

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2022

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 000-50549

Oncternal Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

62-1715807
(IRS Employer
Identification No.)

**12230 El Camino Real, Suite 230
San Diego, CA 92130
(858) 434-1113**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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, \$0.001 par value	ONCT	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer
Emerging growth company

Accelerated filer
Smaller reporting 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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 28, 2022, the registrant had 56,337,022 shares of common stock outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value)

	<u>September 30,</u> 2022	<u>December 31,</u> 2021
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 70,628	\$ 90,765
Prepaid and other	4,162	2,088
Total current assets	74,790	92,853
Right-of-use asset	122	75
Other assets	1,258	657
Total assets	\$ 76,170	\$ 93,585
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,456	\$ 1,959
Accrued liabilities	4,930	3,431
Deferred grant revenue	118	—
Lease liability	122	75
Total current liabilities	7,626	5,465
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, authorized shares – 5,000 at September 30, 2022 and December 31, 2021; issued and outstanding shares – none	—	—
Common stock, \$0.001 par value; authorized shares – 120,000; issued and outstanding shares – 55,517 and 49,429 at September 30, 2022 and December 31, 2021, respectively	56	49
Additional paid-in capital	215,388	202,201
Accumulated deficit	(146,900)	(114,130)
Total stockholders' equity	68,544	88,120
Total liabilities and stockholders' equity	\$ 76,170	\$ 93,585

See accompanying notes.

Oncernal Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited; in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Grant revenue	\$ 382	\$ 2,128	\$ 1,319	\$ 3,759
Operating expenses:				
Research and development	8,442	8,963	24,182	18,068
General and administrative	3,265	2,802	10,169	8,977
Total operating expenses	11,707	11,765	34,351	27,045
Loss from operations	(11,325)	(9,637)	(33,032)	(23,286)
Interest income	200	7	262	26
Net loss	\$ (11,125)	\$ (9,630)	\$ (32,770)	\$ (23,260)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.19)	\$ (0.64)	\$ (0.47)
Weighted-average shares outstanding, basic and diluted	54,212	49,393	51,252	49,285

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited; in thousands)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (32,770)	\$ (23,260)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,629	4,162
Non-cash lease expense	144	125
Changes in operating assets and liabilities:		
Prepaid and other	(2,675)	(765)
Accounts payable	497	1,603
Accrued liabilities	1,499	(238)
Change in lease liability	(144)	(125)
Deferred grant revenue	118	(1,475)
Net cash used in operating activities	(27,702)	(19,973)
Cash flows from financing activities		
Proceeds from issuance of common stock in public offerings, net	7,568	—
Repurchases of common stock for tax withholding obligations	(3)	—
Proceeds from exercise of stock options	—	414
Proceeds from exercise of common stock warrants	—	202
Net cash provided by financing activities	7,565	616
Net decrease in cash and cash equivalents	(20,137)	(19,357)
Cash and cash equivalents at beginning of period	90,765	116,737
Cash and cash equivalents at end of period	<u>\$ 70,628</u>	<u>\$ 97,380</u>
Supplemental disclosure of non-cash financing activities:		
Cashless exercise of warrants	\$ —	\$ 1,836
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 191	\$ —

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited; in thousands)

Three Months Ended September 30, 2022

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2022	52,150	\$ 52	\$ 209,724	\$ (135,775)	\$ 74,001
Issuance of common stock upon vesting of restricted stock units	6	—	—	—	—
Shares repurchased for settlement of minimum statutory tax withholdings	(2)	—	(3)	—	(3)
Issuance of common stock, net of issuance cost of \$141	3,363	4	3,693	—	3,697
Stock-based compensation	—	—	1,974	—	1,974
Net loss	—	—	—	(11,125)	(11,125)
Balance at September 30, 2022	55,517	\$ 56	\$ 215,388	\$ (146,900)	\$ 68,544

Three Months Ended September 30, 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2021	49,385	\$ 49	\$ 198,897	\$ (96,427)	\$ 102,519
Exercise of warrants for cash	42	—	97	—	97
Vesting related to unvested share liability	—	—	2	—	2
Stock-based compensation	—	—	1,488	—	1,488
Net loss	—	—	—	(9,630)	(9,630)
Balance at September 30, 2021	49,427	\$ 49	\$ 200,484	\$ (106,057)	\$ 94,476

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited; in thousands)

Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	49,429	\$ 49	\$ 202,201	\$ (114,130)	\$ 88,120
Issuance of common stock upon vesting of restricted stock units	6	—	—	—	—
Shares repurchased for settlement of minimum statutory tax withholdings	(2)	—	(3)	—	(3)
Issuance of common stock, net of issuance cost of \$287	6,084	7	7,561	—	7,568
Stock-based compensation	—	—	5,629	—	5,629
Net loss	—	—	—	(32,770)	(32,770)
Balance at September 30, 2022	<u>55,517</u>	<u>\$ 56</u>	<u>\$ 215,388</u>	<u>\$ (146,900)</u>	<u>\$ 68,544</u>

Nine Months Ended September 30, 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2020	48,802	\$ 49	\$ 195,699	\$ (82,797)	\$ 112,951
Exercise of stock options for cash	106	—	414	—	414
Exercise of warrants for cash	60	—	202	—	202
Cashless exercise of warrants	459	—	—	—	—
Vesting related to unvested share liability	—	—	7	—	7
Stock-based compensation	—	—	4,162	—	4,162
Net loss	—	—	—	(23,260)	(23,260)
Balance at September 30, 2021	<u>49,427</u>	<u>\$ 49</u>	<u>\$ 200,484</u>	<u>\$ (106,057)</u>	<u>\$ 94,476</u>

See accompanying notes.

