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 12, 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. ☒

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 November 12, 2019, Tocagen Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 12, 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: November 12, 2019

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

Exhibit 99.1

Tocagen Reports Third Quarter 2019 Financial Results and Business Updates

SAN DIEGO – Nov. 12, 2019 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results and business highlights for the third quarter ended September 30, 2019.

“Following the topline readout of our Phase 3 Toca 5 trial, we have been conducting a thorough evaluation of the trial data including analysis of the pre-planned subgroups and molecular data in preparation for our presentation at the upcoming Society for Neuro-Oncology Annual Meeting on November 22,” said Marty Duvall, chief executive officer of Tocagen. “These data will inform our next steps with regulatory agencies to evaluate a potential path forward for Toca 511 & Toca FC in recurrent high grade glioma.”

Third Quarter 2019 and Recent Highlights

- **Toca 5 final analysis**: On September 12, Tocagen announced the pivotal Toca 5 Phase 3 clinical trial evaluating Toca 511 & Toca FC in patients with recurrent high grade glioma (HGG) missed the primary endpoint of overall survival compared to standard of care treatment and all secondary endpoints.
- **Toca 5 data to be presented in plenary session at SNO:** The Phase 3 Toca 5 trial results will be presented on Friday, November 22, 2019 at 11:50 a.m. MT at the Society for Neuro-Oncology Annual Meeting (SNO) by Timothy Cloughesy, M.D., director of the University of California, Los Angeles, neuro-oncology program. Also, a poster will be presented by NRG Oncology outlining the trial design of the planned Phase 2/3 trial of Toca 511 & Toca FC in patients with newly diagnosed glioblastoma. Copies of the presentations will be available on Tocagen’s website following the presentations.
- **Reported updated Toca 6 data:** In November, Tocagen presented updated data, including immune modulation data, from the Phase 1b trial of Toca 6 in advanced solid tumors at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. The preliminary clinical data in 21 patients with a median 4 lines of prior chemotherapy suggested a signal of activity warranting further investigation. The poster can be found here.
- **Initiated corporate restructuring:** On October 3, Tocagen announced a restructuring to extend its cash position and focus resources on the clinical development of Toca 511 & Toca FC.

Third Quarter 2019 Financial Results

License revenue: License revenue was less than $0.1 million for the quarter ended September 30, 2019, compared to $18.0 million for the quarter ended September 30, 2018. The 2018

revenue was related to upfront payments and milestones earned under our license agreement with Apollobio.

Research and Development (R&D) Expenses: R&D expenses were $13.3 million for the quarter ended September 30, 2019, compared to $12.3 million for the quarter ended September 30, 2018. The R&D expenses in both periods were primarily driven by costs to support the Toca 5 trial and manufacturing of drug product. The increase quarter over quarter is primarily due to increased manufacturing related costs offset by reductions in clinical development expenses due to our Toca 5 trial reaching final analysis.

General and Administrative (G&A) Expenses: G&A expenses were $3.8 million for the quarter ended September 30, 2019, compared to $4.3 million for the quarter ended September 30, 2018. The decrease in G&A expenses was primarily due to non-income tax expense of $1.0 million in 2018 offset by increased contracted services to support commercial readiness activities. Based on our clinical trial results, commercial readiness activities have paused.

Net Loss: Net loss was $18.7 million, or $0.78 per common share (basic and diluted), for the quarter ended September 30, 2019, compared to a net loss of $0.4 million, or $0.02 per common share (basic and diluted), for the quarter ended September 30, 2018. The 2019 calculation is based on 23.9 million average common shares outstanding for the third quarter of 2019, compared to 20.0 million average common shares outstanding for the third quarter of 2018.

2019 Nine-Month Results

License revenue: License revenue was less than $0.1 million for the nine months ended September 30, 2019, compared to $18.0 million for the nine months ended September 30, 2018. The 2018 revenue was related to upfront payments and milestones earned under our license agreement with Apollobio.

R&D Expenses: R&D expenses were $37.7 million for the nine months ended September 30, 2019 compared to $35.5 million for the nine months ended September 30, 2018. The increase in R&D expenses for the nine months ended September 30, 2019 primarily reflect increased manufacturing related activities and personnel related costs offset by a reduction in clinical development expenses due to our Toca 5 trial reaching final analysis.

G&A Expenses: G&A expenses were $13.1 million for the nine months ended September 30, 2019 compared to $9.3 million for the nine months ended September 30, 2018, with the increase primarily driven by higher personnel and related costs, including stock-based compensation, due to additional headcount and increased contracted services to support commercial readiness activities. Based on our clinical trial results, commercial readiness activities have paused.

Net Loss: Net loss for the nine months ended September 30, 2019 was $52.9 million, or $2.25 per common share (basic and diluted), compared to a net loss of $29.4 million, or $1.47 per common share (basic and diluted), for the nine months ended September 30, 2018. This calculation is based on 23.5 million average common shares outstanding for the nine months ended September 30, 2019, compared to 19.9 million average shares outstanding for the same period in 2018.

Cash Position
Cash, cash equivalents and marketable securities were $55.3 million at September 30, 2019 compared to $96.1 million at December 31, 2018. In October 2019, Tocagen made a prepayment of $23.3 million toward its loan agreement. This amount was used to prepay $21.5 million of the outstanding principal plus accrued interest and a pro-rated portion of the final payment. After the prepayment, the remaining principal balance is $5.0 million. Due to the corporate restructuring, Tocagen refined its annual cash burn guidance and estimates the total cash used in 2019 to fund operations and capital expenditures will be approximately $60 million (down from approximately $65 million implied in the guidance provided in February 2019).

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 plans to evaluate its lead investigational product candidate, Toca 511 & Toca FC, in a Phase 2/3 trial for patients newly diagnosed with glioblastoma, sponsored by the NCI and conducted by NRG Oncology, and a Phase 1 trial in patients with non-muscle invasive bladder cancer. Tocagen is advancing preclinical programs from its versatile gene therapy platform that represents a new approach in cancer immunotherapy. 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 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)

	September 30, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 55,342	$ 96,086
Prepaid expenses and other assets	15,407	6,995
Total assets	$ 70,749	$ 103,081
Notes payable	27,843	26,201
Other liabilities	23,106	18,735
Total stockholders' equity	19,800	58,145
Total liabilities and stockholders' equity	$ 70,749	$ 103,081

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
License revenue	$ 9	$ 18,009	$ 27	$ 18,027
Operating expenses:				
Research and development	13,295	12,262	37,703	35,461
General and administrative	3,837	4,320	13,133	9,311
Total operating expenses	17,132	16,582	50,836	44,772
Income (loss) from operations	(17,123)	1,427	(50,809)	(26,745)
Other expense, net	(1,612)	(1,810)	(2,124)	(2,607)
Net loss	$ (18,735)	$ (383)	$ (52,933)	$ (29,352)
Net loss per common share, basic and diluted	$ (0.78)	$ (0.02)	$ (2.25)	$ (1.47)
Weighted-average number of common shares outstanding, basic and diluted	23,897,243	19,951,262	23,540,222	19,926,662

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