UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) August 8, 2019

Oncternal Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12230 El Camino Real **Suite 300** **San Diego, California**	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 434-1113

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication 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))

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	**ONCT**	**The Nasdaq Stock Market, LLC**

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 August 8, 2019, Oncternal Therapeutics, Inc. issued a press release announcing its financial results for the second quarter June 30, 2019. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "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 it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	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.

Oncternal Therapeutics, Inc.

Date: August 8, 2019

By: /s/ Richard G. Vincent
Name: Richard G. Vincent
Title: Chief Financial Officer

Oncternal Reports Second Quarter 2019 Financial Results and Provides Business Update

- Interim objective response rate of 100% in evaluable patients with CLL receiving the recommended dosing regimen of cirmtuzumab + ibrutinib supports opening Phase 2

- Two product candidates moving forward in clinical trials

- Conference call today at 5:00 p.m. EDT

SAN DIEGO, August 8, 2019 — Oncternal Therapeutics, Inc., (Nasdaq: ONCT) a clinical-stage biotechnology company developing potential first-in-class product candidates for cancers with critical unmet medical needs, today announced financial results for the second quarter, which ended June 30, 2019, and provided a business update.

“Oncternal is thrilled to provide its first quarterly results as a Nasdaq-listed Company. We are making great progress developing our clinical and preclinical programs as we head into the second half of 2019,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “We are very encouraged by initial results from our lead clinical program’s Phase 1/2 study of cirmtuzumab in combination with ibrutinib in patients with chronic lymphocytic leukemia, and excited to be opening the randomized Phase 2 portion of the study. The early results for cirmtuzumab in combination with ibrutinib in patients with mantle cell lymphoma are also encouraging, and we expect to report data in this patient population before the end of the year. With respect to our other pipeline programs, our clinical study of TK216 in combination with vincristine in patients with Ewing sarcoma is advancing as planned, and we expect to begin enrolling patients in an expansion cohort of this study soon. Finally, we anticipate selecting a construct for IND-enabling studies of our ROR1 CAR-T program before the end of this year.”

Recent Corporate Highlights

- In August 2019, Oncternal announced it has opened for enrollment its randomized Phase 2 study of cirmtuzumab, a ROR1-targeted monoclonal antibody, combined with ibrutinib in patients with chronic lymphocytic leukemia (CLL). The decision to open the Phase 2 portion of the Company’s ongoing Phase 1/2 CIRLL (Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma) clinical trial was triggered by favorable outcomes from the Part 1 dose-finding and Part 2 dose-confirming cohorts of the clinical trial, including the recently announced interim objective response rate (ORR) of 100% for the first nine CLL patients with evaluable data receiving the recommended dosing regimen who have completed 12 weeks of cirmtuzumab plus ibrutinib treatment in Part 2. The Company continues to see a well-tolerated safety profile consistent with that seen with ibrutinib treatment alone.

- In June 2019, Oncternal announced that the reverse merger between GTx, Inc., GTx's merger subsidiary and privately-held Oncternal Therapeutics, Inc., had closed and the combined company was renamed Oncternal Therapeutics, Inc. Trading on the Nasdaq stock exchange under the ticker symbol "ONCT" began on June 10, 2019. The closing of the merger was a transformative event that the Company believes will allow it to pursue its next level of corporate growth and continue to advance its oncology drug candidates in multiple cancer indications.
- In June 2019, Oncternal presented interim data from its ongoing Phase 1/2 study of cirmtuzumab in combination with ibrutinib at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting – the largest oncology conference of the year. Results from the first 12 patients with CLL treated in the Part 1 dose-finding portion of the Phase 1 study showed an interim ORR of 91.7% for the combination of cirmtuzumab plus ibrutinib, including three patients with clinical or confirmed complete responses, and a well-tolerated safety profile consistent with that seen for ibrutinib treatment alone.
- Oncternal also disclosed at the ASCO meeting that six patients with mantle cell lymphoma (MCL), had been treated in a separate cohort of the CIRLL study. One patient with MCL who had relapsed following an allogeneic stem cell transplant experienced a confirmed complete response (CR) after 3 months of cirmtuzumab plus ibrutinib treatment, including complete resolution of a large mediastinal mass. This CR appears to be durable, and has been confirmed after 6, 9 and 11 months of cirmtuzumab plus ibrutinib treatment.