Oncternal Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business, Basis of Presentation and Summary of Significant Accounting Policies

Description of Business

Oncternal Therapeutics, Inc. (the “Company” or “Oncternal”), formerly known as GTx, Inc., was incorporated in Tennessee in September 1997 and reincorporated in Delaware in 2003 and is based in San Diego, California. The Company is a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for the treatment of cancers with critical unmet medical need. The Company’s lead clinical program is zilovertamab, a humanized monoclonal antibody that binds to ROR1 (Receptor-tyrosine kinase-like Orphan Receptor 1). The Company is also developing ONCT-808, a CAR T (chimeric antigen receptor T cells) product candidate that targets ROR1, and ONCT-534, a dual-action androgen receptor inhibitor (“DAARI”) product candidate for the treatment of castration-resistant prostate cancer, including those with clinically important resistance to approved androgen receptor inhibitors.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Oncternal Oncology, Inc. and Oncternal, Inc. All intercompany accounts and transactions have been eliminated in the preparation of the condensed consolidated financial statements.

Liquidity

From inception, the Company has devoted substantially all of its efforts to drug discovery and development and conducting preclinical studies and clinical trials. The Company has a limited operating history and the sales and income potential of the Company’s business and market are unproven. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company’s cost structure.

As of September 30, 2022, the Company had \$70.6 million in cash and cash equivalents and no debt. The Company believes it has sufficient cash to fund its projected operating requirements for at least twelve months from the date of issuance of the condensed consolidated financial statements. However, the Company has experienced net losses and negative cash flows from operating activities since its inception and has an accumulated deficit of \$146.9 million as of September 30, 2022. The Company expects to continue to incur net losses for the foreseeable future and believes it will need to raise substantial additional capital to accomplish its business plan over the next several years. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of public or private equity or debt offerings or other sources, including potential collaborations, strategic alliances and other similar licensing arrangements. If the Company is unable to secure adequate additional funding, the Company may be forced to make reductions in spending, including potentially delaying, scaling back or eliminating certain of its pipeline development programs, extend payment terms with suppliers, or liquidate assets where possible. Any of these actions could materially affect the Company’s business, results of operations and future prospects.

As of September 30, 2022, the Company had capacity to issue up to an additional \$42.1 million of shares of common stock under its at-the-market (“ATM”) equity offering program. Through September 30, 2022, the Company has sold 6,084,321 shares of common stock for net proceeds of \$7.6 million under the ATM program. There can be no assurance that the Company will be able to sell any additional shares of its common stock under the ATM program and no assurance regarding the price at which it will be able to sell any such shares, and any sales of shares of its common stock under the ATM program may be at prices that result in additional dilution to existing stockholders of the Company.

The Company’s ability to obtain additional financing (including through collaboration and/or licensing arrangements) will depend on a number of factors, including, among others, its ability to generate positive data from its clinical trials and preclinical studies, the condition of the capital markets and other risks, many of which are dependent on factors outside of its control. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future.

Basis of Presentation

The accompanying interim condensed financial statements are unaudited. The unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and with generally accepted accounting principles in the United States of America (“GAAP”). These unaudited condensed consolidated financial statements have been prepared on the same basis as the audited, consolidated financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company’s financial position as of the interim date and results of operations for the interim periods presented. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements for the year ended December 31, 2021, filed with the SEC on its Annual Report on Form 10-K on March 10, 2022. The results presented in these unaudited condensed consolidated financial statements are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Use of Estimates

The Company’s condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the condensed consolidated financial statements and accompanying notes requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities. Significant estimates consist of those used to determine grant revenue and accruals for research and development costs. Although these estimates are based on the Company’s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts and money market accounts.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held. Additionally, the Company established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Research and Development Expenses and Accruals

Research and development expenses consist of costs incurred for the Company’s own and for sponsored and collaborative research and development activities. Research and development costs are expensed as incurred and include manufacturing process development costs, manufacturing costs, costs associated with preclinical studies and clinical trials, regulatory and medical affairs activities, quality assurance activities, salaries and benefits, including stock-based compensation, fees paid to third-party consultants, license fees and overhead.

The Company has entered into various research and development contracts with research institutions, clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying condensed consolidated balance sheets as prepaid expenses and other assets or accrued liabilities. The Company records accruals for estimated costs incurred for ongoing research and development activities and all clinical trial expenses are included in research and development expenses. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company’s estimates. At September 30, 2022, the Company’s clinical trial accrual balance of \$1.0 million is included in accrued liabilities.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's current financial assets and liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company has no current financial assets or liabilities measured at fair value on a recurring basis and no transfers between levels have occurred during the periods presented.

Revenue Recognition

The Company generates revenue from certain grant awards or a research subaward (the "Grant Awards") (see Note 4), which provide the Company with payments in return for certain research and development activities over a contractually defined period. Revenue from such Grant Awards is recognized in the period the related qualifying services are rendered and costs are incurred, provided that the applicable conditions under the Grant Awards have been met.

The Grant Awards are on a best-effort basis and do not require scientific achievement as a performance obligation. The Grant Awards are non-refundable. The costs associated with the Grant Awards are expensed as incurred and reflected as a component of research and development expense in the accompanying condensed consolidated statements of operations.

Funds received from the Grant Awards are recorded as revenue as the Company is the principal participant in the arrangement because the activities under the Grant Awards are part of the Company's development programs. In those instances where the Company first receives consideration in advance of providing underlying services, the Company classifies such consideration as deferred revenue until (or as) the Company provides the underlying services. In those instances where the Company first provides the underlying services prior to its receipt of consideration, the Company records a grant receivable. At September 30, 2022, the Company had deferred grant revenue of \$0.1 million.

