
**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 7, 2019

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.)

**4242 Campus Point Court, Suite 500
San Diego, California**
(Address of principal executive offices)

92121
(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 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. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	TOCA	The Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Tocagen Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2019 . 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 7, 2019.

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 7, 2019

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



Tocagen Reports First Quarter 2019 Financial and Business Results

SAN DIEGO – May 7, 2019 – 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, 2019.

“We had a strong start to the year with excellent progress on multiple fronts related to our Phase 3 Toca 5 trial of Toca 511 & Toca FC in patients with recurrent high grade glioma and potential commercial launch,” said Marty Duvall, chief executive officer of Tocagen. “We ended the quarter well capitalized to fund operations into 2020 and look forward to the pending interim analysis of the Toca 5 trial this quarter and the final analysis by the end of the year.”

First Quarter 2019 and Recent Highlights

- **Expanded leadership team** : Fairouz Kabbinavar, M.D., FACP, was appointed senior vice president, clinical development, to oversee the advancement of Tocagen’s platform and lead product candidate, Toca 511 & Toca FC. Prior to joining Tocagen, Dr. Kabbinavar was principal medical director at Genentech where he led the development of cancer immunotherapy TECENTRIQ® (atezolizumab) in small cell lung cancer as well as serving as the clinical lead for the head and neck cancer program. With this addition, Tocagen further adds to its leadership team’s deep biopharmaceutical R&D and commercialization experience, positioning the company for potential BLA filing and commercialization. Acting chief medical officer Lori A. Kunkel, M.D. has returned to the company’s board of directors.
- **Presented Toca 511 & Toca FC data** : In April, Tocagen presented clinical and preclinical data at the American Association for Cancer Research (AACR) Annual Meeting 2019 and the 2019 American Association of Neurological Surgeons (AANS) Annual Meeting. New preclinical data demonstrated increased survival from the combination of Toca 511 & Toca FC with either temozolomide or cyclophosphamide. These results support the planned Phase 2/3 trial (NRG-BN006) evaluating Toca 511 & Toca FC in combination with standard of care, including temozolomide, in patients with newly diagnosed glioblastoma (GBM) to be conducted by NRG Oncology under its NCI-funded grant.

First Quarter 2019 Financial Results

Research and Development (R&D) Expenses: R&D expenses were \$12.4 million for the quarter ended March 31, 2019, compared to \$10.4 million for the quarter ended March 31, 2018. 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 2019 reflects primarily higher manufacturing spend as compared to the same period in 2018.

General and Administrative (G&A) Expenses: G&A expenses were \$4.4 million for the quarter ended March 31, 2019, compared to \$2.4 million for the quarter ended March 31, 2018. The increase in G&A expenses was primarily due to higher personnel costs and contracted services to support the increased activity.

Net Loss: Net loss was \$17.1 million, or \$0.74 per common share (basic and diluted), for the quarter ended March 31, 2019, compared to a net loss of \$12.9 million, or \$0.65 per common share (basic and diluted), for the quarter ended March 31, 2018. The 2019 calculation is based on 23.0 million average common shares outstanding for the first quarter of 2019, compared to 19.9 million average common shares outstanding for the first quarter of 2018. Our average shares outstanding increased primarily as a result of selling 3.0 million shares in a public offering in December 2018.

Cash Position

Cash, cash equivalents and marketable securities were \$80.1 million at March 31, 2019 compared to \$96.1 million at December 31, 2018.

About Toca 511 & Toca FC

Tocagen's lead product candidate is a two-part cancer-selective immunotherapy comprising an investigational biologic, Toca 511 (vocimagene amiretrorepvec), and an investigational small molecule, Toca FC (flucytosine, extended-release). 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, 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 (Toca 5) for recurrent high grade glioma (HGG), a disease with significant unmet medical need. The U.S. Food and Drug Administration awarded Tocagen an orphan drug grant for the Toca 5 trial and has granted Toca 511 & Toca FC Breakthrough Therapy Designation for the treatment of recurrent HGG. The European Medicines Agency has granted Toca 511 PRIME (PRiority MEDicines) designation for the treatment of glioma.

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 results of our and our collaborator's clinical trials and planned clinical trials, expectations regarding the timing of regulatory submissions and reviews, expectations regarding our preclinical research and development activities, expectations regarding our use of cash in 2019, and plans related to development of our current and future product candidates in additional indications. 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)

	March 31, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 80,123	\$ 96,086
Prepaid expenses and other assets	14,605	6,995
Total assets	<u>\$ 94,728</u>	<u>\$ 103,081</u>
Current liabilities	16,177	16,534
Notes payable and other long-term liabilities	33,697	28,402
Total stockholders' equity	<u>44,854</u>	<u>58,145</u>
Total liabilities and stockholders' equity	<u>\$ 94,728</u>	<u>\$ 103,081</u>

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

	Three Months Ended	
	March 31,	
	2019	2018
	(unaudited)	
License revenue	\$ 9	\$ 9
Operating expenses:		
Research and development	12,434	10,436
General and administrative	4,446	2,419
Total operating expenses	16,880	12,855
Loss from operations	(16,871)	(12,846)
Other expense, net	(213)	(34)
Net loss	\$ (17,084)	\$ (12,880)
Net loss per common share, basic and diluted	\$ (0.74)	\$ (0.65)
Weighted-average number of common shares outstanding, basic and diluted	23,040,951	19,905,871

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SOURCE Tocagen Inc.