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) **March 16, 2020**

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 March 16, 2020, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the fourth quarter and year ended December 31, 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 March 16, 2020

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: March 16, 2020

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Oncternal Provides Business Update and Announces Fourth Quarter and Full Year 2019 Financial Results

- *Steady progress of clinical programs in four indications: MCL, Ewing sarcoma, breast cancer, and CLL*
- *Cirmtuzumab in combination with ibrutinib demonstrated a 50% CR rate and 83% best ORR in patients with relapsed/refractory MCL in an interim analysis from an ongoing Phase 1/2 clinical trial*
- *Management to host webcast today at 4:30 pm ET*

SAN DIEGO, March 16, 2020 -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today provided a business update and reported fourth quarter and full year 2019 financial results.

"We are very pleased with recent clinical results from our pipeline of novel cancer treatments for patients with critical unmet medical need," said James Breitmeyer, M.D., Ph.D., President and CEO, Oncternal. "We have seen encouraging results in all four of our clinical indications, including mantle cell lymphoma ("MCL"), Ewing sarcoma, breast cancer and chronic lymphocytic leukemia ("CLL"). We look forward to steadily advancing these programs in 2020 and expect to have multiple data updates throughout the year. Preclinical work is also identifying additional clinical targets for our existing product candidates and for our ROR1 CAR-T program."

Recent Highlights

- In March 2020, we announced an interim clinical data update for cirmtuzumab, a ROR1-targeted monoclonal antibody, in combination with ibrutinib in patients with relapsed/refractory MCL enrolled in our ongoing Phase 1/2 clinical trial, including a 50% complete response ("CR") rate and an 83% best objective response (CR or partial response) rate ("ORR"). This CR rate improved meaningfully from our previously reported CR rate of 33%.
- In February 2020, we presented ROR1 CAR-T preclinical data at the ASCO-SITC Clinical Immuno-Oncology Symposium. ROR1 CAR-T cell therapy demonstrated expansion, persistence and anti-tumor activity in an animal model of human leukemia. This research is being conducted by our collaborators at the University of California San Diego (UC San Diego) under a grant from the California Institute of Regenerative Medicine ("CIRM").
- In December 2019, we presented at the San Antonio Breast Cancer Symposium clinical data from an 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, including an ORR of 57%.
- In December 2019, we opened for enrollment a Phase 1 expansion cohort of our ongoing clinical trial evaluating TK216, a first-in-class, targeted, investigational small-molecule inhibitor of the E26 transformation-specific ("ETS") family of oncoproteins, in patients with relapsed/refractory Ewing sarcoma.
- In December 2019, we presented at the American Society of Hematology Annual Meeting a clinical data update from our ongoing Phase 1/2 clinical study of cirmtuzumab in combination with ibrutinib in patients with MCL or CLL, including a best ORR of 85% and progression-free survival of 100% in patients with CLL.
- In November 2019, we presented at the Connective Tissue Oncology Society Annual Meeting interim clinical data from our ongoing Phase 1 clinical trial evaluating TK216 in patients with relapsed/refractory Ewing sarcoma, including a deep and sustained clinical response reported for a patient who received a TK216 dose regimen that was subsequently selected as a recommended Phase 2 dose.
- In October 2019, we announced the opening of a Phase 1b expansion cohort of our clinical trial of cirmtuzumab in combination with ibrutinib in patients with MCL.

Expected Upcoming Milestones

- Cirmtuzumab program
  - Clinical data update for patients with MCL, including for over 15 patients in the ongoing Phase 1/2 study – in mid-2020
  - Clinical data update for patients with CLL, including 12-month follow-up for 34 patients in the ongoing Phase 1/2 study – in mid-2020
  - Clinical data update for patients with HER2-negative breast cancer in the ongoing Phase 1b study – in the second half of 2020
  - IND-enabling data in additional indications – in mid-2020
- TK216 program
  - Clinical data for 7-12 patients with Ewing sarcoma enrolled in the Phase 1 expansion cohort – in the second half of 2020

- IND-enabling data in additional ETS-driven tumors – in the second half of 2020
- ROR1 CAR-T program
  - First-in-human dosing in China – in the fourth quarter of 2020

Fourth Quarter and Full Year 2019 Financial Results

Our grant revenue was $0.7 million for the fourth quarter ended December 31, 2019. Our grant revenue is derived from a subaward under a grant from CIRM to UC San Diego, which was awarded to advance our Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with MCL or CLL. For the full year 2019, grant revenue was $2.4 million.

Our total operating expenses for the fourth quarter ended December 31, 2019 were $4.9 million. Research and development expenses for the quarter totaled $2.6 million, and general and administrative expenses for the quarter totaled $2.3 million. Net loss for the fourth quarter was $4.2 million, or a loss of $0.27 per share, basic and diluted. For the full year 2019, total operating expenses were $35.5 million, which included a one-time non-cash charge for acquired in-process research and development expenses of $18.1 million that was recorded in connection with the closing of our merger in June 2019. Net loss for the full year 2019 was $34.2 million, or a loss of $3.31 per share, basic and diluted.

As of December 31, 2019, we had $20.1 million in cash and cash equivalents. We believe these funds will be sufficient to fund our operations into the third quarter of 2020. As of December 31, 2019, we had approximately 15.4 million shares of common stock outstanding.

Management Webcast

As previously announced, Oncternal will host a webcast today, March 16, 2020, at 4:30 p.m. ET (1:30 p.m. PT). 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 pathway, 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 patients with chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL) and in an investigator-sponsored, Phase 1b clinical trial in combination with paclitaxel for the treatment of women with HER2-negative metastatic or locally advanced, unresectable breast cancer, and TK216, an investigational targeted small-molecule inhibitor of the ETS family of oncoproteins, that is being evaluated in a Phase 1 clinical trial for patients with Ewing sarcoma alone and in combination with vincristine chemotherapy. 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 to meet critical unmet medical needs; expectations regarding advancing its clinical programs in 2020 and the timing for the disclosure of additional data from the company's ongoing clinical trials of cirmtuzumab and TK216; the timing for first-in-human dosing in China for its ROR1 CAR-T product candidate; the potential to identify additional clinical targets for Oncternal's existing product candidates and the ROR1 CAR-T program; and the company's belief that it has sufficient funds to fund its development programs and operations into the third 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; risks associated with the COVID-19 outbreak, which may adversely impact our business and clinical trials; 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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