Stock-Based Compensation

Stock-based compensation expense represents the fair value of equity awards, on the grant date, recognized in the period using the Black-Scholes option pricing model. The Company recognizes expense for awards with graded vesting schedules over the requisite service period of the awards (usually the vesting period) on a straight-line basis. For equity awards for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is deemed probable. The Company recognizes forfeitures for all awards as such forfeitures occur.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment in the United States.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded weighted-average shares subject to repurchase of zero shares and 5,000 shares from the weighted-average number of common shares outstanding for the three months ended September 30, 2022 and 2021, respectively. The Company has excluded weighted-average shares subject to repurchase of zero shares and 9,000 shares from the weighted-average number of common shares outstanding for the nine months ended September 30, 2022 and 2021, respectively. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares; in thousands):

	September 30,	
	2022	2021
Warrants to purchase common stock	3,478	4,235
Common stock options	8,401	6,019
Restricted stock unit awards	1,009	—
Common stock subject to repurchase	—	4
Total	12,888	10,258

Recently Adopted Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, which intends to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The guidance requires transition disclosures of the nature of and reasons for the accounting change, the transition method, and a qualitative description of the financial statement line items affected. The Company adopted this guidance effective January 1, 2022 and determined there were no modifications or exchanges of freestanding equity-classified written call options subject to ASU 2021-04 during the periods presented.

Accounting Standards Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Statements (Topic 362), which intends to improve financial reporting by requiring earlier recognition of credit losses on certain financial assets, such as available-for-sale debt securities. Subsequent to the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. In November 2019, the FASB issued an amendment making this ASU effective for fiscal years beginning after December 15, 2022 for smaller reporting companies. The Company was a smaller reporting company at the determination date, and therefore the new standard will be effective for the Company on January 1, 2023. An entity must apply the amendments through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective (that is, a modified-retrospective approach), except in certain circumstances. The Company is currently evaluating the potential impact that the adoption of ASU 2016-13 may have on its condensed consolidated financial statements and related disclosures.

2. Balance Sheet Details

Prepaid and other consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Research and development	\$ 215	\$ 294
Clinical trials	2,471	—
Insurance	1,077	765
Other prepaid expenses	173	85
Related party receivable (see Note 3)	114	359
Other receivable	112	585
	<u>\$ 4,162</u>	<u>\$ 2,088</u>

Accrued liabilities consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Research and development	\$ 1,682	\$ 779
Clinical trials	979	518
Legal fees	211	154
Compensation	1,986	1,955
Other	72	25
	<u>\$ 4,930</u>	<u>\$ 3,431</u>

3. Commitments, Contingencies and Related Party Transactions

Lease and Sublease

Rent expense was \$39,000 and \$46,000 for the three months ended September 30, 2022 and 2021, respectively. Rent expense was \$133,000 for each of the nine months ended September 30, 2022 and 2021.

From May 2019 through April 30, 2022, the Company leased 4,677 square feet of office space in San Diego, California. On April 18, 2022, the Company entered into a sublease agreement for office space of 3,748 square feet in San Diego, California which expires on July 31, 2023 (the "San Diego Lease"). Base rent under the San Diego Lease is approximately \$157,000 annually and the monthly rent expense is being recognized on a straight-line basis over the term of the lease.

The San Diego Lease is included in the accompanying condensed consolidated balance sheet at the present value of the lease payments. As the San Diego Lease does not have an implicit interest rate, the present value reflects a 10.0% discount rate which is the estimated rate of interest that the Company would have to pay in order to borrow an amount equal to the lease payments on a collateralized basis over a similar term and in a similar economic environment. The Company recognized a net operating lease right-of-use asset and an aggregate lease liability of \$122,000 as of September 30, 2022. The weighted average remaining lease term was 0.8 years.

Maturities of the lease liability due under this lease agreement as of September 30, 2022, are as follows (in thousands):

Maturity of lease liability	Operating Lease
2022	\$ 39
2023 (7 months)	92
Total lease payments	131
Less imputed interest	(9)
Lease liability	122
Less current portion of lease liability	(122)
Lease liability, long-term	<u>\$ —</u>

Related Party Transactions

Effective in September 2019, the Company and Shanghai Pharmaceutical (USA) Inc. (“SPH USA”), the Company’s largest stockholder and an affiliate of two of the Company’s directors, entered into a Materials and Supply and Services Agreement (“SPH USA Services Agreement”). Pursuant to the SPH USA Services Agreement, the Company and SPH USA have executed and expect to continue to execute various statements of work for the transfer to SPH USA of key reagents and other materials, and for the supply of certain services by the Company to SPH USA, as contemplated under and in furtherance of a license and distribution agreement between the parties (see Note 4). The Company recorded amounts receivable from SPH USA, in prepaid and other assets, related to statements of work totaling \$0.1 million and \$0.4 million as of September 30, 2022 and December 31, 2021, respectively. The Company has an agreement with SPH USA for certain rights to the greater China area (see Note 4).

4. License, Collaboration and Grant Award/Subaward Agreements

Georgetown University (“Georgetown”)

In March 2014, the Company entered into an Exclusive License Agreement (the “Georgetown License Agreement”) with Georgetown, pursuant to which the Company: (i) licensed the exclusive worldwide right to patents and technologies for the development and commercialization of certain product candidates targeting EWS-FLI1 as an anti-tumor therapy for therapeutic, diagnostics, or research tool purposes, (ii) is solely responsible for all development and commercialization activities and costs, and (iii) is responsible for all costs related to the filing, prosecution and maintenance of the licensed patent rights.

