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

February 27, 2019
Date of Report (Date of earliest event reported)

Tocagen Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38052**	**26-1243872**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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. ☒

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2019, Tocagen Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 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 February 27, 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: February 27, 2019

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

Exhibit 99.1

Tocagen Reports Fourth Quarter and Full Year 2018 Financial and Business Results

SAN DIEGO – February 27, 2019 – 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, 2018.

"We had a very strong close to the year, accomplishing all of our 2018 business goals. In particular, NRG Oncology's selection of Toca 511 & Toca FC for a Phase 2/3 trial in newly diagnosed glioblastoma was a major accomplishment for our team and we look forward to initiating this trial in late 2019. Expansion of our late-stage cancer-selective gene therapy program regimen into the front-line indication could pave the way to having a greater impact on more patients in the years ahead," said Marty Duvall, chief executive officer of Tocagen. "Furthermore, having ended the year with approximately $96 million in cash, we have a favorable financial position as we look towards the results in 2019 from our Phase 3 Toca 5 trial in recurrent high grade glioma and build for success going into 2020."

Fourth Quarter 2018 Highlights

- NRG Oncology, a member of the National Cancer Institute's National Clinical Trial Network, announced in November 2018 plans to conduct and sponsor a clinical trial to evaluate Toca 511 & Toca FC for the treatment of patients with newly diagnosed glioblastoma (GBM). The proposed NRG-BN006 Phase 2/3 trial will be the first clinical trial of the Toca 511 & Toca FC regimen in the newly diagnosed GBM setting, and is expected to commence in late 2019. NRG Oncology conducts practice-defining, multi-institutional trials funded primarily by the NCI.
- Under Tocagen's PRIME (PRIority MEdicines) designation for Toca 511 & Toca FC, the European Medicines Agency indicated that the statistical analyses, seamless design and use of overall survival as the primary endpoint in the ongoing Phase 3 Toca 5 clinical trial are appropriate for a potential marketing authorization applications for Toca 511 & Toca FC in Europe.
- Tocagen presented clinical and preclinical data at congresses hosted by the Society for Immunotherapy of Cancer (SITC) and Society for Neuro-Oncology (SNO). We identified immunologic biomarkers in our clinical trials that may help predict patient outcomes following treatment with Toca 511 & Toca FC, and preclinical studies demonstrated the additive benefits of combining Toca 511 & Toca FC with chemotherapy.
- In December 2018, Tocagen raised $30.0 million of gross proceeds in an underwritten public offering of its common stock.

2019 Milestones

- Toca 5 second interim analysis expected in the second quarter of 2019
- Toca 5 final analysis planned for the fourth quarter of 2019
- Prepare to initiate a rolling biologics license application (BLA) for Toca 511 & Toca FC in recurrent high grade glioma
- Build U.S. commercial team for potential launch of Toca 511 & Toca FC
- NRG Oncology to initiate NRG-BN006 clinical trial evaluating Toca 511 & Toca FC in newly diagnosed GBM in late 2019
- Report updated Toca 6 safety and immune activity data in advanced solid tumors

Fourth Quarter 2018 Financial Results

Research and Development (R&D) Expenses: R&D expenses were $15.6 million for the quarter ended December 31, 2018, compared to $8.3 million for the quarter ended December 31, 2017. 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 2018 reflects primarily higher manufacturing spend as compared to the same period in 2017.

General and Administrative (G&A) Expenses: G&A expenses were $3.5 million for the quarter ended December 31, 2018, compared to $2.4 million for the quarter ended December 31, 2017. The increase in G&A expenses was primarily due to higher costs to support increased operations activity.

Net Loss: Net loss was $19.6 million, or $0.96 per common share (basic and diluted), for the quarter ended December 31, 2018, compared to a net loss of $10.8 million, or $0.55 per common share (basic and diluted), for the quarter ended December 31, 2017. The 2018 calculation is based on 20.5 million average common shares outstanding for the fourth quarter of 2018, compared to 19.8 million average common shares outstanding for the fourth quarter of 2017.

2018 Twelve-Month Results

License Revenue: License revenue was $18.0 million for the 12 months ended December 31, 2018, compared to less than $0.1 million for the 12 months ended December 31, 2017. The 2018 revenue was associated with a $16.0 million upfront payment and a $2.0 million development milestone earned upon completion of enrollment in the Toca 5 clinical study, both recognized under Tocagen's license agreement with ApolloBio.

R&D Expenses: R&D expenses were $51.1 million for the 12 months ended December 31, 2018, compared to $29.1 million for the 12 months ended December 31, 2017. The increase in R&D expenses primarily reflects increased costs in manufacturing and our Toca 5 clinical trial.

G&A Expenses: G&A expenses were $12.8 million for the 12 months ended December 31, 2018, compared to $8.6 million for the 12 months ended December 31, 2017, with the increase primarily driven by higher personnel costs and costs to support increased operations activity.

Net Loss: Net loss was $49.0 million, or $2.44 per common share (basic and diluted), for the 12 months ended December 31, 2018, compared to a net loss of $38.9 million, or $2.66 per common share (basic and diluted), for the 12 months ended December 31, 2017. The 2018 calculation is based on 20.1 million average common shares outstanding for the 12 months ended December 31, 2018, compared to 14.6 million average common shares outstanding for the prior year.

Cash Position and Guidance

Cash, cash equivalents and marketable securities were $96.1 million at December 31, 2018 compared to $88.7 million at December 31, 2017. Total gross cash burn to support operations was $51.3 million for the year ended December 31, 2018. Based on current operating plans, Tocagen estimates the total cash used in 2019 to fund operations and capital expenditures will be approximately $65 million.

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)

	December 31, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 96,086	$ 88,725
Prepaid expenses and other assets	6,995	3,348
Total assets	$ 103,081	$ 92,073
Current liabilities	16,534	17,330
Notes payable and other long-term liabilities	28,402	3,661
Total stockholders' equity	58,145	71,082
Total liabilities and stockholders' equity	$ 103,081	$ 92,073

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

	Three Months Ended December 31,		Years Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
License revenue	$ 9	$ 10	$ 18,036	$ 41
Operating expenses:				
Research and development	15,619	8,294	51,080	29,113
General and administrative	3,498	2,403	12,809	8,556
Total operating expenses	19,117	10,697	63,889	37,669
Loss from operations	(19,108)	(10,687)	(45,853)	(37,628)
Other expense, net	(495)	(150)	(3,102)	(1,301)
Net loss	$ (19,603)	$ (10,837)	$ (48,955)	$ (38,929)
Net loss per common share, basic and diluted	$ (0.96)	$ (0.55)	$ (2.44)	$ (2.66)
Weighted-average number of common shares outstanding, basic and diluted	20,453,842	19,831,413	20,059,541	14,607,909

####

Media Contact:
Pam Lord
Canale Communications
(619) 849-6003
pam@canalecomm.com

Investor Contact:
Pete Rahmer
Endurance Advisors
(415) 515-9763
prahmer@enduranceadvisors.com

SOURCE Tocagen Inc.

####