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) **November 7, 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 November 7, 2019, Oncternal Therapeutics, 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.

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 November 7, 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: November 7, 2019

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

ONCTERNAL therapeutics

Oncternal Reports Third Quarter 2019 Financial Results and Provides Business Update

- *Opened randomized, Phase 2 clinical trial of cirmtuzumab in combination with ibrutinib in patients with CLL and Phase 1b expansion cohort in patients with MCL, based on encouraging interim clinical results*
- *Reported first sustained objective response in patient with Ewing sarcoma treated with TK216 in Phase 1 clinical trial*
- *Strengthened leadership team, with appointments of CMO, CSO, CBO, and SVP Manufacturing*
- *Management to host webcast today at 5:00 pm EST*

SAN DIEGO, November 7, 2019 -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced financial results for the third quarter ended September 30, 2019, and provided a business update.

"We are excited about the potential of cirmtuzumab and TK216 in treating multiple types of hematologic and solid tumors, and by the encouraging interim results from our ongoing clinical trials of these product candidates," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We have now rounded out an experienced leadership team with key new hires and are focused on advancing our programs for the benefit of patients with cancer. We look forward to presenting additional interim clinical data for cirmtuzumab in patients with chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL) and breast cancer, and for TK216 in patients with Ewing sarcoma, in the fourth quarter of 2019."

Recent Highlights

- **Opened randomized, Phase 2 clinical trial of cirmtuzumab in patients with CLL** – In August, Oncternal announced the opening of a randomized, Phase 2 study of cirmtuzumab, its investigational anti-ROR1 monoclonal antibody, combined with ibrutinib in patients with CLL. The decision to open the Phase 2 portion of this ongoing Phase 1/2 clinical trial was based on favorable outcomes from the dose-finding and dose-confirming cohorts of the trial that included an observed interim objective response rate (ORR) of 100% for the first nine CLL patients with evaluable data receiving the recommended dosing regimen who completed 12 weeks of cirmtuzumab plus ibrutinib treatment in the dose-confirming cohort, and a well-tolerated safety profile consistent with that seen with ibrutinib alone.
- **Opened Phase 1b expansion cohort of a clinical trial of cirmtuzumab in patients with MCL** – In October, Oncternal announced the opening of a Phase 1b expansion cohort of its clinical trial of cirmtuzumab in combination with ibrutinib for the treatment of patients with MCL. The decision to open the expansion cohort in MCL was based on favorable interim results from the dose-finding cohort of the trial, which included complete responses observed in two patients who had failed multiple prior treatment regimens, and the observation that the combination was well-tolerated with a safety profile consistent with that seen with ibrutinib alone.
- **Reported first sustained objective response in a patient with Ewing sarcoma treated with TK216 in a Phase 1 clinical trial** – In September, Oncternal announced the presentation of a case study of a patient with Ewing sarcoma who achieved a sustained response following treatment with TK216, Oncternal's investigational, targeted ETS oncoprotein inhibitor, in the company's ongoing Phase 1 clinical trial. The patient, who had metastatic, recurrent Ewing sarcoma, achieved a confirmed objective response following two cycles of TK216 therapy given as a single agent. The response was sustained and continued at six months of treatment, with the patient receiving TK216 and vincristine in subsequent treatment cycles. The final remaining residual tumor nodule was later surgically removed, leading to a surgical complete remission. Treatment with TK216 was well-tolerated by this patient.
- **Strengthened leadership team** – In August and September, Oncternal announced appointments of Frank Hsu, M.D., as Chief Medical Officer, Rajesh Krishnan, Ph.D., as Senior VP, CMC and Manufacturing, Gunnar Kaufmann, Ph.D., as Chief Scientific Officer, and Igor Bilinsky, Ph.D., as Chief Business Officer.