Under the terms of the Georgetown License Agreement, commencing in 2015, the Company: (i) shall pay and has paid an annual license maintenance fee of \$10,000 until the first commercial sale occurs, (ii) is required to make up to \$0.2 million in aggregate milestone payments upon the achievement of certain regulatory milestones, and (iii) will be required to pay low single digit royalties based on annual net product sales. The Company accounted for the licensed technology as an asset acquisition because it did not meet the definition of a business. All milestone payments under the Georgetown License Agreement will be recognized as research and development expense upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. As of September 30, 2022, the Company had not triggered or made any milestone payments under the Georgetown License Agreement.

The Georgetown License Agreement may be terminated by either party upon material breach or may be terminated by the Company as to one or more countries with 90 days written notice of termination. The term of the Georgetown License Agreement will continue until the expiration of the last valid claim within the patent rights covering the product. Georgetown may terminate the agreement in the event: (i) the Company fails to pay any amount and fails to cure such failure within 30 days after receipt of notice, (ii) the Company defaults in its obligation to obtain and maintain insurance and fails to remedy such breach within 60 days after receipt of notice, or (iii) the Company declares insolvency or bankruptcy. The Company may terminate the Georgetown License Agreement at any time upon at least 60 days’ written notice.

The University of Texas MD Anderson Cancer Center (“MD Anderson”)

In December 2014, the Company entered into a collaboration agreement (as amended, the “Collaboration”) with MD Anderson, which provides for the conduct of preclinical and clinical research for ONCT-216 in exchange for certain program payments. If MD Anderson successfully completes all the requirements of the Collaboration in full and the program is successfully commercialized, the Company will be required to pay aggregate milestone payments of \$1.0 million based on net product sales. In July 2020 and September 2021, the Company entered into two research agreements with MD Anderson for certain services up to an aggregate cost of \$0.8 million. The Company recorded research and development expense of \$0.1 million and none for each of the three months ended September 30, 2022 and 2021, and \$0.3 million and \$0.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Agreements with the Regents of the University of California (the “Regents”)

In March 2016, and as amended and restated in August 2018, and as amended thereafter, the Company and the Regents entered into a license agreement (as amended, the “Regents License Agreement”) for the development, manufacturing and distribution rights related to the development and commercialization of ROR1 related naked antibodies, antibody fragments or synthetic antibodies, and genetically engineered cellular therapy. The Regents License Agreement provides for the following: (i) in May 2016, an upfront license fee of \$0.5 million was paid and 107,108 shares of common stock were issued, (ii) \$25,000 in annual license maintenance fees commencing in 2017, (iii) reimbursement of certain annual patent costs, (iv) certain development and regulatory milestones aggregating from \$10.0 million to \$12.5 million, on a per product basis, (v) certain worldwide sales milestones based on achievement of tiered revenue levels aggregating \$75.0 million, (vi) low single-digit royalties, including potential future minimum annual royalties, on net sales of each target, and (vii) minimum diligence to advance licensed assets consisting of at least \$1.0 million in development

spend annually through 2021. Under the Regents License Agreement, the Company recorded: (a) \$25,000 in license maintenance fees as research and development expense for the three and nine months ended September 30, 2022, respectively, and none and \$25,000 for the three and nine months ended September 30, 2021, and (b) a nominal amount and \$0.1 million in patent costs as general and administrative expense for the three months ended September 30, 2022 and 2021, and \$0.1 million and \$0.3 million for nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, the Company believes it has met its obligations under the Regents License Agreement.

The Regents License Agreement will expire upon the later of the expiration date of the longest-lived patent rights or the 15th anniversary of the first commercial sale of a licensed product. The Regents may terminate the Regents License Agreement if: (i) a material breach by the Company is not cured within a reasonable time, (ii) the Company files a claim asserting the Regents licensed patent rights are invalid or unenforceable, and (iii) the Company files for bankruptcy. The Company may terminate the agreement at any time upon at least 60 days' written notice.

In July 2016, and as modified by the amended and restated Regents License Agreement in August 2018, the Company entered into a research agreement with the Regents for further research on a ROR1 therapeutic development program. Under this five-year agreement that expired in June 2021, the Regents was paid an aggregate of \$3.6 million. Effective January 1, 2022, the Company entered into a Research Agreement (the "Research Agreement") with the Regents for further research on the ROR1 therapeutic development program. Under this four-year agreement that expires on December 31, 2025, the Regents will have an aggregate budget of \$1.6 million, with quarterly payments of \$125,000 in 2022, \$131,250 in 2023, and \$137,813 in 2024. The Company recorded \$0.1 million and none in research and development expenses under these agreements for each of the three months ended September 30, 2022 and 2021, respectively, and \$0.4 million and \$0.3 million for each of the nine months ended September 30, 2022 and 2021, respectively. Such costs are includable as part of the Company's annual diligence obligations under the Regents License Agreement.

The University of Tennessee Research Foundation ("UTRF")

In March 2015, and as amended and restated in March 2022, the Company and UTRF entered into a license agreement (the "DAARI License Agreement") pursuant to which the Company was granted exclusive worldwide rights in all existing DAARI technologies owned or controlled by UTRF, including all improvements thereto. Under the DAARI License Agreement, the Company is obligated to employ active, diligent efforts to conduct preclinical research and development activities for the DAARI program to advance one or more lead compounds into clinical development. The Company is also obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and additional royalties on sublicense revenues, depending on the state of development of a clinical product candidate at the time it is sublicensed. The Company recorded research and development expense under this agreement of a nominal amount for the three months ended September 30, 2022 and 2021, and \$0.2 million and \$0.1 million for each of the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, the Company believes it has met its obligations under the DAARI License Agreement.

