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 5, 2022**

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 230
San Diego, CA 92130
(858) 434-1113
(Address and zip code; telephone number, including area code, of registrant's principal executive offices)

12230 El Camino Real, Suite 300, San Diego, CA 92130
(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 5, 2022, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the first quarter ended March 31, 2022. 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 5, 2022
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 5, 2022

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Exhibit 99.1

Oncternal Therapeutics Provides Business Update and Announces First Quarter 2022 Financial Results

- *Global registrational Phase 3 study, ZILO-301, of zilovertamab in patients with MCL on track to be initiated in Q3 2022*
- *Presenting interim clinical data update from the ongoing Phase 1/2 clinical trial of zilovertamab in combination with ibrutinib for patients with MCL and CLL at the ASCO Annual Meeting in June 2022*
- *Established clinical manufacturing collaboration with the Dana-Farber Cancer Institute to support cGMP cell preparation and manufacturing of our ROR1-targeting CAR-T cell therapy candidate ONCT-808*
- *Executing IND enabling studies for ONCT-534, the lead candidate in our novel dual-action androgen receptor inhibitor (DAARI) program*
- *Deprioritized development of ONCT-216 and extended cash runway guidance to fund operations well into Q3 2023; with $82.2 million in cash and cash equivalents and no debt as of March 31, 2022*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, May 5, 2022 -- 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 financial results for the first quarter of 2022.

“In the first quarter, we continued to advance our robust pipeline towards important inflection points, including the planned initiation of our zilovertamab registrational Phase 3 study in patients with MCL in Q3 2022, the submission of an IND for our ROR1-targeting CAR-T cell therapy candidate ONCT-808 in mid-2022, and the execution of IND-enabling studies for ONCT-534, our DAARI product candidate that may address key resistance mechanisms in metastatic prostate cancer,” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “Substantial progress of our pipeline has been supported by solid collaborations with our partners and execution by our team, and is being carried out with a focus on prudent cash management. Very importantly, we narrowed our focus on hematological malignancies and prostate cancer, and deprioritized our ONCT-216 program, which helped extend our cash runway well into Q3 2023. We will continue to explore and evaluate all potential sources of capital to enable us to reach our milestones.”

Recent Highlights

- In January 2022, we announced that we reached consensus with the FDA on the design and major study details of the Phase 3 Study, ZILO-301, to treat patients with relapsed or refractory mantle cell lymphoma (MCL) with zilovertamab, an investigational anti-ROR1 monoclonal antibody, in combination with ibrutinib. The agency also provided positive feedback on the proposed key clinical and regulatory requirements of our development program for zilovertamab in patients with MCL.
- In April 2022, we established a clinical manufacturing agreement with the Dana-Farber Cancer Institute to conduct cGMP cell preparation and manufacturing activities for use in first-in-human studies of our ROR1-targeting CAR-T cell therapy candidate ONCT-808.
- In April 2022, we announced the deprioritization of further development of ONCT-216 and the discontinuation of enrollment in the Phase 1/2 study evaluating ONCT-216 in patients with relapsed or refractory Ewing sarcoma.

Expected Upcoming Milestones

- Zilovertamab, our ROR1 antibody program
  - Initiation of global registrational Phase 3, Study ZILO-301, in the third quarter of 2022
  - Interim clinical data update for patients with MCL and CLL treated with zilovertamab plus ibrutinib in ongoing Phase 1/2 clinical study will be presented at the ASCO 2022 Annual Meeting
  - Initiation of Phase 1b investigator sponsored trial of zilovertamab plus docetaxel for patients with metastatic castration-resistant prostate cancer (mCRPC) in mid-2022
- ONCT-808, lead candidate in our autologous ROR1-targeted CAR-T cell therapy program
  - Investigational New Drug (IND) application submission in mid-2022
- ONCT-534, lead candidate in our DAARI program
  - IND-enabling GLP toxicology studies and GMP manufacturing initiated in the second quarter of 2022

First Quarter 2022 Financial Results

Our grant revenue was $0.7 million for the first quarter ended March 31, 2022. Our 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 and two research and development grant awards from the National Institutes of Health (NIH).

Our total operating expenses for the first quarter ended March 31, 2022 were $10.7 million, including $2.0 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $7.0 million, and general and administrative expenses for the quarter totaled $3.7 million. Net loss for the first quarter was $9.9 million, or a loss of $0.20 per share, basic and diluted.

As of March 31, 2022, we had approximately 49.4 million shares of common stock outstanding, $82.2 million in cash and cash equivalents and no debt. We believe these funds will be sufficient to fund our operations well into Q3 2023. Our cash guidance is subject to a number of assumptions, including those related to the severity and duration of the COVID-19 pandemic, and the pace of our research and clinical development programs, among other aspects of our business and the geopolitical environment.

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for the treatment of patients with cancers that have critical unmet medical need. Oncternal pursues drug development targeting promising, yet untapped biological pathways implicated in cancer generation or progression, focusing on hematological malignancies and prostate cancer. The lead clinical program is zilovertamab, an investigational monoclonal antibody designed to inhibit ROR1, a type I tyrosine kinase-like orphan receptor. Zilovertamab 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), in investigator-initiated studies, including a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL, and in a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (mCRPC). 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 early-stage pipeline also includes ONCT-534, a dual-action androgen receptor inhibitor (DAARI), that is in preclinical development as a potential treatment for castration resistant prostate cancer, including those with clinically important resistance to approved androgen receptor inhibitors. 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 Oncternal’s estimated cash and cash equivalents as of March 31, 2022, the anticipated timing for announcing additional preclinical and clinical data; timing of reaching any milestones, including IND submissions; timing for regulatory communications; Oncternal’s expected cash runway; and the potential that Study ZILO-301 can serve as a registrational clinical trial; and the expected initiation of clinical trials, including Study ZILO-301. 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; we have not conducted head-to-head studies of zilovertamab in combination with ibrutinib compared to ibrutinib monotherapy and data from separate studies may not be directly comparable due to the differences in study protocols, conditions and patient populations; 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; later developments with the FDA may be inconsistent with the minutes from the completed end of Phase 2 meeting, including that the proposed Study ZILO-301 that may not support registration of zilovertamab in combination with ibrutinib which is a review issue with the FDA upon submission of a BLA; 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.

Contact Information:

Investors
Richard Vincent
858-434-1113
rvincent@oncternal.com

Media
Corey Davis, Ph.D.
LifeSci Advisors
212-915-2577
cdavis@lifesciadvisors.com

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 82,159	$ 90,765
Total assets	85,488	93,585
Total liabilities	5,294	5,465
Accumulated deficit	(124,034)	(114,130)
Total stockholders' equity	80,194	88,120

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

	Three Months Ended March 31,	
	2022	2021
Grant revenue	$ 746	$ 748
Operating expenses:		
Research and development	6,979	3,913
General and administrative	3,679	2,794
Total operating expenses	10,658	6,707
Loss from operations	(9,912)	(5,959)
Interest income	8	11
Net loss	$ (9,904)	$ (5,948)
Net loss per share, basic and diluted	$ (0.20)	$ (0.12)
Weighted-average shares outstanding, basic and diluted	49,429	49,094