Expected Upcoming Milestones

- Cirmtuzumab program
  - Presentation of additional interim data from the ongoing Phase 1/2 clinical study of cirmtuzumab in combination with ibrutinib in patients with CLL or MCL at the American Society of Hematology (ASH) 2019 annual meeting in December 2019. The abstract for the presentation, which is entitled, "Cirmtuzumab, a ROR1 Targeted Mab, Reverses Cancer Stemness, and Its Combination with Ibrutinib is Safe and Effective: Planned Analysis of the CIRLL Phase 1/2 Trial for CLL and MCL," is available on the conference website

- Presentation of interim data from the ongoing, investigator-sponsored Phase 1 clinical study of cirmtuzumab in combination with paclitaxel in patients with Her2 negative, metastatic or locally advanced unresectable breast cancer in the fourth quarter of 2019
- TK216 program
  - Presentation of interim data from the ongoing Phase 1 clinical study of TK216 in patients with Ewing sarcoma at the Connective Tissue Oncology Society (CTOS) annual meeting in November 2019
- ROR1 CAR-T program
  - Selection of a candidate CAR-T construct for hematologic malignancies in the first half of 2020

Financial Results for the Third Quarter 2019

Oncternal's grant revenue was $0.5 million for the quarter ended September 30, 2019. The company's grant revenue is derived from a subaward under a grant from the California Institute for Regenerative Medicine (CIRM) to the University of California San Diego, which was awarded to advance Oncternal's Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with CLL or MCL.

The company's total operating expenses for the third quarter ended September 30, 2019, were $5.5 million. Research and development expenses for the quarter totaled $3.1 million, and general and administrative expenses for the quarter totaled $2.4 million. Net loss for the third quarter was $4.9 million, or a loss of $0.32 per share, basic and diluted.

As of September 30, 2019, Oncternal had $23.1 million in cash and cash equivalents. The company believes these funds will be sufficient to fund its operations through the second quarter of 2020. As of September 30, 2019, Oncternal had approximately 15.4 million shares of common stock outstanding.

Management Webcast

Oncternal will host a webcast conference today, November 7, 2019, at 2:00 p.m. PST (5:00 p.m. EST) to review quarterly results and provide an update on the company's development programs. The live webcast 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 the development of novel oncology therapies for the treatment of cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer generation or progression. The pipeline includes cirmtuzumab, an investigational monoclonal antibody designed to inhibit the ROR1 receptor, a type I tyrosine kinase-like orphan receptor, that is being evaluated in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL), and TK216, an investigational small-molecule compound that is designed to inhibit E26 transformation specific (ETS) family oncoproteins, that is being evaluated in a Phase 1 clinical trial alone and in combination with vincristine chemotherapy for patients with Ewing sarcoma. In addition, Oncternal has a program to develop a CAR-T therapy that targets 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 in the potential of its clinical product candidates in treating multiple types of liquid and solid tumors; expectations regarding the timing for the disclosure of additional interim data from the company's ongoing clinical trials of cirmtuzumab and TK216; the timing for selecting a candidate CAR-T construct for hematologic and solid tumors; and the company's belief that it has sufficient funds to fund its development programs and operations through 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: Oncternal's dependence on the success of cirmtuzumab, TK216 and its other product development programs; 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; 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; the risk that the regulatory landscape that applies to the development programs for the company's product candidates may change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals; 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; the risk that the company may not be able to obtain sufficient additional financing when needed or at all as required to achieve its goals, which could force the company to delay, limit, reduce or terminate its product development programs or other operations; 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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Source: Oncternal Therapeutics, Inc.

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

	September 30, 2019	December 31, 2018
	(Unaudited)	
Cash and cash equivalents	$ 23,096	$ 20,645
Total assets	25,049	21,962
Total liabilities	6,899	5,005
Accumulated deficit	(61,416)	(31,384)
Total convertible preferred stock and stockholders' equity (deficit)	18,150	16,957

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Grant revenue	$ 544	$ 329	$ 1,689	$ 2,044
Operating expenses:				
Research and development	3,108	1,809	7,591	6,612
In-process research and development	—	—	18,088	—
General and administrative	2,385	454	4,937	1,589
Total operating expenses	5,493	2,263	30,616	8,201
Loss from operations	(4,949)	(1,934)	(28,927)	(6,157)
Other income (expense):				
Change in fair value of warrant liability	—	23	(1,268)	101
Other income	—	—	—	216
Interest expense	—	—	—	(1)
Interest income	57	13	163	40
Total other income (expense)	57	36	(1,105)	356
Net loss	$ (4,892)	$ (1,898)	$ (30,032)	$ (5,801)
Net loss per share, basic and diluted	$ (0.32)	$ (0.53)	$ (3.48)	$ (1.62)
Weighted-average shares outstanding, basic and diluted	15,340	3,609	8,636	3,573