#### 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): January 13, 2020

#### **Oncternal Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter) 000-50549

Delaware (State or Other Jurisdiction of Incorporation)

(Commission File Number) 62-1715807 (IRS Employer Identification No.)

92130

(Zip Code)

12230 El Camino Real Suite 300 San Diego, California

(Address of Principal Executive Offices)

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  $\Box$ 

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.

Oncternal Therapeutics, Inc. ("Oncternal" or the "Company"), plans to use an updated presentation in its upcoming meetings with investors and analysts. A copy of the updated presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01.

Oncternal's updated corporate slide presentation has been posted to the Company's website, <u>www.oncternal.com</u>. Oncternal plans to use its website to disseminate future updates to its corporate presentations and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information set forth in this Item 7.01 is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

By filing this Current Report on Form 8-K and furnishing the information in this Item 7.01, Oncternal makes no admission as to the materiality of Item 7.01 in this report or the presentation available on Oncternal's website. The information contained in the presentation is summary information that is intended to be considered in the context of Oncternal's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that Oncternal makes, by press release or otherwise, from time to time. Oncternal or obligation to publicly update or revise the information contained in this Item, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating its website or through other public calcource.

#### Cautionary Note Regarding Forward-Looking Statements

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 expected timing for achieving key milestones, including completing and announcing results of clinical trials of the Company's product candidates, and the anticipated market potential, duration of patent coverage, and ability to obtain and maintain favorable regulatory designations for the Company's product candidates and preclinical programs. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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: risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing 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, as follow-up on the outcome of any particular patient continues, and as more patients in the study; the risk that interim results of a clinical trial do not necessarily predict. If all results seen in other patients

Item 9.01.

(d) Exhibits.

Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Updated Corporate Slide Presentation

#### SIGNATURES

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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: January 13, 2020

By: /s/ James B. Breitmeyer

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



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#### FORWARD LOOKING STATEMENTS

This presentation includes forward-looking statements (including within the meaning of §21E of the U.S. Securities Exchange Act of 1934, as amended, and § 27A of the U.S. Securities Act of 1933, as amended). Forward looking statements, which generally include statements regarding goals, plans, intentions and expectations, are based upon current beliefs and assumptions of Oncternal Therapeutics, Inc. ("Oncternal," or the "Company") and are not guarantees of future performance. Statements that are not historical facts are forward-looking statements, and include statements regarding the expected timing for achieving key milestones, including completing and announcing results of clinical trials of the Company's product candidates, and the anticipated market potential, duration of patent coverage, and ability to obtain and maintain favorable regulatory designations for the Company's product candidates and preclinical programs.

All forward looking statements are subject to risks and uncertainties, which include, but are not limited to: risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; uncertainties associated with the clinical development and process for obtaining regulatory approval of Oncternal's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that results seen in a case study of one patient may not predict the results seen in other patients in the clinical trial, including the possibility that there may not be additional complete or sustained responses from any other patients in the study; 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, as follow-up on the outcome of any particular patient continues, 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 Oncternal's product candidates; potential changes in the regulatory environment for developing and obtaining approval of product candidates and preclinical programs, which may result in delays or termination of development of such product candidates or preclinical programs, or unexpected costs in obtaining regulatory approvals; and the risk that Oncternal may be unable to obtain sufficient additional capital to continue to advance the development of its product candidates and preclinical programs.

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 in this presentation are current only as of the date on which the statements were made. Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC by Oncternal, including its most recent Annual Report on Form 10-K, Form 10-K/A, Quarterly Report on Form 10-Q, and Current Reports on Form 8-K filed with the SEC. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Cirmtuzumab, TK216 and Oncternal's CAR-T targeting ROR-1 are investigational product candidates or preclinical programs that have not been approved by the U.S. Food and Drug Administration for any indication.

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# **Breakthrough Oncology Opportunities, Cutting Edge Science**

# THREE NOVEL ONCOLOGY PRODUCT CANDIDATES IN DEVELOPMENT

- **TK216**: targeted ETS inhibitor in Phase 1b in Ewing sarcoma
  - Additional opportunities in cancers with ETS alterations: AML, prostate, DLBCL
- Cirmtuzumab: ROR1 mAb in randomized Phase 2 CLL, Phase 1b MCL, Phase 1b HER2-negative metastatic breast cancer
   Additional opportunities in lung, prostate and ovarian cancer
- ROR1 CAR-T: preclinical development

## **EXPERIENCED MANAGEMENT AND BOARD OF DIRECTORS**

## MULTIPLE DATA CATALYSTS EXPECTED IN 2020

- Clinical data updates in MCL, CLL, breast cancer and Ewing sarcoma
- ROR1 CAR-T expected to reach clinic in 4Q 2020 in China with Shanghai Pharma

