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 12, 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 Suite 300 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 8.01Other Events.

On December 12, 2019, Oncternal Therapeutics, Inc.("Oncternal" or the "Company") announced the presentation of updated interim clinical data from the ongoing Phase 1b clinical study of cirmtuzumab, an investigational anti-ROR1 monoclonal antibody, in combination with paclitaxel in patients with HER2-negative, metastatic or locally advanced unresectable breast cancer. The results were presented at the San Antonio Breast Cancer Symposium (SABCS) in San Antonio, Texas, on December 12, 2019.

As of the data cut-off date of November 27, 2019, a total of eight patients with HER2-negative, metastatic or locally-advanced unresectable breast cancer were enrolled in the study. Seven of the eight patients were evaluable for safety and efficacy. Four of the patients had triple negative breast cancer (TNBC) at study enrollment. Four of the seven evaluable patients achieved a partial response, for an objective response rate of 57%, including one partial response that continued on cirmtuzumab alone for 30 weeks after discontinuing paclitaxel. The combination of cirmtuzumab and paclitaxel has been well tolerated in this trial, with no study discontinuations for toxicity and no dose-limiting toxicities observed to date. Adverse events have been consistent with the known safety profile of paclitaxel alone. Pharmacokinetic analysis of serial plasma samples for free unbound antibody from two patients provided results similar to those observed in previous studies of chronic lymphocytic leukemia patients, consistent with a projected half-life of 30 days. No decline in antibody concentration over time was observed, consistent with the absence of neutralizing antibodies.

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. 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 for interim data results to be replicated 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 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, 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 12, 2019

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