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 8, 2018
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, CA** (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 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 November 8, 2018, Tocagen Inc. issued a press release announcing its financial results for the second quarter ended September 30, 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 November 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.

Tocagen Inc.

Date: November 8, 2018

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

Exhibit 99.1

Tocagen Reports Third Quarter 2018 Financial and Business Results

SAN DIEGO – Nov. 8, 2018 – 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, 2018.

"We conclude the eventful third quarter of 2018 having met important milestones, including early completion of enrollment and the first interim analysis of our ongoing Phase 3 Toca 5 trial. We've also further improved our balance sheet to advance our lead program and execute against our goals," said Marty Duvall, chief executive officer of Tocagen. "With the planned second interim and final analyses for Toca 5 anticipated in 2019, we are preparing for a potential rolling BLA submission and planning for commercial launch."

Third Quarter 2018 and Recent Highlights

- **First interim analysis of Toca 5 Phase 3 trial:** In August 2018, Tocagen announced the Toca 5 pivotal Phase 3 trial evaluating Toca 511 (vocimagene amiretrorepvec) & Toca FC (extended-release flucytosine) in patients with recurrent high grade glioma (rHGG) will continue without modification following a pre-planned first interim analysis of data. An Independent Data Monitoring Committee completed its analysis at 50% of events occurring in the trial and recommended the trial continue without modification. Tocagen estimates the second interim analysis, at 75% of events in the trial, will occur in the first half of 2019 and that the final analysis will occur by the end of 2019.
- **Completed Toca 5 enrollment:** In September 2018, Tocagen completed the planned enrollment of 380 patients in the ongoing Toca 5 Phase 3 trial approximately three months ahead of schedule.
- **Received milestone payment from ApolloBio:** Completing the Toca 5 enrollment triggered a milestone payment of $2 million from ApolloBio, Tocagen's licensee of Toca 511 & Toca FC within the greater China region.
- **Initiated commercial organization buildout:** In September 2018, Mohamed Ladha joined Tocagen as vice president, head of commercial. Mr. Ladha will build, oversee and execute the global commercial strategies for Tocagen's oncology products upon regulatory approval in the United States and other key markets.
- **Presented Toca 6 data:** Tocagen presented new clinical data on Toca 511 & Toca FC in advanced solid tumors at the International Cancer Immunotherapy Conference in late September. Data showed favorable safety, vector deposition in "hot" and "cold" tumors and immune changes consistent with preclinical and clinical observations. Based on these data, Tocagen is now planning future safety and efficacy trials in select tumor types.
- **Publication of Toca 511 & Toca FC data:** In October 2018, two peer-reviewed clinical data manuscripts appeared in print related to Toca 511 & Toca FC in rHGG. Data published by Timothy F. Cloughesy and co-authors in *Neuro-Oncology* demonstrated multiyear durable responses observed in rHGG patients treated in a Toca 511 & Toca FC Phase 1 trial. Data published by Daniel J. Hogan and co-authors in *Clinical Cancer Research* demonstrated Toca 511 & Toca FC treatment was not associated with concerning integration sites and clonal

expansion. These manuscripts first published online May 12, 2018 and June 26, 2018, respectively.

Third Quarter 2018 Financial Results

License Revenue: License revenue was $18.0 million for the quarter ended September 30, 2018, compared to less than $0.1 million for the quarter ended September 30, 2017. The 2018 revenue was associated with a $16.0 million upfront payment recognized under Tocagen's license agreement with ApolloBio and a $2.0 million development milestone earned upon completion of enrollment in the Toca 5 clinical study.

Research and Development (R&D) Expenses: R&D expenses were $12.3 million for the quarter ended September 30, 2018, compared to $7.6 million for the quarter ended September 30, 2017. The increase in R&D expenses in 2018 was primarily driven by higher costs to support the expanded Toca 5 Phase 3 clinical study and manufacturing activities related to Toca 511.

General and Administrative (G&A) Expenses: G&A expenses were $4.3 million for the quarter ended September 30, 2018, compared to $2.2 million for the quarter ended September 30, 2017. The increase in G&A expenses was primarily due to foreign non-income tax expense of approximately $1 million paid under Tocagen's license agreement with ApolloBio and an increase in non-cash stock-based compensation expense.

