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

August 8, 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 August 8, 2019, Tocagen Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 8, 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: August 8, 2019

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

Exhibit 99.1

Tocagen Reports Second Quarter 2019 Financial Results and Business Updates

SAN DIEGO – August 8, 2019 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, today reported financial results and business highlights for the second quarter ended June 30, 2019.

"We are making excellent progress towards achieving our corporate objectives for the year. We are focused on providing the final analysis of our pivotal Phase 3 Toca 5 trial and preparing for a potential rolling BLA filing with FDA. The Toca 5 trial involving 403 patients with recurrent brain cancer will generate an extensive data set and holds promise to shape the treatment of these patients with a novel, multi-modality cancer-selective gene therapy in combination with surgery," said Marty Duvall, chief executive officer of Tocagen. "We also continue to execute our life cycle strategy for Toca 511 & Toca FC with the submission to FDA of a draft protocol for the planned Phase 2/3 trial of Toca 511 & Toca FC in patients with newly diagnosed glioblastoma sponsored by NRG Oncology, which remains on track to activate by the end of 2019. In addition, we recently advanced plans to evaluate Toca 511 & Toca FC in non-CNS tumors with a trial for patients with non-muscle invasive bladder cancer, which is also expected to initiate by the end of the year."

Second Quarter 2019 and Recent Highlights
2019 Corporate Milestones

- **Toca 5 second interim analysis completed**: On May 21, Tocagen announced the pivotal Toca 5 Phase 3 clinical trial evaluating Toca 511 & Toca FC in patients with recurrent high grade glioma (HGG) would continue without modification following a planned second interim analysis conducted by an Independent Data Monitoring Committee. Tocagen expects to report the final analysis of the Toca 5 trial this year.
- **Progress related to Toca 511 & Toca FC BLA and commercialization:** With Breakthrough Therapy Designation, Tocagen is preparing for the initiation of a rolling biologics license application, pending positive data from Toca 5. The company's launch readiness activities span disease state awareness, branding activities, distribution, channel and pricing strategies, payor and key opinion leader engagements and beginning to build the commercial and medical affairs infrastructure and team.
- **NRG Oncology trial in newly diagnosed glioblastoma (ndGBM) proceeding:** The Phase 2/3 trial to be conducted by NRG Oncology (NRG-BN006) evaluating Toca 511 & Toca FC in combination with standard of care (SOC) versus SOC alone in patients with ndGBM is proceeding towards initiation by year-end 2019.

- **Planned reporting of updated Toca 6 data**: Tocagen remains on track to provide updated data including immune modulation data from this Phase 1b trial in advanced solid tumors at an upcoming scientific congress this year.
- **Activation of Toca 8 clinical program in bladder cancer:** As part of Tocagen's life cycle plans for Toca 511 & Toca FC and based on encouraging preclinical data and results from the Toca 6 trial, the company plans to initiate a Phase 1b trial, Toca 8, in non-muscle invasive bladder cancer (NMIBC) in the second half of this year.
- **Preclinical research publication:** Tocagen's most recent preclinical research paper described the use of Tocagen's retroviral replicating platform to successfully deliver a single chain monoclonal antibody fragment against PD-L1 resulting in durable and highly selective anti-tumor activity compared to systemically administered anti-PD-L1 or anti-PD-1 monoclonal antibodies.

Second Quarter 2019 Financial Results

Research and Development (R&D) Expenses: R&D expenses were $12.0 million for the quarter ended June 30, 2019, compared to $12.8 million for the quarter ended June 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 decrease quarter over quarter is primarily due to reduced clinical trial costs in 2019 compared to 2018 as the Toca 5 trial nears completion.

General and Administrative (G&A) Expenses: G&A expenses were $4.9 million for the quarter ended June 30, 2019, compared to $2.6 million for the quarter ended June 30, 2018. The increase in G&A expenses was primarily due to higher personnel and related costs, including stock-based compensation, due to additional headcount and increased contracted services to support commercial readiness activities.

Net Loss: Net loss was $17.1 million, or $0.72 per common share (basic and diluted), for the quarter ended June 30, 2019, compared to a net loss of $16.1 million, or $0.81 per common share (basic and diluted), for the quarter ended June 30, 2018. The 2019 calculation is based on 23.7 million average common shares outstanding for the second quarter of 2019, compared to 19.9 million average common shares outstanding for the second quarter of 2018.

2019 Six-Month Results

R&D Expenses: R&D expenses were $24.4 million for the six months ended June 30, 2019 compared to $23.2 million for the six months ended June 30, 2018. The increase in R&D expenses for the six months ended June 30, 2019 primarily reflect increased personnel and related costs to support the Toca 5 clinical trial as well as manufacturing and other activities to support the potential commencement of a regulatory filing later this year following the completion of the study.

G&A Expenses: G&A expenses were $9.3 million for the six months ended June 30, 2019 compared to $5.0 million for the first six months ended June 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.

Net Loss: Net loss for the first six months ended June 30, 2019 was $34.2 million, or $1.46 per common share (basic and diluted), compared to a net loss of $29.0 million, or $1.45 per common share (basic and diluted), for the six months ended June 30, 2018. This calculation is based on 23.4 million average common shares outstanding for the six months ended June 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 $68.3 million at June 30, 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 HGG. 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)

	June 30, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 68,324	$ 96,086
Prepaid expenses and other assets	16,910	6,995
Total assets	$ 85,234	$ 103,081
Current liabilities	17,308	16,534
Notes payable and other long-term liabilities	31,440	28,402
Total stockholders' equity	36,486	58,145
Total liabilities and stockholders' equity	$ 85,234	$ 103,081

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
License revenue	$ 9	$ 9	$ 18	$ 18
Operating expenses:				
Research and development	11,974	12,763	24,408	23,199
General and administrative	4,850	2,573	9,296	4,992
Total operating expenses	16,824	15,336	33,704	28,191
Loss from operations	(16,815)	(15,327)	(33,686)	(28,173)
Other expense, net	(299)	(762)	(512)	(796)
Net loss	$ (17,114)	$ (16,089)	$ (34,198)	$ (28,969)
Net loss per common share, basic and diluted	$ (0.72)	$ (0.81)	$ (1.46)	$ (1.45)
Weighted-average number of common shares outstanding, basic and diluted	23,673,061	19,922,355	23,358,752	19,914,159

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