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) **March 9, 2023**

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)

(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 March 9, 2023, Oncternal Therapeutics, Inc., issued a press release announcing its financial results for the fourth quarter and year ended December 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 March 9, 2023
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: March 9, 2023

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Exhibit 99.1

Oncternal Therapeutics Provides Business Update and Announces Fourth Quarter and Full Year 2022 Financial Results

- *Encouraging and improving interim Phase 1/2 study results for zilovertamab plus ibrutinib in patients with MCL and CLL, including those with mutated TP53 and/or del(17p), presented at ASH in December 2022*
- *Zilovertamab global Phase 3 registrational Study ZILO-301 for the treatment of patients with MCL initiated*
- *Phase 1/2 study for ONCT-808, our autologous CAR-T program targeting ROR1-expressing hematologic malignancies, initiated with initial clinical data expected in late 2023*
- *Helpful FDA pre-IND comments received for ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI), supportive of an IND filing by mid-2023*
- *Management to host webcast today at 5:00 pm ET*

SAN DIEGO, March 9, 2023 -- 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 fourth quarter and full year 2022 financial results.

“2022 was an important year for Oncternal. With the recent initiation of our Phase 1/2 clinical study for ONCT-808 in advanced hematological malignancies, and the upcoming filing of our IND for ONCT-534 in advanced prostate cancer, we expect to have three product candidates in the clinic later this year” said James Breitmeyer, M.D., Ph.D., Oncternal’s President and CEO. “The data presented at ASH 2022 further validated the rationale for our Phase 3 study for patients with MCL, and also strengthened our belief that zilovertamab may provide a new treatment option for patients with CLL with 17p deletion or TP53 mutations, which is a substantial and highly underserved group of patients. We look forward to a catalyst-rich year ahead while continuing to exercise prudent cash management as we expect our existing cash resources will last into the first quarter of 2024.”

Recent Highlights

- In December 2022, we announced an interim clinical data update from ongoing Study CIRM-0001, a Phase 1/2 clinical trial of zilovertamab in combination with ibrutinib for the patients with relapsed or refractory (R/R) Mantle Cell Lymphoma (MCL) and treatment naïve or R/R chronic lymphocytic leukemia (CLL) [NCT03088878] at the American Society of Hematology (ASH) 2022 Annual Meeting.
    - Objective response rate (ORR) of 89% (25 of 28 evaluable patients) observed for patients with R/R MCL treated with zilovertamab plus ibrutinib, which compares favorably to the historical ORR of 66% for ibrutinib monotherapy
    - Complete response (CR) rate of 43% for R/R MCL patients treated with zilovertamab plus ibrutinib (12 of 28 evaluable patients), which compares favorably to the historical ORR of 20% for ibrutinib monotherapy
    - 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
    - Median progression-free survival (PFS) had not been reached for R/R MCL patients with TP53 mutation treated with zilovertamab plus ibrutinib, with a landmark PFS of approximately 85% at 15 months, which compares favorably to the historical ibrutinib monotherapy median PFS of 4 months
    - Landmark PFS of 100% at 42 months for patients with CLL with 17p deletion or TP53 mutations treated with zilovertamab plus ibrutinib, which compares favorably to a recent data update from the ALPINE study of patients with R/R CLL, with a landmark PFS of 55.7% at 24 months for ibrutinib monotherapy, and 77.6% at 24 months for zanubrutinib monotherapy
    - Mutation in the TP53 gene is the most commonly acquired mutation in cancer, including hematological malignancies. TP53 aberrations are associated with markedly decreased survival and predict inadequate therapeutic response, thus being among the strongest predictive and prognostic factors guiding treatment decisions in CLL and MCL
- In December 2022, we received helpful feedback from the FDA from our pre- Investigational New Drug (IND) meeting for ONCT-534, our novel dual-action androgen receptor inhibitor (DAARI)
- In January 2023, we obtained our first Institutional Review Board (IRB) approval for the Phase 1/2 study of ONCT-808, our autologous CAR-T targeting ROR1-expressing hematologic malignancies (NCT05588440)