The California Institute for Regenerative Medicine ("CIRM") Award

In August 2017, and as amended and restated in December 2020, CIRM awarded an \$18.3 million grant to researchers at UC San Diego to advance the Company's Phase 1/2 clinical trial evaluating zilovertamab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including mantle cell lymphoma ("MCL"), and chronic lymphocytic leukemia ("CLL"). This study is known as CIRM-0001, or Cirmtuzumab and Ibrutinib for Relapsed Lymphoma or Leukemia (the "CIRLL study"). The Company: (i) is conducting this study in collaboration with UC San Diego, (ii) received \$14.5 million in development milestones under research subaward agreements during the award project period from October 1, 2017 through March 31, 2022, (iii) was committed to certain co-funding requirements, (iv) received \$0.7 million and \$2.2 million in subaward payments in the nine months ended September 30, 2022 and 2021, respectively, and (v) was required to provide UC San Diego progress and financial update reports throughout the award period. The subaward does not bear a royalty payment commitment, nor is the subaward otherwise refundable. For the three months ended September 30, 2022 and 2021, the Company recorded revenue of none and \$2.1 million, respectively, and recorded revenue of \$0.4 million and \$3.7 million for the nine months ended September 30, 2022 and 2021, respectively. Related qualifying subaward costs for the three months ended September 30, 2022 and 2021 were none and \$4.2 million, respectively, and \$0.5 million and \$7.5 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, the Company believes it has met its obligations under the CIRM award and UC San Diego subawards.

The National Institute of Health ("NIH") Grant Awards

In August 2021, the NIH awarded the Company two research and development grants for up to \$2.2 million to support pre-clinical activities for the Company's ONCT-216 and ONCT-534 programs, including \$0.7 million payable to subawardees. Under the terms of the grants, the Company is entitled to receive reimbursement in arrears of incurring allowable expenditures. The earned NIH funds are non-refundable and the Company is required to provide periodic progress performance reports. During the three months

ended September 30, 2022, the Company received \$0.3 million in award payments from the NIH and recorded \$0.4 million in grant revenue and during the nine months ended September 30, 2022, the Company received \$1.2 million in award payments from the NIH and recorded \$1.1 million in grant revenue. As of September 30, 2022 and December 31, 2021, the Company had deferred grant revenue of \$0.1 million and none, respectively.

Clinical Trial and Supply Agreements

In April 2018, and as amended in August 2019, the Company entered into a Clinical Trial and Supply Agreement with Pharmacyclics, LLC, an AbbVie Company, to supply ibrutinib for the CIRLL study. Effective in June 2022, the Company entered into a Clinical Trial and Supply Agreement with Pharmacyclics, LLC, to supply ibrutinib for the Company's global ZILO-301 Phase 3 study. Such agreements do not bear any upfront costs, inventory purchase costs, milestone or royalty payment commitments or other financial obligations.

License and Development Agreement ("LDA") with SPH USA, a Related Party

In November 2018, and as amended in August 2020, the Company entered into the LDA with SPH USA for: (i) the territory of the People's Republic of China, Hong Kong, Macau, and Taiwan ("Greater China"), and (ii) rights to manufacture, develop, market, distribute and sell all of the Company's product candidates under the Georgetown License Agreement and the Regents License Agreement (exclusive to Greater China only). Under the LDA, SPH USA is solely responsible for: (a) all preclinical and clinical development activities required in order to obtain regulatory approval in Greater China for such product candidates, (b) any third-party license milestone or royalty payments owed under the Georgetown License Agreement and the Regents License Agreement, and (c) paying the Company a low single digit royalty on net sales in the territory.

The LDA will expire upon the expiration of the last royalty term for the last licensed product. The LDA may be terminated by: (i) SPH USA on a country by country or product by product basis with 180 days written notice, (ii) either party upon material breach that is not cured within 90 days, and (iii) either party in the event the other party declares insolvency or bankruptcy. There has been no significant activity under this agreement for each of the three and nine months ended September 30, 2022 and 2021 (see Note 3).

Contingent Value Rights Agreement ("CVR Agreement")

Pursuant to the GTx merger agreement entered into in June 2019 (the "Merger"), the Company, a representative of holders of the CVRs, and Computershare, Inc. as rights agent, entered into the CVR Agreement. Pursuant to the CVR Agreement, the Company's stockholders of record as of immediately prior to the Merger received one CVR for each share of the Company's common stock held immediately prior to the Merger.

As amended on November 1, 2021, the CVR Agreement entitles holders of CVRs to receive: (i) 50% of certain net proceeds received by the Company during the 15-year period after the closing of the Merger (the "CVR Term") from a transaction, if any, resulting in the grant, sale, or transfer of DAARI technology to a third party that occurs during the 10-year period after the closing of the Merger (or in the 11th year if based on a term sheet approved during the initial 10-year period); and (ii) 5% of net sales of products by Parent or its affiliates during the CVR Term incorporating the DAARI technology. As of September 30, 2022, no transactions or net sales relating to the DAARI technology had occurred.

5. Stockholders' Equity

ATM Program

In December 2021, the Company entered into an Open Market Sale AgreementSM (the "Sales Agreement") with Jefferies LLC, pursuant to which the Company is able to offer and sell, from time to time in its sole discretion, shares of its common stock having an aggregate offering price of up to \$50.0 million. The Company has no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. During the three and nine months ended September 30, 2022, the Company sold 3,363,005 and 6,084,321 shares of common stock for net proceeds of \$3.7 million and \$7.6 million, respectively.

Common Stock Warrants

A summary of warrant activity and changes in warrants outstanding is presented below:

	Number of Shares Underlying Warrants	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)
Balance at December 31, 2021	4,234,910	\$ 10.50	3.31
Issued	—	\$ —	—
Forfeited	(757,190)	\$ 41.52	—
Exercised	—	\$ —	—
Balance at September 30, 2022	<u>3,477,720</u>	\$ 3.75	3.13

All warrants met the criteria for classification in stockholders' equity.

