# 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): June 30, 2020**

# 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**<br>**Suite 300**<br>**San Diego, California** | **92130** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (858) 434-1113**

**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 Capital Market** |

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 8.01 Other Events.**

On June 30, 2020, Oncternal Therapeutics, Inc. ("Oncternal" or the "Company") announced an updated clinical strategy for its investigational ROR1 monoclonal antibody, cirmtuzumab, that prioritizes development in mantle cell lymphoma ("MCL"), based on encouraging interim clinical results from the ongoing Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma ("CIRLL") Phase 1/2 clinical trial that were presented at the American Society of Clinical Oncology 2020 Annual Meeting ("ASCO 2020") in May 2020.

The Company reported a 58% complete response ("CR") rate, a 83% overall best objective response rate ("ORR"), and a progression free survival rate of 17.5 months with a median follow-up of 8.3 months, for patients with relapsed/refractory MCL in the ongoing Phase 1/2 CIRLL clinical trial of cirmtuzumab in combination with ibrutinib, a Bruton's tyrosine kinase ("BTK") inhibitor, at ASCO 2020. These response rates in heavily pretreated patients were higher than the historical published CR of 23% and ORR of 67% for single-agent ibrutinib for patients with MCL who had received more than one prior therapy (Rule 2019, Haematologica). Four of these patients with MCL had been previously treated with and responded to ibrutinib, prior to participating in the CIRLL study. All four of these patients responded to the combination of cirmtuzumab and ibrutinib, two achieving CRs and two achieving partial responses. The Company believes that the interim results presented at ASCO 2020 are clinically relevant given the unmet medical need for patients with MCL.

As a result, the Company is amending the CIRLL study to increase the number of patients with relapsed/refractory MCL to be enrolled in the Phase 2 Expansion Cohort to at least 20 patients and to allow enrollment of patients with a broader range of prior BTK inhibitor treatments.

The Company has also requested a meeting with the U.S. Food and Drug Administration ("FDA") to discuss the results of the recent interim analysis of the CIRLL study and to seek guidance on a potential accelerated approval pathway for cirmtuzumab plus ibrutinib in patients with relapsed/refractory MCL.

At ASCO 2020, the Company also reported a 100% progression-free survival rate, 88% ORR and 3% CR rate, with a median follow-up of 12.8 months, for patients with chronic lymphocytic leukemia ("CLL") treated with cirmtuzumab in combination with ibrutinib in the CIRLL study. These interim data did not satisfy the hypothesis that ibrutinib plus cirmtuzumab would produce a CR rate 25% greater than the historical response rate for ibrutinib alone. Based on these interim results, Oncternal will continue treatment and follow-up of the patients with CLL who are already enrolled in the CIRLL study for up to two years or until disease progression, but will limit total enrollment of patients in the randomized Phase 2 CLL cohort to approximately 35 patients, in order to focus resources on the MCL portion of the study. The Company believes that, while significant unmet medical need exists in both CLL and MCL, the MCL indication may offer a more rapid path to potential regulatory approval.

Additionally, Oncternal plans to further explore clinical combination strategies for cirmtuzumab for patients with hematologic malignancies. Accordingly, the Company is supporting a new, investigator-sponsored Phase 2 clinical trial of cirmtuzumab in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL in collaboration with the University of California San Diego School of Medicine ("UC San Diego"). Preclinical studies performed in the laboratory of Dr. Thomas Kipps at UC San Diego reported synergy between cirmtuzumab and venetoclax, providing a rationale for this combination clinical trial (Rassenti 2017, PNAS).

Also on June 30, 2020, the Company announced that the FDA has granted the Company orphan drug designations of cirmtuzumab for treatment of MCL and for treatment of CLL/small lymphocytic lymphoma.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat rare diseases or conditions, which are defined as diseases or conditions that affect fewer than 200,000 people in the United States or that affect more than 200,000 people but where there is no reasonable expectation that the costs of developing and marketing the drug will be recovered through future sales of the drug in the United States. Orphan drug designation for cirmtuzumab qualifies Oncternal for certain benefits including tax credits for qualified clinical trials, exemption from certain FDA application fees, and the potential for market exclusivity upon regulatory approval, if received, for an orphan-designated indication.

MCL is an aggressive form of non-Hodgkin's lymphoma. MCL prevalence is estimated to be approximately 13,000 to 21,000 patients in the United States. MCL is an aggressive cancer that carries a poor prognosis, with a median survival of about two to five years and a 10-year survival rate of approximately 5%-10%.

CLL is the most common form of leukemia in adults, accounting for 25-30% of all leukemias in the United States. CLL prevalence is estimated to be approximately 158,000 to 178,000 patients in the U.S. Despite various recently approved therapies, CLL generally remains incurable.

**Cautionary Note Regarding Forward-Looking Statements**

Oncternal cautions you that statements included in this report 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 the company’s current beliefs and expectations. Forward looking statements include statements regarding Oncternal’s beliefs, goals, intentions and expectations, and include: the potential of cirmtuzumab to treat ROR1 expressing cancers, including MCL, CLL, Her2-negative breast cancer and other solid tumors, and benefit patients with unmet medical needs; Oncternal’s intention to expand enrolment patients with elapsed/refractory MCL; the potential benefits of the investigator-sponsored Phase 2 clinical trial of cirmtuzumab in combination with venetoclax; and the expected benefits associated with orphan drug designation. Forward looking statements are subject to risks and uncertainties inherent in Oncternal’s business, which include, but are not limited to: the risk that preclinical studies and interim results of a clinical trial do not necessarily 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, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab and Oncternal’s other product candidates, which could adversely impact the company’s ability to complete clinical trials and obtain regulatory approval for such product candidates; Oncternal has encountered delays, and may encounter additional delays or difficulties, in enrolling patients in its clinical trials as a result of the COVID-19 pandemic; the COVID-19 pandemic may disrupt Oncternal’s business operations, increasing its costs; uncertainties associated with the clinical development and process for obtaining regulatory approval of cirmtuzumab and Oncternal’s other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; Oncternal’s dependence on the success of cirmtuzumab and its other product development programs; the risk that the regulatory landscape that applies to the development program for cirmtuzumab and the company’s other product candidates may change over time; the risk that the approval of one of our product candidates may be blocked for seven years if a competitor obtains approval of the same drug or biologic, as defined by the FDA, or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease; the risk that competitors may develop technologies or product candidates more rapidly than Oncternal, or that are more effective than Oncternal’s product candidates, which could significantly jeopardize Oncternal’s ability to develop and successfully commercialize its product candidates; the risk that the benefits associated with orphan drug designation may not be realized, including that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained; the risk that, if an orphan designated product, including cirmtuzumab, receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity; the possibility that competitors may receive approval of different products for the indication for which an orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity; Oncternal’s limited operating history and the fact that it has incurred significant losses, and expects to continue to incur significant losses for the foreseeable future; the risk that the company will have insufficient funds to finances its operations after the fourth quarter of 2020 and may not be able to obtain sufficient additional financing when needed or at all as required to achieve its goals, which could force the company to delay, limit, reduce or terminate its product development programs or other operations, and other risks described in the company’s prior periodic public filings with the U.S. Securities & Exchange Commission. All forward-looking statements in this report 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.

**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: June 30, 2020

By: /s/ James B. Breitmeyer
Name: James B. Breitmeyer, M.D., Ph.D.
Title: President and Chief Executive Officer