
**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

April 18, 2018
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.)

3030 Bunker Hill Street, Suite 230
San Diego, California
(Address of principal executive offices)

92109
(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 1.01. Entry into a Material Definitive Agreement.

On April 18, 2018, Tocagen Inc. (“Tocagen”), Beijing Apollo Venus Biomedical Technology Limited and ApolloBio Corp. (collectively, “ApolloBio”) entered into a license agreement (the “Agreement”) pursuant to which Tocagen granted to ApolloBio an exclusive license to develop and commercialize Toca 511 & Toca FC within the greater China region, including mainland China, Hong Kong, Macao and Taiwan (the “Licensed Territory”).

Pursuant to the Agreement, ApolloBio will make an upfront payment of \$16.0 million to Tocagen as a condition to the effectiveness of the license and other rights granted under the Agreement (as more fully described below). Tocagen will be also be eligible for additional future payments totaling up to \$111.0 million upon meeting certain development and commercial milestones, including \$4.0 million in near-term development milestones, including completion of enrollment in the Toca 5 study, in addition to low double-digit tiered royalty payments based on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances. ApolloBio will be responsible for all development and commercialization costs in the Licensed Territory.

ApolloBio must register the Agreement with People’s Republic of China (“PRC”) authorities and obtain currency conversion approval from PRC authorities to make the upfront payment, other than an initial installment payment that is payable within 10 days of execution of the Agreement. In the event that the initial installment of the upfront payment is not paid within 10 days of execution of the Agreement, or the remainder of the upfront payment is not paid within 90 days after execution of the Agreement, Tocagen has the right to terminate the Agreement upon written notice to ApolloBio. Other payments to be made under the Agreement are also subject to PRC currency exchange approval and may be subject to other approvals by PRC authorities. The license and other rights granted to ApolloBio under the Agreement are expected to become effective in the second quarter of 2018.

Unless earlier terminated, the Agreement will expire upon the expiration of the last-to-expire royalty term for any and all licensed products, which royalty term is, with respect to a licensed product in a particular region (*i.e.*, mainland China, Hong Kong, Macao and Taiwan) of the Licensed Territory (each, a “Region”), the latest of (i) 10 years after the first commercial sale of such licensed product in such Region, (ii) the expiration of all regulatory exclusivity as to such licensed product in such Region and (iii) the date of expiration of the last valid patent claim covering such licensed product in such Region. Either party may terminate the Agreement upon a material breach by the other party that remains uncured following 60 days (or, with respect to any payment breach, 10 days) after the date of written notice of such breach. ApolloBio may terminate the Agreement at any time by providing 90 days’ prior written notice to Tocagen. In addition, Tocagen may terminate the Agreement upon written notice to ApolloBio under specified circumstances if ApolloBio challenges the licensed patent rights.

The foregoing summary of the Agreement does not purport to be complete and is qualified in its entirety by reference to the complete Agreement, a copy of which will be filed, with confidential terms redacted, with the Securities and Exchange Commission as an exhibit to Tocagen’s Quarterly Report on Form 10-Q for the quarterly period ending June 30, 2018.

On April 19, 2018, Tocagen and ApolloBio issued a joint press release announcing the Agreement. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated April 19, 2018.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this report regarding matters that are not historical facts may be considered “forward-looking statements,” including, but not limited to, statements regarding the payments Tocagen expects to receive from ApolloBio under the Agreement, including the timing and amounts of such payments, ApolloBio’s development and regulatory capabilities and resources, the development and regulatory environment for oncology candidates and gene therapy candidates in the greater China region, and the market potential for oncology products and gene therapy products in the greater China region. Forward-looking statements are typically, but not always, identified by the use of words such as “may,” “would,” “believe,” “intend,” “plan,” “anticipate,” “estimate,” “expect,” and other similar terminology. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to: ApolloBio’s ability to obtain required currency exchange and other approvals from PRC authorities for payments under the Agreement; the uncertain timing of obtaining such approvals; regulatory developments in the greater China region, the United States and other countries; ApolloBio’s ability to execute on its strategy, including the availability to ApolloBio of sufficient capital for such purpose; the success, cost and timing of ApolloBio obtaining approval to import Toca 511 and Toca FC manufactured outside of the greater China region for use in clinical trials or for commercial distribution; tariffs or restrictions that PRC authorities may impose on the import of pharmaceutical products manufactured outside of the greater China region; the amount of PRC withholding tax and value added tax that ApolloBio will be required to deduct from any payments to Tocagen under the Agreement; the extent, if any, to which Tocagen is able to recover any such withheld amounts; ApolloBio’s diligence obligations and resource commitments with respect to the development and commercialization of other products in-licensed by ApolloBio from third parties and ApolloBio’s own internally-developed products; timing and success of Tocagen’s clinical trials and planned clinical trials of Toca 511 & Toca FC; timing and success of obtaining FDA approval of Toca 511 & Toca FC; and other risks detailed in Tocagen’s recent filings on Forms 10-K and 10-Q with the Securities and Exchange Commission. All forward-looking statements contained in this report speak only as of the date on which they were made. Tocagen undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

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.

Dated: April 19, 2018

Tocagen Inc.