Expected Upcoming Milestones

- Cirmtuzumab Program
    - Oncternal anticipates reporting additional data from its Phase 1/2 study of cirmtuzumab in combination with ibrutinib from patients with CLL at a scientific conference in the fourth quarter of 2019
    - Oncternal anticipates reporting additional data from its Phase 1/2 study of cirmtuzumab in combination with ibrutinib from patients with MCL at a scientific conference in the fourth quarter of 2019
    - Oncternal anticipates reporting data from its Phase 1 study of cirmtuzumab in combination with paclitaxel from patients with breast cancer at a scientific conference in the fourth quarter of 2019
- TK216 Program
    - Oncternal anticipates completing the dose finding portion of its Phase 1 study of TK216 for patients with Ewing sarcoma and opening the expansion cohort in the third quarter of 2019
    - Oncternal anticipates reporting data from its Phase 1 study of TK216 from patients with Ewing sarcoma at a scientific conference in the fourth quarter of 2019

- ROR1 CAR-T Program
    - Oncternal anticipates selecting a candidate CAR-T construct for IND-enabling studies in hematologic cancers in the second half of 2019, and opening clinical trials for hematological cancers in 2020
    - Oncternal anticipates selecting a candidate CAR-T construct for IND-enabling studies in solid tumors in 2020

Financial Results

On June 7, 2019, the former privately-held Oncternal Therapeutics, Inc. ("Private Oncternal"), completed a reverse merger transaction with GTx, Inc. and its merger subsidiary. Under the merger agreement, a wholly-owned subsidiary of GTx, Inc. merged with and into Private Oncternal, with Private Oncternal surviving as a wholly-owned subsidiary of the merged parent company. The surviving parent entity changed its corporate name from GTx, Inc. to Oncternal Therapeutics, Inc., and commenced trading on the Nasdaq stock exchange under the ticker symbol "ONCT."

The transaction was accounted for as a reverse asset acquisition in accordance with generally accepted accounting principles. Under this method of accounting, Private Oncternal was deemed to be the accounting acquirer for financial reporting purposes. As a result, effective as of the closing date of the merger, the reported historical operating results prior to the merger closing date will be those of Private Oncternal. Information regarding the reverse merger transaction and our financial results is also included on form 10-Q to be filed with the SEC.

Grant revenue was $0.7 million for the quarter ended June 30, 2019. Our grant revenue is derived from a California Institute for Regenerative Medicine (CIRM) grant subaward with the University of California, San Diego. The grant was awarded to advance our lead program in a Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies CLL and MCL.

Total operating expenses for the second quarter ended June 30, 2019 were $22.3 million, which included in-process research and development expenses of $18.1 million that was recorded in connection with the closing of our merger transaction in June 2019.

Research and development expenses for the quarter totaled $2.6 million.

General and administrative expenses for the quarter totaled $1.6 million.

Including the one-time merger charge, net loss for the second quarter was $22.8 million, or a loss of $3.38 per share, basic and diluted.

As of June 30, 2019, Oncternal has $28.5 million in cash and cash equivalents. The Company believes these funds will be sufficient to fund its operations into the second quarter of 2020. As of June 30, 2019, we had 15.4 million shares of common stock outstanding.