Expected Upcoming Milestones

- Zilovertamab, our ROR1 antibody
    - Opening of additional countries for global clinical registrational Phase 3 Study ZILO-301
    - Continuing evaluation of potential to treat patients with CLL & MCL and TP53 mutations and/or 17p deletions
- ONCT-808, our autologous ROR1-targeted CAR T cell therapy

- Initial clinical data available by the end of 2023
- ONCT-534, our dual-action androgen receptor inhibitor
  - U.S. IND application submission planned in mid-2023

Fourth Quarter and Full Year 2022 Financial Results

Our grant revenue was $0.2 million for the fourth quarter ended December 31, 2022, and was $1.5 million for the full year 2022.

Our total operating expenses for the fourth quarter ended December 31, 2022 were $12.1 million, including $1.8 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 $3.3 million. Net loss for the fourth quarter was $11.4 million, or a loss of $0.20 per share, basic and diluted. For the full year 2022, total operating expenses were $46.4 million, including $7.4 million in non-cash stock-based compensation expense, and our net loss was $44.2 million, or a loss of $0.84 per share, basic and diluted.

As of December 31, 2022, we had approximately 57.5 million shares of common stock outstanding, $63.7 million in cash, cash equivalents and short-term investments and no debt. We believe these funds will be sufficient to fund our operations into the first quarter of 2024.

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. Oncternal's lead clinical program is zilovertamab, an investigational monoclonal antibody designed to inhibit the function of Receptor Tyrosine Kinase-Like Orphan Receptor 1 (ROR1). Study ZILO-301 (NCT05431179), a global Phase 3 study to evaluate zilovertamab in combination with ibrutinib for the treatment of patients with relapsed/refractory mantle cell lymphoma (R/R MCL) has been initiated. Zilovertamab continues to be evaluated in ongoing Phase 1/2 Study CIRM-0001 (NCT03088878) in combination with ibrutinib for the treatment of patients with MCL, chronic lymphocytic leukemia (CLL) and marginal zone lymphoma (MZL). Zilovertamab is also being evaluated in two investigator-initiated studies: a Phase 2 clinical trial of zilovertamab in combination with venetoclax, a Bcl-2 inhibitor, in patients with R/R CLL (NCT04501939), and a Phase 1b study of zilovertamab in combination with docetaxel in patients with metastatic castration-resistant prostate cancer (NCT05156905). ONCT-808 is an autologous chimeric antigen receptor T (CAR T) cell therapy that targets ROR1, with an active U.S. IND as of the end of September 2022. Oncternal has initiated Study ONCT-808-101 (NCT05588440) for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including patients who have failed previous CD19 CAR T treatment. ONCT-534 is a dual-action androgen receptor inhibitor (DAARI) with preclinical activity in prostate cancer models against both unmutated androgen receptor (AR), and against multiple forms of AR mutation as a potential treatment for castration resistant prostate cancer, including those with unmet medical need due to resistance to androgen receptor inhibitors. Final IND-enabling studies for ONCT-534 are under way. 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 the initiation, enrollment and expansion of clinical studies; timing for regulatory filings and communications; Oncternal's expected cash runway; and the potential that Study ZILO-301 can serve as a registrational clinical trial. 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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Exhibit 99.1

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 63,724	$ 90,765
Total assets	68,651	93,585
Total liabilities	7,682	5,465
Accumulated deficit	(158,300)	(114,130)
Total stockholders' equity	60,969	88,120

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Grant revenue	$ 171	$ 556	$ 1,490	$ 4,315
Operating expenses:				
Research and development	8,798	6,018	32,980	24,086
General and administrative	3,288	2,618	13,457	11,595
Total operating expenses	12,086	8,636	46,437	35,681
Loss from operations	(11,915)	(8,080)	(44,947)	(31,366)
Interest income	515	7	777	33
Net loss	$ (11,400)	$ (8,073)	$ (44,170)	$ (31,333)
Net loss per share, basic and diluted	$ (0.20)	$ (0.16)	$ (0.84)	$ (0.64)
Weighted-average shares outstanding, basic and diluted	56,576	49,426	52,594	49,321