By: /s/ Mark Foletta

Mark Foletta
Executive Vice President, Chief Financial
Officer



Tocagen and ApolloBio Enter License Agreement to Develop and Commercialize Toca 511 & Toca FC in the Greater China Region

Tocagen eligible to receive up to \$127 million in upfront payment, development and commercial milestones, plus additional double-digit tiered sales royalties

Upfront and near-term development milestones payments total up to \$20 million

SAN DIEGO AND BEIJING – April 19, 2018 – Tocagen Inc. (Nasdaq: TOCA), a clinical-stage, cancer-selective gene therapy company, and Beijing Apollo Venus Biomedical Technology Limited, an affiliate of ApolloBio Corp. (NEEQ: 430187), a biopharmaceutical company focused on oncology (collectively, “ApolloBio”), today announced they have entered into a license agreement providing ApolloBio with an exclusive license to develop and commercialize Toca 511 & Toca FC within the greater China region, including mainland China, Hong Kong, Macao and Taiwan.

Toca 511 & Toca FC is a cancer-selective immunotherapy currently under evaluation in an international Phase 3 trial, called Toca 5, for patients with recurrent high grade glioma (HGG), a type of brain tumor. The product candidate has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and PRIority MEDicines (PRIME) designation from the European Medicines Agency (EMA).

Under the terms of the agreement, ApolloBio will make an upfront payment of \$16 million to Tocagen, plus potential payments of \$4 million in near-term development milestones, including completion of enrollment in the Toca 5 study. Tocagen will be eligible for additional future payments totaling up to \$11 million upon meeting certain development and commercial milestones. In addition, low double-digit tiered royalty payments will be made based on net sales. ApolloBio will be responsible for all development and commercialization costs in the licensed territory.

“As an innovative biopharmaceutical company in China, ApolloBio is well positioned to leverage China’s recent regulatory changes supporting the development of new medicines,” said Marty Duvall, chief executive officer of Tocagen. “ApolloBio brings valuable regional expertise in product development, regulation and healthcare access, positioning our lead product to advance towards patients in the greater China region as quickly and efficiently as possible.”

The total number of new diagnoses of HGG expected in 2018 is about 180,000 worldwide and about 47,000 in the greater China region. Standard treatment for newly diagnosed HGG includes safe surgical removal of as much of the tumor as possible, followed by radiation therapy and chemotherapy. However, HGG recurs in most patients even after maximal treatment and there are currently very few treatment options available.

“We are committed to accelerating the availability of novel immuno-oncology treatments to patients with high unmet medical needs in the greater China region,” said Dr. Weiping Yang, chief executive officer of ApolloBio. “Toca 511 & Toca FC is a highly promising, best-in-class cancer-selective immunotherapy and we look forward to working with Tocagen to advance this innovative late-stage product towards commercialization.”

The license grant to ApolloBio is subject to the satisfaction of customary conditions and is expected to become effective in the second quarter of 2018. For more details, please refer to the corresponding Form 8-K filed today with the U.S. Securities and Exchange Commission (SEC).

About Toca 511 & Toca FC

Tocagen's lead product candidate is a two-part cancer-selective immunotherapy comprised of an investigational biologic, Toca 511 and an investigational small molecule, Toca FC. Toca 511 (vocimagene amiretrorepvec) 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, extended-release formulation of the 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 in the tumor microenvironment resulting in anti-cancer immune activation and subsequent tumor killing.

About ApolloBio Corp.

ApolloBio Corp. (NEEQ:430187) is an innovative Chinese biomedical company committed to research and development of innovative new medicines, accessing such new medicines through in-licensing, and additionally providing medical services. ApolloBio is focused on pharmaceutical products with significant market potential in China in the field of oncology; providing efficient access for American biomedical companies to enter into the Chinese market; and aiming to bring the newest and best medicines across the globe to the Chinese people. For more information, visit www.apollobio.com.

About Tocagen Inc.

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 for recurrent high-grade glioma (HGG), a disease with significant unmet medical need. The U.S. Food and Drug Administration (FDA) has granted Toca 511 & Toca FC Breakthrough Therapy Designation for the treatment of recurrent HGG and the European Medicines Agency (EMA) 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 the payments we expect to receive from ApolloBio under the license agreement, including the timing and amounts of such payments, ApolloBio's development and regulatory capabilities and resources, the development and regulatory environment for oncology candidates and gene therapy candidates in the greater China region, and the market potential for oncology products and gene therapy products in the greater China region. Risks that contribute to the uncertain nature of the forward-looking statements include: ApolloBio's ability to obtain required currency exchange and other approvals from PRC authorities for payments under the agreement; the uncertain timing of obtaining such approvals; regulatory developments in the greater China region, the United States and other countries; ApolloBio's ability to execute on its strategy, including the availability to ApolloBio of sufficient capital for such purpose; the success, cost and timing of ApolloBio obtaining approval to import Toca 511 and Toca FC manufactured outside of the greater China region for use in clinical trials or for commercial distribution; tariffs or restrictions that PRC authorities may impose on the import of pharmaceutical products manufactured outside of the greater China region; the amount of PRC withholding tax and value added tax that ApolloBio will be required to deduct from any payments to us under the agreement; the extent, if any, to which we are able to recover any such withheld amounts; ApolloBio's diligence obligations and resource commitments with respect to the development and commercialization of other products in-licensed by ApolloBio from third parties and ApolloBio's own internally-developed products; timing and success of our clinical trials and planned clinical trials of Toca 511 & Toca FC; and timing and success of obtaining FDA approval of Toca 511 & Toca FC. 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.

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Media Contact:

Monica May
Canale Communications
(619) 849-5383
monica@canalecomm.com

Investor Contact:

Gitanjali Jain Ogawa
Solebury Trout
(646) 378-2949
Gogawa@troutgroup.com