Oncternal Management Hosting Conference Call and Live Webcast

Oncternal will host a conference call today, August 8, 2019, at 2:00 p.m. PDT (5:00 p.m. EDT) to review quarterly results and provide an update on clinical and preclinical development programs. A live webcast of the call will be available online and may be accessed from the "Investors" page of the company website at http://investor.oncternal.com/. A replay of the webcast will be available beginning approximately one hour after the conclusion of the call and will remain available for at least 30 days thereafter.

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on developing a diverse pipeline of product candidates for the treatment of cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer generation and progression. The pipeline includes its lead clinical program, cirmtuzumab, a monoclonal antibody designed to inhibit the ROR1 receptor that is being evaluated in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of CLL and MCL, and TK216, a small-molecule compound that is designed to inhibit ETS-family oncoproteins, which is being evaluated in a Phase 1 clinical trial alone and in combination with vincristine as a treatment for Ewing sarcoma, a rare pediatric cancer. In addition, Oncternal has a CAR-T program targeting ROR1, which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. More information is available at www.oncternal.com.

Forward-Looking Information

Oncternal cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the Company's current beliefs and expectations. Forward looking statements include statements regarding: Oncternal's belief that favorable outcomes from the ongoing Phase 1 portion of the CIRLL clinical trial support opening the randomized Phase 2 portion; Oncternal's plans for enrolling patients in, and presenting data from its clinical studies of cirmtuzumab and TK216; the anticipated timing of initiation and enrollment of clinical trials for our product candidates; expectations on the timing of data readouts from our clinical studies and presentation of such results at scientific conferences; plans to select a construct for IND-enabling studies of our ROR1 CAR-T program or otherwise advance our programs; the Company's belief that the closing of the merger was a transformative event that will allow it to pursue its next level of corporate growth and continue to advance its oncology drug candidates in multiple cancer indications, and that it has sufficient funds to fund its development programs and operations into the second quarter of 2020. The inclusion of forward-looking statements should not be regarded as a representation by Oncternal that any of its plans will be achieved. Actual results may differ from those set forth in this

release due to the risks and uncertainties inherent in Oncternal's business, including, without limitation: uncertainties associated with the clinical development and process for obtaining regulatory approval of cirmtuzumab, TK216 and Oncternal's other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; Oncternal's dependence on the success of cirmtuzumab, TK216 and its other product development programs; the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab and Oncternal's other product candidates; Oncternal's limited operating history and the fact that it has incurred significant losses, and expects to continue to incur significant losses for the foreseeable future; risks related to the inability of Oncternal to obtain sufficient additional capital to continue to advance the development of cirmtuzumab, TK216 and its other product candidates; and other risks described in Oncternal's prior press releases as well as in public periodic filings with the U.S. Securities & Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	June 30, 2019 (Unaudited)	December 31, 2018
Cash and cash equivalents	$ 28,516	$ 20,645
Total assets	30,903	21,962
Total liabilities	7,967	5,005
Accumulated deficit	(56,524)	(31,384)
Total convertible preferred stock and stockholders' equity (deficit)	22,936	16,957

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Operations Data
(Unaudited; in thousands, except per share data

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Grant revenue	$ 674	$ 1,527	$ 1,144	$ 1,715
Operating expenses:				
Research and development	2,587	3,513	4,483	4,802
In-process research and development	18,088	—	18,088	—
General and administrative	1,619	555	2,551	1,136
Total operating expenses	22,294	4,068	25,122	5,938
Loss from operations	(21,620)	(2,541)	(23,978)	(4,223)
Other income (expense):				
Change in fair value of warrant liability	(1,285)	114	(1,268)	77
Other income	—	—	—	216
Interest expense	—	—	—	(1)
Interest income	59	15	106	28
Total other income (expense)	(1,226)	129	(1,162)	320
Net loss	$(22,846)	$(2,412)	$(25,140)	$(3,903)
Net loss per share, basic and diluted	$ (3.38)	$ (0.68)	$ (4.81)	$ (1.10)
Weighted-average shares outstanding, basic and diluted	6,765	3,573	5,229	3,555