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): **April 2, 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, 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 April 2, 2020, Oncternal Therapeutics, Inc. ("Oncternal" or the "Company") disclosed additional interim data from the ongoing open-label, first-in-human, multicenter Phase 1 clinical trial evaluating TK216 as a single agent and in combination with vincristine in patients with relapsed/refractory Ewing sarcoma, which is a rare pediatric cancer. TK216 is the Company's product candidate designed to inhibit the ETS (E26 Transformation Specific) family of oncoproteins, which have been shown in preclinical studies to alter gene transcription and RNA processing and lead to increased cell proliferation and invasion.

As of the data cut-off date of March 26, 2020, seven patients treated at the recommended Phase 2 dose of TK216 (200 mg/m^2/day for 14 days without or with vincristine) were evaluable for clinical responses. Two of the seven patients (28.5%) had achieved partial responses (PR) with substantial tumor regression, two patients had stable disease and three had progressive disease. Two additional patients had rapidly progressive disease early in the first treatment cycle and exited the trial before being evaluable for toxicity or efficacy and, per protocol, were replaced with two new patients currently enrolled in the trial.

The first patient who achieved a deep and sustained PR at the recommended Phase 2 dose of TK216 had Ewing sarcoma of the clavicle with lung metastases and had received and failed multiple lines of therapy prior to participating in this clinical trial, including radiation, multiple chemotherapies and other targeted therapies. Following two cycles of TK216 as a single agent, all target lung lesions regressed and the patient achieved a PR. Vincristine was later added starting in the third cycle, and after six months of treatment, a single remaining 7 mm lung nodule was resected, resulting in a surgical complete remission. The patient remained enrolled in the trial with no evidence of disease after more than twelve months of treatment. TK216, with or without vincristine, was well tolerated by this patient, with minimal myelosuppression.

The second patient who achieved a deep PR at the recommended Phase 2 dose of TK216 was initially diagnosed with a 10 cm Ewing sarcoma tumor near the right kidney and extensive, bilateral lung metastases. This patient had received and failed multiple lines of therapy prior to participating in the TK216 clinical trial, including extensive chemotherapy and surgery. At the time the patient enrolled in the trial in January 2020, multiple lung nodules were rapidly enlarging. The patient received TK216 at 200 mg/m^2/day for 14 days and vincristine at 0.75 mg/m^2 on day one for each treatment cycle, and experienced myelosuppression in the first cycle of treatment. This was manageable with growth factor support and did not recur with the next treatment cycle, without TK216 dose reduction. After two cycles of treatment, the patient had a 90% reduction of target lesions (with the sum of the longest diameters of the target lesions reduced from 20 mm to 2 mm), and resolution of non-target lesions.

The expansion cohort of this clinical trial will continue to evaluate the recommended Phase 2 dose regimen of TK216 in combination with vincristine and is anticipated to enroll 18 patients.

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: statements regarding the enrollment of patients in the expansion cohort of the Phase 1 clinical trial of TK216 in patients with relapsed/refractory Ewing sarcoma. The inclusion of forward-looking statements should not be regarded as a representation by Oncternal that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the Company's business, including, without limitation: uncertainties associated with the clinical development and process for obtaining regulatory approval of TK216 and the Company's other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; 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 TK216 and the Company's other product candidates; risks associated with the COVID-19 pandemic, which may adversely impact our business and clinical trials, including delaying the enrollment of patients; the risk that the regulatory landscape that applies to the development programs for the Company's 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 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 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: April 2, 2020

By: /s/ James B. Breitmeyer

Name: James B. Breitmeyer, M.D., Ph.D.

Title: President and Chief Executive Officer