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 4, 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 November 4, 2021, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the third quarter ended September 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 November 4, 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: November 4, 2021

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

EXHIBIT 99.1

Oncternal Provides Business Update and Announces Third Quarter 2021 Financial Results

- *Progressed the development of zilovertamab (formerly cirmtuzumab) for the treatment of patients with mantle cell lymphoma, including ongoing interactions with the US FDA on potential registration pathways*
- *Identified ONCT-808 as the lead candidate for our autologous CAR-T program targeting ROR1-expressing malignancies*
- *Established collaboration with Celularity Inc. to evaluate placental derived-cellular therapies targeting ROR1*
- *Joined NextGenNK, Karolinska Institutet's Competence Center for the development of next generation NK cell-based cancer immunotherapies*
- *Formed a cell therapy scientific advisory board to support the advancement of our ROR1 cell therapies pipeline*
- *Designated ONCT-534 (formerly GTx-534) as the lead candidate in our preclinical dual-action androgen receptor inhibitor (DAARI) program, based on significant preclinical assessments. ONCT-534 is a potential next-generation treatment option for patients with resistant prostate cancer, addressing the emerging unmet medical need of androgen receptor splice variant (AR-SV)-expressing tumors*

SAN DIEGO, November 4, 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 third quarter of 2021. Oncternal management will host a webcast today at 5:00 p.m. ET to provide a business update and discuss its third quarter of 2021 financial results.

"We are excited about the progress of our pipeline during this quarter, especially as we continue to advance towards a registration study for our lead asset, zilovertamab, which we believe can play a key role in the treatment paradigm of patients with mantle cell lymphoma" said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We are also very pleased to introduce ONCT-534, a pre-clinical first-in-class dual-action androgen inhibitor, as part of our pipeline. Tumor-resistance mechanisms related to the expression of splice variants such as AR-V7 represents an important unmet need for prostate cancer patients, and we are committed to developing new treatment options for them. Finally, our cell therapy program targeting ROR1 continues to move forward, with progress on both our lead candidate ONCT-808, an autologous CAR-T, and potential next-generation therapies based on NK cells."

Recent Highlights

Zilovertamab (ROR1 antibody, formerly cirmtuzumab or UC-961):

- Interactions with FDA continue on potential registration pathways.
- An abstract titled Phase 1b/2 Study of Cirmtuzumab and Ibrutinib in Mantle Cell Lymphoma (MCL) or Chronic Lymphocytic Leukemia (CLL) (Abstract 3534)(NCT0308887) has been accepted for a poster presentation at the American Society of Hematology (ASH) Annual Meeting in Atlanta on December 13, 2021. Abstracts are available on the ASH website at www.hematology.org.
    - This abstract reflects early data from June 2021, shortly after our interim data was presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting. The results remain encouraging and consistent with previous data releases and will be further updated with additional patients and follow-up at the ASH meeting.
- The investigator-sponsored study of zilovertamab 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 in a publication.
- The investigator-sponsored study of zilovertamab for treatment of patients with detectable CLL on venetoclax at UC San Diego (NCT04501939) is actively enrolling patients.

ONCT-216 (ETS inhibitor, formerly TK216):

- Interim clinical data update for ONCT-216 in patients with relapsed or refractory Ewing sarcoma was accepted for oral presentation at the 2021 Connective Tissue Oncology Society (CTOS) Virtual Annual Meeting on November 13, 2021.
- The Phase 2 expansion cohort targeting up to 21 Ewing sarcoma patients is active and enrolling patients, designed to evaluate clinical responses to single agent ONCT-216 using an optimized dosing regimen, treating for 28 days per cycle, to intensify the amount of ONCT-216 administered over time.

ROR1 Cell-Therapy Program:

- Selected ONCT-808 as our lead autologous CAR-T targeting ROR1 candidate and made progress on key IND-enabling activities.
- Initiated a collaboration with Celularity Inc. (Nasdaq: CELU) to evaluate placental derived T and NK-cell therapies targeting ROR1.
- Formed a cell therapy scientific advisory board (SAB) with cross-disciplinary industry and academic experts to support the advancement of our ROR1 cell therapy pipeline.
- Joined Karolinska Institutet's NextGenNK Competence Center for the development of next generation NK cell-based cancer immunotherapies.

