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 5, 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 August 5, 2021, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the second quarter ended June 30, 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 August 5, 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: August 5, 2021

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Oncternal Provides Business Update and Announces Second Quarter 2021 Financial Results

- *Presented encouraging interim clinical data for cirmtuzumab in combination with ibrutinib in patients with mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) in a poster session at ASCO 2021*
- *Expanded the ongoing Phase 1/2 study to evaluate cirmtuzumab plus ibrutinib in patients with MCL who are refractory to prior BTK inhibitor treatment (ibrutinib, acalabrutinib or zanubrutinib), or who are at high risk for progression, having had an inadequate response to ibrutinib (stable disease or partial response)*
- *Presented encouraging interim clinical data for TK216 in patients with relapsed or refractory Ewing sarcoma in an oral session at ASCO 2021*
- *Expanded the ongoing Phase 1/2 study to evaluate an intensified dosing regimen of TK216 in patients with Ewing sarcoma*
- *Appointed Salim Yazji, M.D., as Chief Medical Officer and Pablo Urbaneja as Senior Vice President of Corporate Development*
- *Management to host webcast today at 5:00 p.m. ET*

SAN DIEGO, August 5, 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 second quarter of 2021. Oncternal management will host a webcast today at 5:00 p.m. ET to provide a business update and discuss its second quarter of 2021 financial results.

“We presented very encouraging data from our clinical programs, expanded our ongoing study of cirmtuzumab for patients with MCL, we continue to progress towards initiating a first-in-human trial of our ROR1 targeted CAR-T, and started evaluating an intensified dosing regimen for TK216, an ETS inhibitor which has generated encouraging results in Ewing sarcoma. Furthermore, we strengthened our management team, and we continue to have a strong balance sheet and look forward to multiple potential catalysts in the coming months,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO.

Recent Highlights

Cirmtuzumab (ROR1 antibody):

- In June 2021, we presented encouraging interim clinical data for cirmtuzumab in combination with ibrutinib in patients with mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) in a poster session at ASCO 2021 (NCT0308887). The data remain consistent and confirm and extend previous results. An objective response rate (ORR) of 83% (15 of 18 evaluable patients) was observed for heavily pre-treated patients with MCL treated with cirmtuzumab plus ibrutinib, which compares favorably to the historical ORR of 66% for ibrutinib monotherapy (Rule, 2017). The complete response (CR) rate of 39% for MCL patients treated with cirmtuzumab plus ibrutinib (7 of 18 evaluable patients) also compares favorably to the historical CR rate of 20% for ibrutinib monotherapy, with CRs remaining durable for 8-30+ months. The median progression-free survival (PFS) and overall survival (OS) were not reached for MCL patients with a median follow-up of 18.9 months. The median PFS and OS were also not reached for CLL patients, with a median follow-up of 22.1 months. The combination of cirmtuzumab and ibrutinib continues to be well tolerated, with a safety profile consistent with or slightly improved compared to historical data for ibrutinib monotherapy. For example, in patients with MCL, Grade 3-4 neutrophil decrease was documented in 11.5% of patients with cirmtuzumab plus ibrutinib, compared to 29% for ibrutinib alone from its registration study.
- In July 2021, we opened a new treatment cohort of the ongoing Phase 1/2 study to evaluate cirmtuzumab plus ibrutinib in up to 34 patients with MCL who are refractory to prior BTK inhibitor treatment (ibrutinib, acalabrutinib or zanubrutinib), or who are at high risk for progression, having had an inadequate response to ibrutinib (stable disease or partial response).
- The investigator-sponsored study of cirmtuzumab and paclitaxel for metastatic or locally advanced, unresectable breast cancer at UC San Diego (NCT02776917) has completed enrollment and the results are expected to be presented at a scientific conference or publication.
- The investigator-sponsored study of cirmtuzumab consolidation for treatment of patients with detectable CLL on venetoclax at UC San Diego (NCT04501939) remains active and enrolling patients.

TK216 (ETS inhibitor):

- In June 2021, we presented encouraging interim clinical data for TK216 in patients with relapsed or refractory Ewing sarcoma in an oral session at ASCO 2021 (NCT02657005). The data remain consistent and confirm and extend previous results. Two patients who achieved a CR remain with no evidence of disease, one for over 24 months and the other for over 14 months on study. The treatments continued to be well tolerated, with reversible myelosuppression as the most common side effect.

- In July 2021, we added a new Phase 2 expansion cohort targeting up to 21 Ewing sarcoma patients to evaluate clinical responses to single agent TK216 using an optimized dosing regimen, treating for 28 days per cycle, to intensify the amount of TK216 administered over time.

Corporate:

- In Q2 2021, we appointed Salim Yazji, M.D., as Chief Medical Officer and Pablo Urbaneja as Senior Vice President of Corporate Development.

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 in the fourth quarter of 2021
  - FDA interaction regarding potential registration trial of cirmtuzumab in patients with MCL
  - Preclinical data in additional ROR1-expressing tumors in the fourth quarter of 2021
- ROR1 CAR-T program
  - First-in-human dosing in the first half of 2022
- TK216 (ETS inhibitor) programs
  - Clinical data update for patients with Ewing sarcoma treated in the ongoing Phase 1/2 study in the fourth quarter of 2021
  - Preclinical data in additional ETS-driven tumors in the fourth quarter of 2021

Second Quarter 2021 Financial Results

Our grant revenue was $0.9 million for the second quarter ended June 30, 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 second quarter ended June 30, 2021 were $8.6 million, including $1.8 million in non-cash stock based compensation. Research and development expenses for the quarter totaled $5.2 million, and general and administrative expenses for the quarter totaled $3.4 million. Net loss for the second quarter was $7.7 million, or a loss of $0.16 per share, basic and diluted.

As of June 30, 2021, we had $103.7 million in cash and cash equivalents. We believe these funds will be sufficient to fund our operations into 2023. As of June 30, 2021, we had approximately 49.4 million shares of common stock outstanding.

Management Webcast

As previously announced, Oncternal will host a webcast today, August 5, 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, as well as a Phase 2 clinical trial of cirmtuzumab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL. Oncternal is also developing a chimeric antigen receptor T cell (CAR-T) therapy that targets ROR1, which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. 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 1/2 clinical trial for patients with Ewing sarcoma alone and in combination with vincristine chemotherapy. 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; timing for regulatory communications; 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)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 103,663	$ 116,737
Total assets	108,419	118,809
Total liabilities	5,900	5,858
Accumulated deficit	(96,427)	(82,797
Total stockholders' equity	102,519	112,951

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,	
	2021	2020	2021	2020
Grant revenue	$ 883	$ 623	$ 1,631	$ 1,201
Operating expenses:				
Research and development	5,192	3,815	9,105	6,510
General and administrative	3,381	2,343	6,174	4,977
Total operating expenses	8,573	6,158	15,279	11,487
Loss from operations	(7,690)	(5,535)	(13,648)	(10,286)
Interest income	8	—	18	13
Net loss	$ (7,682)	$ (5,535)	$ (13,630)	$ (10,273)
Net loss per share, basic and diluted	$ (0.16)	$ (0.34)	$ (0.28)	$ (0.65)
Weighted-average shares outstanding, basic and diluted	49,364	16,241	49,230	15,798