Net Loss: Net loss was $0.4 million, or $0.02 per common share (basic and diluted), for the quarter ended September 30, 2018, compared to a net loss of $10.0 million, or $0.50 per common share (basic and diluted), for the quarter ended September 30, 2017. The reduction in net loss in 2018 was due to $18.0 million in revenue recognized under Tocagen's license agreement with ApolloBio. Tocagen recognized $1.5 million in income taxes for the quarter ended September 30, 2018 related to the license agreement with ApolloBio. The 2018 calculation is based on 20.0 million average common shares outstanding for the third quarter of 2018, compared to 19.8 million average shares outstanding for the third quarter of 2017.

2018 Nine-Month Results

License Revenue: License revenue was $18.0 million for the nine months ended September 30, 2018, compared to less than $0.1 million for the nine months ended September 30, 2017. The 2018 revenue was associated with a $16.0 million upfront payment recognized under Tocagen's license agreement with ApolloBio and a $2.0 million development milestone earned upon completion of enrollment in the Toca 5 clinical study.

R&D Expenses: R&D expenses were $35.5 million for the nine months ended September 30, 2018 compared to $20.8 million for the nine months ended September 30, 2017. Similar to the third quarter results, the R&D expenses primarily reflect increased costs to support the expanded Toca 5 Phase 3 clinical study, manufacturing activities related to Toca 511 & Toca FC and personnel and related costs due to increased headcount.

G&A Expenses: G&A expenses were $9.3 million for the nine months ended September 30, 2018 compared to $6.2 million for the nine months ended September 30, 2017. Similar to the third quarter

results, the G&A expenses primarily reflect the foreign non-income tax expense paid under Tocagen's license agreement with ApolloBio and an increase in non-cash stock-based compensation expense.

Net Loss: Net loss for the nine months ended September 30, 2018 was $29.4 million, or $1.47 per common share (basic and diluted), compared to a net loss of $28.1 million, or $2.19 per common share (basic and diluted), for the nine months ended September 30, 2017. This calculation is based on 19.9 million average common shares outstanding for the nine months ended September 30, 2018, compared to 12.8 million average shares outstanding for the same period in 2017.

Cash Position and Guidance
Cash, cash equivalents and marketable securities were $79.8 million at September 30, 2018 compared to $88.7 million at December 31, 2017. Tocagen refined its annual cash burn guidance and estimates the total cash used in 2018 to fund operations and capital expenditures will be approximately $50 million, resulting in a year-end cash balance of approximately $70 million, up from approximately $40 million implied in guidance provided in January 2018.

About Toca 511 & Toca FC
Tocagen's lead product candidate is a two-part cancer-selective immunotherapy comprising 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 (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. 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, expectations regarding our preclinical research and development activities, expectations regarding our use of cash and cash on hand at the end of the year, 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, 2018	December 31, 2017
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 79,849	$ 88,725
Prepaid expenses and other assets	10,504	3,348
Total assets	$ 90,353	$ 92,073
Current liabilities	14,594	17,330
Notes payable and other long-term liabilities	28,092	3,661
Total stockholders' equity	47,667	71,082
Total liabilities and stockholders' equity	$ 90,353	$ 92,073

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
License revenue	$ 18,009	$ 10	$ 18,027	$ 31
Operating expenses:				
Research and development	12,262	7,563	35,461	20,819
General and administrative	4,320	2,184	9,311	6,153
Total operating expenses	16,582	9,747	44,772	26,972
Income (loss) from operations	1,427	(9,737)	(26,745)	(26,941)
Other expense, net	(1,810)	(216)	(2,607)	(1,151)
Net loss	$ (383)	$ (9,953)	$ (29,352)	$ (28,092)
Net loss per common share, basic and diluted	$ (0.02)	$ (0.50)	$ (1.47)	$ (2.19)
Weighted-average number of common shares outstanding, basic and diluted	19,951,262	19,809,449	19,926,662	12,847,206

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