Equity Incentive Plans

Stock Option Awards

Contemporaneous with the Merger closing: (i) Oncternal's 2015 Equity Incentive Plan, as amended ("2015 Plan") was assumed by the Company, and (ii) the Company adopted the 2019 Incentive Award Plan ("2019 Plan") under which the sum of: (a) 1,954,150 shares of common stock, and (b) an annual increase on the first day of each calendar year beginning January 1, 2020, and ending on and including January 1, 2029, equal to the lesser of (A) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares of common stock as is determined by the Board, are reserved for issuance.

In July 2015, Oncternal adopted the 2015 Plan which provided for the issuance of shares of common stock for incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock awards to its employees, members of its board of directors and consultants. In general, the options issued under the 2015 Plan expire ten years from the date of grant and vest over a four-year period. Certain grants vest based on the achievement of development or regulatory milestones. The 2015 Plan was terminated as to new grant awards in June 2019.

The 2019 Plan provides for the issuance of shares of common stock for incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock awards to its employees, members of its board of directors and consultants. In general, the stock options issued under the 2019 Plan expire ten years from the date of grant and vest over a four-year period. Certain stock option grants vest based on the achievement of development or regulatory milestones. The 2019 Plan allows for the early exercise of all stock option grants if authorized by the board of directors at the time of grant.

In February 2021, the Company's board of directors adopted the 2021 Employment Inducement Incentive Award Plan (the "Inducement Plan"). The Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Inducement Plan is used exclusively for the issuance of non-statutory stock options to certain new hires who satisfied the requirements to be granted inducement grants under Nasdaq rules as an inducement material to the individual's entry into employment with the Company. The terms of the Inducement Plan are substantially similar to the terms of the 2019 Plan. As amended in May 2021 and December 2021, the Company has reserved 2,800,000 shares of common stock under the Inducement Plan.

As of September 30, 2022, 1,344,866 shares remain available for issuance under the 2019 Plan and Inducement Plan. A summary of the Company's stock option activity under the 2015 Plan, 2019 Plan and Inducement Plan is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	6,444,744	\$ 5.28		\$ 613,190
Granted	2,559,718	\$ 1.68		
Forfeited	(603,629)	\$ 4.40		
Exercised	—	\$ —		
Outstanding at September 30, 2022	<u>8,400,833</u>	\$ 4.24	8.3	\$ 49,763
Options vested and expected to vest as of September 30, 2022	8,400,833	\$ 4.24	8.3	\$ 49,763
Options vested and exercisable as of September 30, 2022	3,126,458	\$ 4.87	7.2	\$ 44,274

For the nine months ended September 30, 2022 and 2021, the weighted average grant date fair value per share of option grants was \$1.34 and \$4.48, respectively. The intrinsic value is calculated as the difference between the fair value of the Company's common stock at the time of the option exercise and the exercise price of that stock option. For the nine months ended September 30, 2022 and 2021, the weighted-average intrinsic value of stock options exercised was none and \$3.89 per share, respectively.

Restricted Stock Unit Awards

Restricted stock unit awards ("RSUs") are rights to receive shares of the Company's common stock upon satisfaction of specific vesting conditions. The Company began issuing RSUs in the first quarter of 2022. The RSUs generally vest over a two-year period. Restricted stock unit activity under Equity Incentive Plans is summarized as follows:

	Number of Restricted Stock Units	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2021	—		
Granted	1,056,507		
Vested	(6,494)		
Forfeited/ Repurchased	(40,930)		
Nonvested at September 30, 2022	<u>1,009,083</u>	0.9	\$ 1.64
Units expected to vest as of September 30, 2022	1,009,083	0.9	\$ 1.64

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants, were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.7%	1.0%	2.1%	0.8%
Expected volatility	102.9%	100.3%	100.3%	91.8%
Expected term (in years)	6.1	6.0	6.1	6.2
Expected dividend yield	—%	—%	—%	—%

Expected volatility. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the life sciences industry with comparable characteristics to the Company including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Due to limited historical exercise behavior, it determined the expected life assumption using the simplified method for employees, which is an average of the contractual term of the option and its vesting period. The expected term for nonemployee options is generally the remaining contractual term.

Risk-free interest rate. The risk-free interest rate is based on the implied yield on the U.S. Treasury securities with a maturity date similar to the expected term of the associated stock option award.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

RSU awards represent rights to receive shares of common stock contingent upon satisfaction of specific vesting conditions. The stock-based compensation expense for these awards was determined using the closing price on the grant date applied to the total number of shares that were anticipated to fully vest.

Stock-based compensation expense recognized for all equity awards has been reported in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 1,144	\$ 920	\$ 3,027	\$ 2,097
General and administrative	830	568	2,602	2,065
	<u>\$ 1,974</u>	<u>\$ 1,488</u>	<u>\$ 5,629</u>	<u>\$ 4,162</u>

As of September 30, 2022, the unrecognized compensation cost related to non-vested stock options was \$13.9 million, which is expected to be recognized over a weighted-average period of 2.8 years.

