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 9, 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 August 9, 2022, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the second quarter ended June 30, 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 August 9, 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: August 9, 2022

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Exhibit 99.1

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

- *Interim Phase 1/2 results for zilovertamab plus ibrutinib in MCL presented at ASCO 2022, with ORR of 85% and CR rate of 41%, compare favorably to historical single agent ibrutinib data and support moving into Phase 3 Study ZILO-301*
- *Interim data from p53-mutated CLL patients in the same Phase 1/2 study showed encouraging activity in sub-group analyses, with landmark PFS of 100% at 36 months, compares favorably to historical PFS for ibrutinib monotherapy*
- *Established a clinical trial and supply agreement with Pharmacyclics for the donation of ibrutinib for our global registrational Phase 3 study, ZILO-301, of zilovertamab in patients with MCL, which is on track to be initiated in September 2022*
- *Advanced development of ONCT-808, the lead candidate for our autologous CAR-T program targeting ROR1-expressing malignancies, with IND submission on track for later this month*
- *Executing IND enabling studies for ONCT-534, the lead candidate in our novel dual-action androgen receptor inhibitor (DAARI) program*
- *Extended cash runway guidance to fund operations into the first half of 2024 with $78.9 million in cash and cash equivalents and no debt as of June 30, 2022*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, August 9, 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 second quarter of 2022.

"The second quarter of 2022 was highlighted by an encouraging data update at ASCO from our Phase 1/2 study of zilovertamab plus ibrutinib in patients with MCL and CLL. We were especially excited by the results in MCL and CLL patients with loss of p53 function, which is a challenging population to treat with current standard of care BTK inhibitor monotherapy" said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We are now looking forward to critical near-term catalysts for the company, including the planned initiation of our Phase 3 Study ZILO-301, the submission of our IND for the first-in-human study of ONCT-808, our ROR1-targeting CAR expressing T cell therapy candidate, and the further advancement towards the clinic of ONCT-534, our Dual-Acting Androgen Receptor Inhibitor (DAARI) product candidate that may address key resistance mechanisms in metastatic prostate cancer. All this is underpinned by focused execution and prudent cash and resource management. We currently expect our cash runway will last into the first half of 2024."

Recent Highlights

- In June 2022, we announced an interim clinical data update from the ongoing Phase 1/2 clinical trial of zilovertamab in combination with ibrutinib for patients with mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) [NCT03088878] at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting:
    - Objective response rate (ORR) of 85% (23 of 27 evaluable patients) observed for patients with MCL treated with zilovertamab plus ibrutinib, which compares favorably to the historical ORR of 66% for ibrutinib monotherapy
    - Complete response (CR) rate of 41% for patients with MCL treated with zilovertamab plus ibrutinib (11 of 27 evaluable patients), which compares favorably to the historical ORR of 20% for ibrutinib monotherapy
    - Median progression-free survival (PFS) of 35.9 months for patients with MCL treated with zilovertamab plus ibrutinib at a median follow-up of 15.1 months, which compares favorably to the historical ibrutinib monotherapy median PFS of 12.8 months
    - In patients with MCL harboring mutated p53, median PFS of 17.3 months (95% CI: 2.9, NE), which compares favorably to the historical median PFS of 4.0 months (95% CI: 2.1, 8.3) for ibrutinib monotherapy
    - In patients with p53 pathway-deficient CLL, landmark PFS with zilovertamab plus ibrutinib of 100% at 24 months and 100% at 30 months, which compare favorably to the historical ibrutinib monotherapy landmark PFS of ~68% and ~55% at 24 months and 30 months, respectively. Mutations in or loss of p53 protein, which has been called the "guardian of the genome," is a well-known negative factor in many types of cancer, through genomic instability and loss of tumor suppression
    - The combination of zilovertamab and ibrutinib continued to be well tolerated, with a safety profile consistent with or improved compared with historical data for ibrutinib monotherapy

- In June 2022, we established a clinical trial collaboration and supply agreement with Pharmacyclics, which includes the supply of ibrutinib to support our global registrational Phase 3 study ZILO-301, to treat patients with relapsed or refractory MCL with zilovertamab plus ibrutinib.
- In April 2022, a Phase 1b investigator sponsored trial of zilovertamab plus docetaxel for patients with metastatic castration-resistant prostate cancer (mCRPC) was initiated at the University of California, San Diego.
- 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.

Expected Upcoming Milestones

- Zilovertamab, our ROR1 antibody program
  - Initiation of global registrational Phase 3 Study ZILO-301, in September 2022
  - Interim clinical data update for patients with MCL and CLL treated with zilovertamab plus ibrutinib in ongoing Phase 1/2 clinical study CIRM-0001, in the fourth quarter of 2022
- ONCT-808, lead candidate in our autologous ROR1-targeted CAR-T cell therapy program
  - Investigational New Drug (IND) application submission in August 2022
- ONCT-534, lead candidate in our DAARI program
  - FDA pre-IND interactions in the fourth quarter of 2022

Second Quarter 2022 Financial Results

Our grant revenue was $0.2 million for the second quarter ended June 30, 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 second quarter ended June 30, 2022 were $12.0 million, including $1.7 million in non-cash stock-based compensation expense. Research and development expenses for the quarter totaled $8.8 million, and general and administrative expenses for the quarter totaled $3.2 million. Net loss for the second quarter was $11.7 million, or a loss of $0.23 per share, basic and diluted.

As of June 30, 2022, we had approximately 52.2 million shares of common stock outstanding, $78.9 million in cash and cash equivalents and no debt. We believe these funds will be sufficient to fund our operations into the first half of 2024. 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 (CAR-T) cell therapy that targets ROR1, which is currently in advanced 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 advanced 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 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.

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

	June 30, 2022 (Unaudited)	December 31, 2021
Cash and cash equivalents	$ 78,900	$ 90,765
Total assets	81,526	93,585
Total liabilities	7,525	5,465
Accumulated deficit	(135,775)	(114,130)
Total stockholders' equity	74,001	88,120

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,	
	2022	2021	2022	2021
Grant revenue	$ 191	$ 883	$ 937	$ 1,631
Operating expenses:				
Research and development	8,761	5,192	15,740	9,105
General and administrative	3,225	3,381	6,904	6,174
Total operating expenses	11,986	8,573	22,644	15,279
Loss from operations	(11,795)	(7,690)	(21,707)	(13,648)
Interest income	54	8	62	18
Net loss	$ (11,741)	$ (7,682)	$ (21,645)	$ (13,630)
Net loss per share, basic and diluted	$ (0.23)	$ (0.16)	$ (0.44)	$ (0.28)
Weighted-average shares outstanding, basic and diluted	50,064	49,364	49,748	49,230