# 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) **December 9, 2019**

# 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 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 8.01 Other Events.**

On December 9, 2019, Oncternal Therapeutics, Inc. ("Oncternal" or the "Company") announced the presentation of updated interim clinical data from the ongoing Phase 1/2 CIRLL (Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma) clinical trial, in which cirmtuzumab, an investigational anti-ROR1 monoclonal antibody, is being evaluated in combination with ibrutinib in patients with chronic lymphocytic leukemia ("CLL") or mantle cell lymphoma ("MCL"). The results were presented at the American Society of Hematology (ASH) Annual Meeting in Orlando on December 7, 2019.

Thirty-four patients with CLL who had never been treated with a BTK inhibitor were enrolled in the dose-finding and dose-confirming cohorts of this clinical trial, including 12 treatment-naïve and 22 relapsed/refractory patients, and all 34 were evaluable for efficacy. As of the data cut-off in early November 2019,

- Twenty nine of the 34 patients achieved a response, for an overall best objective response rate of 85%.
- One patient achieved a complete response (CR) and remained in remission six months after completion of the trial and discontinuation of all anti-CLL therapy. In addition, three patients met radiographic and hematologic response criteria for Clinical CR, bone marrow biopsy not performed but pending.
- Five patients had stable disease.
- The total clinical benefit rate was 100%.
- None of the patients progressed or died, for a progression-free survival (PFS) of 100% with a median follow-up of 7.4 months.
- Patients achieved responses rapidly, with 68% of patients achieving a clinical response by three months on combination therapy.
- The rise in leukemic cell counts that is typically seen in the first six months with ibrutinib monotherapy was blunted with the cirmtuzumab plus ibrutinib combination, and leukemic cell counts returned toward baseline and normal levels rapidly.

Twelve patients with relapsed/refractory MCL, eight of whom were evaluable for efficacy, were enrolled in the dose-finding cohort of this trial. As of the data cut-off, five of the eight evaluable patients had achieved a clinical response, for an overall best objective response rate of 63% at a median follow-up of six months. Two patients with aggressive or bulky and heavily pre-treated MCL achieved CR, the longest of which is continuing with the patient on study for over 17 months. In addition, three patients had stable disease, for a total clinical benefit rate of 100%.

Cirmtuzumab as a single agent has been very well tolerated in this study. The combination of cirmtuzumab plus ibrutinib has also been well tolerated, with adverse events consistent with those reported for ibrutinib alone. There have been no dose limiting toxicities and no serious adverse events attributed to cirmtuzumab alone.

Genetic analysis of CLL cells from three patients showed pre-treatment transcriptome profiles associated with a stemness signature and NF-kB-driven inflammation. Both genetic signatures were reversed in these patients following cirmtuzumab treatment.

## 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, forward-looking statements can be identified 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, and the potential for interim data to be replicated or continue to show improved clinical efficacy as the ongoing trial continues; statements regarding Oncternal's clinical development plans; and Oncternal's belief that ROR1 is a potentially attractive target for cancer therapy. Forward looking statements are subject to risks and uncertainties inherent in Oncternal's business, which include, but are not limited to: the risk that 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, including interim response results may not be confirmed by later assessments; 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; 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, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals; 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; 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 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 press releases as well as in public periodic filings with the U.S. Securities & 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.

**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: December 9, 2019

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