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# **Robust Pipeline – Novel Product Candidates in Multiple Indications**





# Anticipated Pipeline Milestones in 2020



• TK216	
<ul> <li>Phase 1b in Ewing sarcoma: expansion cohort data</li> </ul>	2H 2020
<ul> <li>Expect 5-10 additional patients enrolled by mid-2020</li> </ul>	
<ul> <li>IND-enabling data in additional ETS-driven tumors</li> </ul>	2H 2020
<ul> <li>Targeting prostate, AML, DLBCL</li> </ul>	
Cirmtuzumab	
<ul> <li>Phase 1b additional data in MCL</li> </ul>	Mid-2020
Follow-up for 12 patients in Part 1	
<ul> <li>Phase 1/2 additional data in CLL</li> </ul>	Mid-2020
<ul> <li>12-month follow-up for 34 patients in Parts 1&amp;2</li> </ul>	
<ul> <li>Phase 1b additional data in HER2-negative breast cancer</li> </ul>	2H 2020
<ul> <li>IND-enabling data in additional indications</li> </ul>	Mid-2020
Targeting NSCLC, prostate, ovarian cancer	
<ul> <li>ROR1 CAR-T first-in-human dosing in China</li> </ul>	4Q 2020

# **Experienced Team**







## Patient Story: Sustained Clinical Response with TK216 in Patient with Extensively Treated Metastatic Relapsed / Refractory Ewing Sarcoma



- 19-year old male
- Presented in 2015 with metastatic Ewing sarcoma involving his clavicle and lungs
- Received and failed numerous treatments:
  - surgery
  - radiation
  - chemotherapies (vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide, irinotecan, temozolomide)
  - bevacizumab
  - pazopanib

- Enrolled in Phase 1 study of TK216 at MSKCC in 2019
- Received TK216 in final, highest dose-finding dosage cohort (200 mg/m<sup>2</sup>/day TK216 for 14 days)
- After two cycles of **single-agent** TK216: resolution of all target pulmonary metastases
  - Treatment well tolerated, with minimal myelosuppression
- Sustained response after 6 months of TK216
   Vincristine added after 2nd cycle
- Residual non-target 7 mm lung lesion excised, leading to surgical complete remission
- No evidence of disease at 8 months on study



Baseline: February 2019 ONCT Corporate Presentation - Jan. 2020

After 2 cycles TK216 only

Lung metastases resolved

Meyers MSKCC, 2019 CTOS



April 2019



- · Orphan disease, second most common pediatric bone tumor
  - U.S. incidence ~430 p.a.<sup>(1)</sup>
  - U.S. prevalence ~4,000<sup>(1)</sup>
- Median age at diagnosis 15 years
- No standard second-line treatment and poor prognosis:
  - Metastatic EWS: 5-year OS ~30%
  - Recurrent EWS: 5-year OS ~10-15%
- Nearly all Ewing sarcoma driven by translocations of ETS family oncogenes (EWS-FLI1 85-90%, EWS-ERG ~10%)
  - ETS transcription factors regulate many genes implicated in cancer development and progression
- ETS = (E26 Transformation-Specific oncogene family)

(1) Incidence 1.3 per million, prevalence 12 per million – SEER data "ICD-0-3/WHO 2008 Ewing Tumor", accessed January 3, 2020; NCI Ewing Sarcoma Treatment (PDQ), accessed September 11, 2019; company analysis

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# **TK216: First-in-Class Targeted ETS Oncoprotein Inhibitor**



- Enrolling expansion cohort, Phase 1b clinical trial (n=18) in relapsed/refractory Ewing sarcoma
- Orphan Drug Designation and Fast Track Status granted by FDA

#### **MECHANISM OF ACTION**

- Novel small molecule inhibitor of ETS family oncoproteins
  - Designed to prevent/disrupt formation of transcriptionally-active protein complex
- ETS transcription factors regulate many target genes implicated in cancer development and progression

#### **OPPORTUNITY**

- Fast-to-market strategy in Ewing sarcoma
  - Potentially Pediatric Voucher eligible
- Significant market potential in other cancers with ETS alterations:
  - AML, prostate cancer, DLBCL
- Patent coverage through 2037

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ETS = E26 Transformation-Specific oncogene family

Active complex



Inactive complex



Interim data presented at CTOS 2019:

- 3+3 dose and schedule escalation cohorts<sup>1</sup>
  - 32 patients with relapsed, refractory Ewing sarcoma
  - Average of 4 prior therapies
- <u>Safety</u>: generally well-tolerated, with dose limiting toxicity of manageable myelosuppression
- <u>PK</u>: drug plasma levels met or exceeded those associated with anticancer activity in preclinical models
- <u>Activity</u>: major, sustained tumor regression observed in 1 of 3 patients treated at highest dose schedule (200 mg/m<sup>2</sup>/day for 14 days)
- Expansion cohort opened in December 2019
  - N=18
  - 200 mg/m<sup>2</sup>/day TK216 for 14 days



1 – Meyers MSKCC, 2019 CTOS Tokyo





TK216 – Data	Anticipated	in	2020
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<ul> <li>Phase 1b in Ewing sarcoma: expansion cohort data</li> <li>Expect to enroll 5-10 additional patients by mid-2020</li> </ul>	2H 2020
<ul> <li>IND-enabling data in additional ETS-driven tumors</li> <li>AML, prostate, DLBCL</li> </ul>	2H 2020



#### Patient Story: Durable Complete Response in Patient with Relapsed Mantle Cell Lymphoma in Clinical Trial of Cirmtuzumab and Ibrutinib



- 67-year old male
- Diagnosed with MCL in 2009
- Previously received and failed 5 treatment regimens including chemotherapy, biologics, autologous stem cell transplant, and allogeneic stem cell transplant before enrolling onto this study
- 9x7 cm mediastinal / chest wall lesion

Baseline



After 3 months

**Complete Response** 

Cirmtuzumab + Ibrutinib

Rapid clinical response with confirmed CR after 3

months cirmtuzumab + ibrutinib

cirmtuzumab + ibrutinib

• CR confirmed and durable at 14+ months



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Choi, 2019 ASCO 15

# Cirmtuzumab: First-in-class ROR1 Monoclonal Antibody

# **DEVELOPMENT STATUS**

- Well-tolerated and active in completed CLL Phase 1
- Phase 1b enrolled in CLL in combination with ibrutinib
- Randomized Phase 2 enrolling in CLL in combination with ibrutinib
- Phase 1b enrolling in MCL in combination with ibrutinib
- Phase 1b enrolling in HER2-negative breast cancer

## **MECHANISM OF ACTION**

- High-affinity humanized ROR1 monoclonal antibody
- Inhibits Wnt5a signaling
  - Decreased proliferation, invasion, metastasis, stemness

## OPPORTUNITY

- Potential in multiple hematologic and solid cancers
- Supported by ~\$14M non-dilutive CIRM grant
- Patent coverage through 2033

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ROR1 = Receptor tyrosine kinase-like Orphan Receptor 1 CIRM = California Institute for Regenerative Medicine



Cirmtuzumab + BTKi Target Product Profile in CLL and MCL: Achieve Deeper Responses Than BTKi Alone, with Better Tolerability or Minimal Added Toxicity

Potential differentiation for cirmtuzumab + BTKi (ibrutinib) combination in CLL and MCL:

- Achieve more rapid and deeper responses than BTKi alone, with better tolerability or minimal added toxicity
- Become standard-of-care combination therapy for patients with CLL and MCL, particularly for patients who are older and/or have significant co-morbidities
  - Certain other combination therapies are associated with significant toxicities
  - Average age of patients diagnosed with CLL is 71<sup>(1)</sup> and MCL mid-60s<sup>(2)</sup>



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# **ROR1** Overexpressed in Multiple Tumors and Associated with More Aggressive Cancer





 Cancer cells overexpressing ROR1 show increased survival, migration and resistance to chemotherapy ROR1 Expressed on Multiple Solid and Liquid Tumors

MCL	95%
CLL	95%
Uterus	96%
Lymphoma	90%
Prostate	90%
Skin	89%
Pancreatic	83%
Adrenal	83%
Lung	77%
Breast	75%
Testicular	73%
Colon	57%
Ovarian	54%





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## **Cirmtuzumab Demonstrated Promising Preclinical Data in Multiple Tumor Models**



- Discovered by Professor Thomas Kipps (UC San Diego)
- High affinity anti-ROR1 humanized monoclonal antibody
  - Observed t<sub>½</sub> ~30 days supports monthly dosing
- Binds important inhibitory epitope blocking Wnt5a interaction
- No binding to normal adult tissues in GLP tissue crossreactivity studies

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Rassenti 2017 PNAS

Synergistic with paclitaxel in TNBC PDX xenograft model (c<sup>2</sup>1.5 Size ( Lumor 0 00 50 (Days) 20 30 40 Zhang 2016 Cancer Res Anti-tumor activity in PDX models . of ovarian cancer Control - Cirmtuzumab Tumor Size (cm<sup>3</sup>) 0.0 0.0