As of September 30, 2022, the unrecognized compensation cost related to non-vested restricted stock units was \$1.2 million, which is expected to be recognized over a weighted-average period of 1.3 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows (in thousands):

	September 30, 2022
Common stock warrants	3,478
Common stock options issued and outstanding	8,401
Restricted stock unit awards	1,009
Common stock available for issuance under the Inducement Plan and 2019 Plan	1,345
	<u>14,233</u>

6. COVID-19 Pandemic and CARES Act

The COVID-19 pandemic has presented substantial public health and economic challenges and continues to affect economies, financial markets and business operations around the world. The pandemic may continue to directly or indirectly affect the timeline for the Company's preclinical and manufacturing activities, planned regulatory submissions and clinical trials, including the Company's global Phase 3 study of zilovertamab. The Company considered the impacts of COVID-19 on the assumptions and estimates used to prepare its condensed consolidated financial statements and determined that there were no material adverse impacts on the Company's results of operations and financial position at September 30, 2022. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact the Company's business results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, the success or failure of ongoing vaccination programs, the emergence and spread of additional variants of COVID-19, as well as the economic impact on local, regional, national and international markets.

In response to the COVID-19 pandemic, the CARES Act was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property, and authorized the Paycheck Protection Program. The CARES Act had no material impact on the Company's income tax provision for the nine months ended September 30, 2022. The Company continues to monitor changes and revisions to the CARES Act and its impact on the Company's condensed consolidated financial position, results of operations and cash flows.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with: (i) our unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q for the period ended September 30, 2022, and (ii) our audited financial statements and notes thereto for the year ended December 31, 2021 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2021. Except as otherwise indicated herein or as the context otherwise requires, references in this Quarterly Report to “Oncternal” “the Company,” “we,” “us” and “our” refer to Oncternal Therapeutics, Inc., a Delaware corporation.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategies and plans, prospective products, product approvals, research and development costs, the expected continued impact of COVID-19, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “could,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including those described in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 10, 2022, and in Part II, Item 1A, “Risk Factors” of this Quarterly Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies for cancers with critical unmet medical need. Our development efforts are focused on promising, yet untapped, biological pathways implicated in cancer generation or progression. Our pipeline includes:

- Zilvertamab (formerly cirmtuzumab or UC-961) is an investigational, humanized, potentially first-in-class, monoclonal antibody designed to: (i) bind to a specific functionally important epitope of Receptor tyrosine kinase-like Orphan Receptor 1, or ROR1, a growth factor receptor that is widely expressed on many tumor types and that activates pathways leading to increased tumor proliferation, invasiveness, and drug resistance in preclinical models, and (ii) inhibit ROR1 function.

We initiated our Phase 3 global registrational study of zilvertamab, ZILO-301, for the treatment of patients with relapsed or refractory mantle cell lymphoma, or MCL, in the second half of 2022. The Phase 3 clinical trial ZILO-301 is a randomized, double-blind, placebo-controlled study evaluating the potential benefit for up to approximately 250 MCL patients who achieve either a partial response or stable disease during an open-label lead-in with ibrutinib monotherapy, following which patients will receive zilvertamab or placebo while continuing to receive ibrutinib. The primary endpoint of the study is progression-free survival, and key secondary endpoints include objective response rate, duration of response, complete response rate, overall survival and the proportion of subjects experiencing grade 3 or 4 neutrophil count decrease. Zilvertamab is currently being evaluated in the Cirmtuzumab and Ibrutinib for Relapsed Lymphoma or Leukemia, or CIRLL, study, a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including MCL, chronic lymphocytic leukemia, or CLL, or marginal zone lymphoma, or MZL. In the first quarter of 2022, we completed the enrollment of patients with MCL and CLL in the Phase 1/2 CIRLL study, and those patients are completing therapy or are in long-term follow-up. In addition, we are supporting two investigator-sponsored studies being conducted at the UC San Diego School of Medicine, or UC San Diego: (i) a Phase 2 clinical trial for metastatic castration-resistant prostate cancer study, including patients with resistance to approved androgen inhibitors, and (ii) a Phase 2 clinical trial of zilvertamab in combination with venetoclax, a Bcl 2 inhibitor, in patients with relapsed/refractory CLL.

- ONCT-808, our lead cell therapy product candidate, is an autologous chimeric antigen receptor T cell, or CAR T, therapy that targets ROR1, a target that is highly expressed by multiple solid tumors and hematological malignancies and confers both an aggressive phenotype and survival advantage to tumor cells. ONCT-808 is advancing into clinical development as a potential treatment for hematologic malignancies and solid tumors and is being developed in collaboration with the

Karolinska Institutet and under agreements with Lentigen Technology, Inc. (lentivirus manufacturing) and Miltenyi Biotec B.V. & Co. KG. (cell processing). In October 2022, we announced that we received a Study May Proceed letter from the U.S. Food and Drug Administration, or the FDA, related to our investigational new drug application, or IND, for ONCT-808 for the treatment of patients with relapsed or refractory aggressive B-cell lymphoma, including patients who have failed previous CD19 CAR T treatment. The IND was cleared by the FDA 30 days after the application was submitted.

- ONCT-534, is a dual action androgen receptor inhibitor, or DAARI, product candidate in preclinical development as a potential treatment for advanced castration-resistant prostate cancers. We initiated GLP toxicology studies in two relevant animal models and GMP manufacturing activities in the second quarter of 2022.

Our pipeline previously included ONCT-216, an investigational small molecule designed to inhibit the ETS, or E26 Transformation Specific, family of oncoproteins, which had shown in preclinical studies to alter gene transcription and RNA processing that led to decreased cell proliferation and invasion. In April 2022, we deprioritized the development of ONCT-216 and stopped the enrollment of patients in a Phase 1/2 clinical trial in patients with relapsed or refractory Ewing sarcoma.