Dual-Action Androgen Inhibitor (DAARI) Program:

- Selected ONCT-534 (formerly GTx-534) as our lead DAARI preclinical product candidate, based on significant new preclinical data and assessments. We believe ONCT-534 will address unmet medical needs related to tumor resistance to currently approved products for patients with advanced prostate cancer.
- Presented preclinical in-vitro and in-vivo data as a virtual poster presentation at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics in October. The data presented showed that ONCT-534 binds to the AR-AF-1, or N-terminal domain of the androgen receptor (AR) and induces degradation of both AR full length proteins and AR-SV proteins, including the AR-V7 splice variant. ONCT-534 demonstrated potent anti-tumor activity in AR-V7 expressing tumor xenografts in an animal model.

Corporate:

- Appointed Steven Hamburger, Ph.D. as Senior Vice President, Regulatory Affairs and Quality Assurance.

Expected Upcoming Milestones

- Zilovertamab (ROR1 antibody) program
  - Clinical data update for patients with MCL and CLL treated with zilovertamab plus ibrutinib in the ongoing Phase 1b/2 study to be presented at the American Society for Hematology (ASH) 2021 Annual Meeting in Atlanta in December 2021
  - Ongoing FDA interactions regarding potential registration pathways for zilovertamab in patients with MCL
- ONCT-216 (ETS inhibitor) programs
  - Clinical data update for patients with relapsed or refractory Ewing sarcoma to be shared in an oral presentation at the Connective Tissue Oncology Society (CTOS) 2021 Virtual Annual Meeting in November 2021
- ROR1 CAR-T program
  - IND submission in the first half of 2022
- The Company will host an R&D Day on January 25, 2022 to provide a comprehensive update of its pipeline of product candidates and key development priorities, which will include key opinion leaders in the fields of MCL therapies, cellular immunotherapies, and androgen receptor resistance in prostate cancer

Third Quarter 2021 Financial Results

Our grant revenue was $2.1 million for the third quarter ended September 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 1b/2 clinical trial evaluating zilovertamab in combination with ibrutinib for the treatment of patients with MCL or CLL, and from two grant awards received from the National Institutes of Health, or NIH, during the third quarter ended September 30, 2021 for up to $2.2 million to support pre-clinical and other research activities for our ONCT-216 and ONCT-534 programs, including $0.7 million payable to subawardees.

Our total operating expenses for the third quarter ended September 30, 2021 were $11.8 million, including $1.5 million in non-cash stock-based compensation. Research and development expenses for the quarter totaled $9.0 million, and general and administrative expenses for the quarter totaled $2.8 million. Net loss for the third quarter was $9.6 million, or a loss of $0.19 per share, basic and diluted.

As of September 30, 2021, we had $97.4 million in cash and cash equivalents. We believe these funds will be sufficient to fund our operations into 2023. As of September 30, 2021, we had approximately 49.4 million shares of common stock outstanding.

Management Webcast

As previously announced, Oncternal will host a webcast today, November 4, 2021, at 5:00 p.m. ET (2:00 p.m. PT). The live webcast will be available online at 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 zilovertamab (formerly 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 1b/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 zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL. Oncternal is also developing ONCT-808, 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 ONCT-216 (formerly 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. The early-stage pipeline also includes ONCT-534 (formerly GTX-534), a dual-action androgen receptor inhibitor, that is in pre-clinical development as a potential treatment for castration resistant prostate cancer and other androgen-receptor dependent diseases. 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 IND submissions; 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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Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 97,380	$ 116,737
Total assets	100,296	118,809
Total liabilities	5,820	5,858
Accumulated deficit	(106,057)	(82,797
Total stockholders' equity	94,476	112,951

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,	
	2021	2020	2021	2020
Grant revenue	$ 2,128	$ 585	$ 3,759	$ 1,787
Operating expenses:				
Research and development	8,963	3,047	18,068	9,558
General and administrative	2,802	1,933	8,977	6,910
Total operating expenses	11,765	4,980	27,045	16,468
Loss from operations	(9,637)	(4,395)	(23,286)	(14,681)
Interest income	7	—	26	13
Net loss	$ (9,630)	$ (4,395)	$ (23,260)	$ (14,668)
Net loss per share, basic and diluted	$ (0.19)	$ (0.22)	$ (0.47)	$ (0.85)
Weighted-average shares outstanding, basic and diluted	49,363	20,126	49,285	17,251