30

60

Days

90

Supporting Preclinical Data in Solid Tumors



#### Phase 1/2 Study of Cirmtuzumab and Ibrutinib in Patients with CLL and MCL CIRLL: Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma

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## CIRLL Trial Cirmtuzumab + Ibrutinib: Phase 1 Interim Data



- Adverse events typical for ibrutinib alone
  - No dose limiting toxicities or discontinuations due to cirmtuzumab
  - No ≥ Grade 3 common adverse events attributed to cirmtuzumab alone
- MCL cohort: updated data since ASH 2019
  - Best Objective Response Rate of 66.7% (6 of 9 evaluable)
  - Complete response rate of 33.3% (3 of 9 evaluable)
    - All 3 CRs documented at 3 months in heavily pretreated patients
- CLL Cohort
  - Best Objective Response Rate of 85%
    - 1 confirmed complete response and 3 clinical complete responses<sup>1</sup>
  - No progressive disease observed at median follow-up of 7.4 months for Progression Free Survival of 100%
  - Initial rise in leukemic ALC (absolute lymphocyte count) typically seen with ibrutinib blunted with cirmtuzumab & ibrutinib combination

1 - Confirmatory bone marrow biopsies pending

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Source: Choi, 2019 ASH (data cutoff early November 2019) & subsequent company data as of January 10, 2020

CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

#### ASH 2019 presentation of interim data

- CIRLL study
- 34 patients with CLL evaluable for efficacy
   ages 57-86
  - ages 37-86
     median 2 prior therapies
- 8 patients with MCL evaluable for efficacy
  - Ages 49-70median 3 prior
- therapies

  Cirmtuzumab Dose
- Finding: 2-16 mg/kg or 300 or 600 mg fixed dose for up to 18 months
- Ibrutinib at approved dose for CLL + MCL

#### **CIRLL Trial: Interim MCL Part 1 Data Complete Responses in Three Heavily Pretreated Patients**

CR

PR

SD

SD

CR

SD

PR

PR 3

CR 5 4

2

0

2



<sup>\*\*</sup> Change in tumor size (SPD: Sum of Perpendicular Diameters)



Prior ibrutinib/rituximab, HyperCVAD 1.

6

2. Prior chemo, auto-stem cell transplant (SCT), CAR-T

10

8

3. Prior auto-SCT, allo-SCT

4

Source: Choi, 2019 ASH (data cutoff early November 2019) & subsequent company data as of January 10, 2020

12

14

16

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22

•(3)

20

18

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## CIRLL Trial: Interim Part 1&2 Results in CLL Showed 100% PFS and Reduced Lymphocytosis



- No progression or deaths while on study
- PFS 100%, median follow-up 225 days (7.4 months)

Reduced lymphocytosis compared to historical ibrutinib data







SPD = Sum of Perpendicular Dimensions of measurable disease

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Source: Choi, 2019 ASH (data cutoff early November 2019) 24

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#### HER2-negative Breast Cancer: Interim Phase 1 Data Cirmtuzumab + Paclitaxel Presented at SABCS 2019: ORR 57%





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•	Phase 1b additional data in MCL - Follow-up for 12 patients in Part 1	Mid-2020
•	Phase 1/2 additional data in CLL - 12-month follow-up for 34 patients in Parts 1&2	Mid-2020
•	Phase 1b additional data in HER2-negative breast cancer	2H 2020
•	IND-enabling data in additional indications - Targeting NSCLC, prostate, ovarian cancer	Mid-2020









#### **DEVELOPMENT STATUS**

- Preclinical data in hematologic and solid tumor models
- Utilizing cirmtuzumab scFv as targeting component
- Ongoing process optimization and scale-up
- UCSD collaboration with non-dilutive financing from California Institute for Regenerative Medicine (CIRM)
- Shanghai Pharma collaboration, which covers certain manufacturing and clinical development costs

#### OPPORTUNITY

- Selective targeting strategy applicable to multiple tumors with ROR1 expression
- Target initial human proof-of-concept in hematological cancers, then expansion into solid tumors

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# **Financial Information**

Ticker	ONCT (Nasdaq)	
Cash & Cash Equivalents @ 9-30-19 Cash Runway through 2Q 2020	\$23.1M	
Debt	\$0	
Capitalization:		
Common Shares Outstanding	15.4M	
Options	2.5M	
Warrants	0.8M	
Fully Diluted	18.7M	
Non-Dilutive Support		
<ul> <li>CIRM Grant for CIRLL Study</li> </ul>	~\$14M	
Ibrutinib CTM for CIRLL Study	Expanded Supply Agreement	

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# Anticipated Pipeline Milestones in 2020



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