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) **May 6, 2021**

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, CA 92130
(858) 434-1113
(Address and zip code; telephone number, including area code, of registrant's principal executive offices)

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 May 6, 2021, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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 May 6, 2021

104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 6, 2021

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Exhibit 99.1

Oncternal Provides Business Update and Announces First Quarter 2021 Financial Results

- *Interim results of a Phase 1b trial of cirmtuzumab and paclitaxel in locally advanced/unresectable or metastatic HER2-negative breast cancer compare favorably to historical single-agent paclitaxel data (57% ORR vs. ~30% ORR historical single-agent paclitaxel)*
- *In a preclinical study of cirmtuzumab added to high-grade serous ovarian cancer cell lines, cirmtuzumab demonstrated single agent activity and enhanced the anti-proliferative effect of commonly used chemotherapies*
- *Oncternal appointed Chase Leavitt as General Counsel*
- *Oncternal presenting clinical updates on cirmtuzumab in MCL/CLL and TK216 in Ewing sarcoma at the ASCO Annual Meeting in June 2021*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, May 6, 2021 -- Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today reported financial results for the first quarter of 2021. Oncternal management will host a webcast today at 5:00 p.m. ET to discuss its first quarter of 2021 financial results and to provide a business update.

“We are continuing to advance our ROR1-focused platform in both liquid and solid tumors, while laying the groundwork for developing new ROR1 targeting cell therapies. Based on encouraging data recently reported at the American Association for Cancer Research (AACR) Annual Meeting, we are evaluating cirmtuzumab for other clinical development opportunities in solid tumors while continuing our FDA dialogue on a potential registration strategy in mantle cell lymphoma (MCL). In addition, we are supporting TK216, an ETS inhibitor which has generated encouraging results in Ewing sarcoma,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “We also look forward to presenting several key clinical data at the American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held virtually from June 4-8, 2021.”

Recent Highlights

- In April 2021, we presented two scientific posters at the AACR Annual Meeting, which showcased the promise of cirmtuzumab in treating solid tumors.
    - In a Phase 1b investigator-initiated clinical trial in heavily pre-treated patients with metastatic HER2-negative breast cancer treated with a combination of cirmtuzumab and paclitaxel, eight of 14 evaluable patients had a partial response (PR), one of which remained durable for 52 weeks, for an objective response rate (ORR) of 57%. Four additional patients (29%) had stable disease (SD). These results were consistent with the previously reported interim results of the study, and compared favorably to historical results for single-agent paclitaxel, particularly for patients such as these who had received a median of six prior therapies for metastatic disease. Cirmtuzumab when given with paclitaxel was well-tolerated and demonstrated no added toxicity over what was expected with paclitaxel alone. The trial is expected to enroll a total of 15 evaluable patients.
    - In a preclinical study of cirmtuzumab used to treat high-grade serous ovarian cancer (HGSOC) and endometrial cell lines *in vitro* alone or in combination with chemotherapeutic agents cisplatin and paclitaxel, cirmtuzumab demonstrated single agent activity and enhanced the anti-proliferative effects of chemotherapeutic agents in both ovarian and endometrial cancer cell models. Oncternal is currently evaluating next steps for cirmtuzumab in solid tumors including breast and ovarian cancer.
- In April 2021, we appointed Chase Leavitt as General Counsel.
- In April 2021, we announced that updated interim clinical trial results from Oncternal’s study of TK216 in patients with Ewing sarcoma will be presented in an oral session, and updated interim clinical trial results from Oncternal and UCSD’s study of cirmtuzumab plus ibrutinib in patients with MCL or chronic lymphocytic leukemia (CLL) will be presented in a poster session at the ASCO Annual Meeting in June 2021.

Expected Upcoming Milestones

- Cirmtuzumab (ROR1 antibody) programs
    - Clinical data update for patients with MCL and CLL treated with cirmtuzumab plus ibrutinib in the ongoing Phase 1/2 study will be presented at the ASCO Annual Meeting
    - Preclinical data in additional ROR1-expressing tumors is expected to be available in the third quarter of 2021
- ROR1 CAR-T program
    - First-in-human dosing is expected in the first half of 2022

- TK216 (ETS inhibitor) program
    - Clinical data update for patients with Ewing sarcoma treated in the ongoing Phase 1/2 study will be presented at the ASCO Annual Meeting
    - Preclinical data in additional ETS-driven tumors is expected to be available in the third quarter of 2021

First Quarter 2021 Financial Results

Our grant revenue was $0.7 million for the first quarter ended March 31, 2021. Our grant revenue is derived from a sub-award under a grant from the California Institute for Regenerative Medicine (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.

Our total operating expenses for the first quarter ended March 31, 2021 were $6.7 million. Research and development expenses for the quarter totaled $3.9 million, and general and administrative expenses for the quarter totaled $2.8 million. Net loss for the first quarter was $5.9 million, or a loss of $0.12 per share, basic and diluted.

As of March 31, 2021, we had $111.2 million in cash and cash equivalents. We believe these funds will be sufficient to fund our operations into 2023. As of March 31, 2021, we had approximately 49.4 million shares of common stock outstanding.

Management Webcast

As previously announced, Oncternal will host a webcast today, May 6, 2021, at 5:00 p.m. ET (2:00 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 clinical 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 mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) 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. The clinical pipeline also includes 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 utilizing the cirmtuzumab antibody backbone 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 https://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 Oncternal's current beliefs and expectations. Forward-looking statements include statements regarding Oncternal's development programs, including the anticipated timing for announcing additional preclinical and clinical data; timing of reaching any milestones, including initiating ROR1 CAR-T studies; Oncternal's evaluation of clinical development opportunities; and Oncternal's expected cash runway. Forward-looking statements are subject to risks and uncertainties inherent in Oncternal's business, including risks associated with the clinical development and process for obtaining regulatory approval of Oncternal's product candidates, such as potential delays in the commencement, enrollment and completion of clinical trials; the risk that results seen in a case study of one patient likely will not predict the results seen in other patients in the clinical trial; the risk that interim results of a clinical trial do not 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, as follow-up on the outcome of any particular patient continues, and as more patient data become available; and other risks described in Oncternal's filings with the U.S. Securities and 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

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 111,211	$ 116,737
Total assets	114,057	118,809
Total liabilities	5,754	5,858
Accumulated deficit	(88,745)	(82,797)
Total stockholders' equity	108,303	112,951

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

	Three Months Ended March 31,	
	2021	2020
Grant revenue	$ 748	$ 578
Operating expenses:		
Research and development	3,913	2,696
General and administrative	2,794	2,633
Total operating expenses	6,707	5,329
Loss from operations	(5,959)	(4,751)
Interest income	11	13
Net loss	$ (5,948)	$ (4,738)
Net loss per share, basic and diluted	$ (0.12)	$ (0.31)
Weighted-average shares outstanding, basic and diluted	49,094	15,355