# 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 7, 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**
**Suite 300**
**San Diego, CA 92130**
**(858) 434-1113**
(Address and zip code; telephone number, including area code, of registrant's principal executive offices)

**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 7, 2020, Oncternal Therapeutics, Inc. (the "Company") announced 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 mantle cell lymphoma ("MCL") and chronic lymphocytic leukemia ("CLL"). The clinical trial is being partially funded by the California Institute for Regenerative Medicine. The data were presented at the American Society of Hematology 2020 Virtual Annual Meeting.

As of the data cut-off date of October 30, 2020, 15 patients with relapsed/refractory MCL enrolled in the dose-finding and dose-expansion cohorts of this clinical trial were evaluable for efficacy:

- The overall best objective response rate ("ORR") was 87% (13 of 15 evaluable patients), improved over the 83% ORR reported at the American Society of Clinical Oncology 2020 Annual Meeting.
- The complete response ("CR") rate, determined by Cheson criteria, remains 57% (7 of 12 evaluable patients) for Part 1 of the study, and is 47% (7 of 15 evaluable patients) for Part 1 + Part 2, including the three patients from Part 2 who have shorter follow up. One of the seven patients had a complete metabolic response as assessed by PET scan, with an indeterminate bone marrow biopsy on blinded review. All complete responses remained durable, ranging from 5-25 months as of the cutoff date, with no progressions reported after achieving a CR. Six patients (40%) achieved a partial response (PR). In addition, two patients had stable disease ("SD"), for a total best clinical benefit rate (CR, PR and SD) of 100%.
- Median progression-free survival ("PFS") was not reached, with the 95% confidence interval above 17.5 months, after a median follow-up of 12.1 months.
- Patients had received a median of two prior therapies (range 1-5) before participating in this clinical trial, with 73% of patients with two or more prior lines of therapy. Four patients had received prior treatment with ibrutinib and all four achieved clinical responses in this clinical trial, with two CRs and two PRs. Fourteen of the 15 evaluable patients (93%) had high or intermediate MCL International Prognostic Index (MIPI-b) risk score at study entry.
- Historical data published for single-agent ibrutinib for 370 patients with relapsed/refractory MCL, who had received a median of two prior therapies, reported an ORR of 66%, CR rate of 20%, PR rate of 46%, and median PFS of 12.8 months (Rule et al., 2017, *British Journal of Haematology*).

As of the data cut-off date on October 30, 2020, 56 evaluable patients with CLL were enrolled in the dose-finding, dose-confirming and randomized cohorts of this clinical trial, 49 of whom were treated with the combination of cirmtuzumab and ibrutinib:

- Forty-five of the 49 patients achieved a clinical response, for an overall best objective response rate of 92%, including one patient who achieved a CR. In addition, four patients had stable disease, for a total clinical benefit rate (CR, PR, and SD) of 100%.
- The median PFS was not reached for patients with treatment-naïve CLL (n=19) after a median follow-up of 16.6 months, and median PFS was 29.5 months for patients with relapsed/refractory CLL (n=30) after a median follow-up of 17.1 months.

The combination of cirmtuzumab plus ibrutinib has 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.

**Forward-Looking Information**

The Company 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 the Company’s beliefs, goals, intentions and expectations including, without limitation, statements regarding the Company’s development plans. Forward looking statements are subject to risks and uncertainties inherent in the Company’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 the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab, TK216 and the Company’s other product candidates, which could adversely impact the company’s ability to complete clinical trials and obtain regulatory approval for such product candidates; the Company 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 the Company’s business operations, increasing its costs; uncertainties associated with the clinical development and process for obtaining regulatory approval of cirmtuzumab and the Company’s other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the Company’s dependence on the success of cirmtuzumab, TK216 and its other product development programs; FDA may not agree with the study design for a pivotal trial in MCL which may increase the costs or delay the final data of such trial; the risk that the approval of one of the Company’s 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 its 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 the Company, or that are more effective than the Company’s product candidates, which could significantly jeopardize the Company’s ability to develop and successfully commercialize its product candidates; the Company’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 finance its planned operations 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; 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; and other risks described in the Company’s public periodic 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, the Company 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.

**Item 9.01. Exhibits.**

*(d) Exhibits.*

| Exhibit No. | Description |
|---|---|
| 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: December 7, 2020

By: /s/ James B. Breitmeyer

Name: James B. Breitmeyer

Title: Chief Executive Officer