & Toca FC at the time of surgical resection were presented by trial investigators at the 2018 American Academy of Neurology (AAN) Annual Meeting and 2018 American Association of Neurological Surgeons (AANS) Annual Scientific Meeting. Tocagen previously presented data from this study as of August 15, 2017. In the presentations at AAN and AANS, updated data showed Toca 511 & Toca FC continue to demonstrate a favorable safety profile and all study responders remained alive and in complete response as of December 20, 2017. As of this cutoff date, the median duration of durable response had not yet been reached, with a median follow-up period of 37.4 months.
- **Presented preliminary Toca 6 Phase 1 data:** At the American Association for Cancer Research (AACR) Annual Meeting 2018, research collaborators presented preliminary clinical data that suggest the potential feasibility of intravenous (IV) administration of Toca 511 from the ongoing Toca 6 Phase 1 trial of Toca 511 & Toca FC in patients with advanced solid tumors. Safety, tolerability and confirmation of vector deposition in metastatic tumors was demonstrated in five patients with advanced solid tumors who received Toca 511 intravenously. These data inform Tocagen’s plans to initiate additional studies evaluating the efficacy of Toca 511 & Toca FC in patients with advanced cancers.

First Quarter 2018 Financial Results

Research and Development (R&D) Expenses: R&D expenses were \$10.4 million for the quarter ended March 31, 2018, compared to \$6.6 million for the quarter ended March 31, 2017. The increase in R&D expenses in 2018 was primarily driven by higher costs to support the expanded Toca 5 trial and increased activities in manufacturing of Toca 511 & Toca FC.

General and Administrative (G&A) Expenses: G&A expenses were \$2.4 million for the quarter ended March 31, 2018, compared to \$1.9 million for the quarter ended March 31, 2017. The increase in G&A

expenses was primarily due to increased stock-based compensation expense and costs associated with being a public company during the first quarter of 2018.

Net Loss: Net loss was \$12.9 million, or \$0.65 per common share (basic and diluted), for the quarter ended March 31, 2018, compared to a net loss of \$9.1 million, or \$4.11 per common share (basic and diluted), for the quarter ended March 31, 2017. The 2018 calculation is based on 19.9 million average common shares outstanding for the first quarter of 2018, compared to 2.2 million average common shares outstanding for the first quarter of 2017.

Cash Position and Guidance

Cash, cash equivalents and marketable securities were \$74.0 million at March 31, 2018 compared to \$88.7 million at December 31, 2017. Subsequent to the close of the first quarter 2018, Tocagen signed a license agreement with ApolloBio and expects to receive \$16 million by early in the third quarter of 2018, according to the terms of the licensing agreement. Tocagen reiterates its annual guidance and continues to estimate 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 (vocimagene amiretrorepvec) 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, infected cancer cells carry the CD gene and produce CD. Toca FC is an orally administered, extended-release formulation of the 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 in the tumor microenvironment resulting in anti-cancer immune activation and subsequent tumor killing.

About Tocagen Inc.

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 (rHGG), 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 rHGG and the European Medicines Agency (EMA) has granted Toca 511 PRIME (PRiority MEdicines) designation for the treatment of glioma. 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 enrollment, timing and success of our clinical trials and planned clinical trials, expectations regarding our preclinical development activities, plans related to development of our current and future product candidates in additional indications, and expectations regarding near term payments from our partner in the greater China region. 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; the ability of our China partner to receive the necessary government approvals to make the required payments to us; 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)

| | March 31 , 2018 | December 31, 2017 |
|--|----------------------------|------------------------------|
| | <u>(unaudited)</u> | |
| Cash, cash equivalents and marketable securities | \$ 73,998 | \$ 88,725 |
| Prepaid expenses and other assets | 4,741 | 3,348 |
| Total assets | <u>\$ 78,739</u> | <u>\$ 92,073</u> |
| Current liabilities | 16,902 | 17,330 |
| Notes payable and other long-term liabilities | 2,159 | 3,661 |
| Total stockholders' equity | 59,678 | 71,082 |
| Total liabilities and stockholders' equity | <u>\$ 78,739</u> | <u>\$ 92,073</u> |

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

| | Three Months Ended | |
|---|--------------------|-------------------|
| | March 31, | |
| | 2018 | 2017 |
| | <u>(unaudited)</u> | |
| License revenue | \$ 9 | \$ 11 |
| Operating expenses: | | |
| Research and development | 10,436 | 6,624 |
| General and administrative | 2,419 | 1,940 |
| Total operating expenses | <u>12,855</u> | <u>8,564</u> |
| Loss from operations | (12,846) | (8,553) |
| Other expense, net | (34) | (520) |
| Net loss | <u>\$ (12,880)</u> | <u>\$ (9,073)</u> |
| Net loss per common share, basic and diluted | <u>\$ (0.65)</u> | <u>\$ (4.11)</u> |
| Weighted-average number of common shares outstanding, basic and diluted | 19,905,871 | 2,207,747 |

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