Since the inception of Oncternal Therapeutics, Inc. in 2013, we have devoted most of our resources to organizing and staffing, business planning, raising capital, acquiring product candidates and securing related intellectual property rights and advancing our zilovetamab and ONCT-216 clinical development programs as well as our ONCT-808 and ONCT-534 preclinical programs. Under research subaward agreements between us and UC San Diego, we were eligible to receive \$14.6 million in development milestones during the award project period from October 1, 2017 to March 31, 2022. Through September 30, 2022, we have funded our operations primarily through: (i) gross proceeds of \$132.9 million from the issuance of common stock, (ii) gross proceeds of \$49.0 million from the issuance of convertible preferred stock, (iii) receipt of \$14.5 million in subaward grant payments from UC San Diego, and (iv) cash proceeds of \$18.3 million received in connection with the closing of the merger with GTx, Inc. in June 2019, or the GTx Merger. As of September 30, 2022, we had cash and cash equivalents of \$70.6 million and no debt.

We have incurred net losses in each year since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net loss was \$32.8 million for the nine months ended September 30, 2022 and we had an accumulated deficit of \$146.9 million as of September 30, 2022. Substantially all of our net losses have resulted from costs incurred in connection with: (i) advancing our research and development programs, (ii) general and administrative costs associated with our operations, including the costs associated with operating as a public company, and (iii) in-process research and development costs associated with the GTX Merger. We expect to continue to incur significant and increasing operating losses for at least the next several years. We expect that our expenses and capital funding requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- advance zilovetamab, through clinical development in multiple indications, with an initial focus in MCL;
- advance ONCT-808 through clinical development, initially in hematological malignancies;
- advance ONCT-534 into clinical development, initially in castration resistant prostate cancer;
- respond to the impacts of the COVID-19 pandemic, which has slowed enrollment into our clinical trials and impacted our supply chain activities;
- evaluate zilovetamab in additional ROR1-positive hematologic malignancies and solid tumors;
- continue to develop additional product candidates; acquire or in-license other product candidates and technologies;
- maintain, expand and protect our intellectual property portfolio;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our planned product development and future commercialization efforts.

We will not generate product sales revenue unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. In addition, we expect to incur additional costs associated with operating as a public company.

As a result, we believe we will need substantial additional funding to support our continuing operations and pursue our business strategy. Until such time as we can generate significant product sales revenue, if ever, we expect to finance our operations through a combination of public or private equity or debt offerings or other sources, including potential collaborations, strategic alliances and other similar arrangements. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the first half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Beyond that point, we will need to raise additional capital to finance our operations, which cannot be assured.

Business Update Regarding COVID-19

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and continues to affect economies, financial markets and business operations around the world. The pandemic may continue to directly or indirectly affect the timeline for our manufacturing activities, planned regulatory submissions and clinical trials, including ZILO-301, our global Phase 3 study of zilovertamab. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, the success or failure of ongoing vaccination programs worldwide, the emergence and spread of additional variants of COVID-19, as well as the economic impact on local, regional, national and international markets.

Components of Results of Operations

Grant Revenue

Our grant revenue has been derived from a California Institute for Regenerative Medicine, or CIRM, grant subaward with UC San Diego and research and development grants from the National Institutes of Health, or NIH.

In August 2017, CIRM awarded an \$18.3 million grant to researchers at UC San Diego to advance the CIRLL study throughout the award project period from October 1, 2017 through March 31, 2022. We are conducting this study in collaboration with UC San Diego and received \$14.5 million during the project period related to development milestone payments under research subaward agreements. In addition, we were committed to certain co-funding requirements and we were required to provide UC San Diego progress and financial update reports throughout the award project period. We received \$0.7 million and \$2.2 million in subaward payments in the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we believe we have met our obligations under the CIRM award and UC San Diego subawards.

In August 2021, the NIH awarded us two research and development grants for up to \$2.2 million to support pre-clinical and other research activities for our ONCT-216 and ONCT-534 programs, including \$0.7 million payable to subawardees. During the nine months ended September 30, 2022, we received \$1.2 million in award payments, and recorded \$1.1 million in grant revenue and \$0.1 million of deferred revenue.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for the preclinical and clinical development of our lead product candidate, zilovertamab, as well as ONCT-808, ONCT-534 and ONCT-216, which include:

- expenses under agreements with consultants, third-party contract organizations, and investigative clinical trial sites that conduct research and development activities on our behalf;
- costs related to the development and manufacture of preclinical study and clinical trial material;

- salaries and employee-related costs, including stock-based compensation;
- costs incurred under our collaboration and third-party licensing agreements; and
- laboratory and vendor expenses related to the execution of preclinical and clinical trials.

We accrue all research and development costs in the period for which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers. Advance payments for goods or services to be received in future periods for use in research and development activities are deferred and then expensed as the related goods are delivered and as services are performed. Any unearned advances would be refunded when known.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in: (i) developing our product candidates preclinically, advance them into later stages of clinical development, and as we begin to conduct larger clinical trials globally, and (ii) additional operational personnel to support our planned product development efforts. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. The de-prioritization of the development of ONCT-216 will result in lower future ONCT-216 expenses in future periods.

Our direct research and development expenses are tracked by product candidate and consist primarily of external costs, such as fees paid under third-party license agreements and to outside consultants, contract research organizations, or CROs, contract manufacturing organizations and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track our costs by product candidate unless we can include them as subaward costs.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development, including any potential expanded dosing beyond the original protocols based in part on ongoing clinical success and the potential effects of the COVID-19 pandemic. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments of each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, insurance costs, facility costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. Personnel-related costs consist of salaries, benefits and stock-based compensation. We expect our general and administrative expenses will increase as we: (i) incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director's and officer's insurance premiums, and investor relations costs, (ii) hire additional personnel, and (iii) protect our intellectual property.

Interest Income

Interest income consists of interest earned on our cash equivalents, which primarily consist of money market funds. Our interest income has not been significant due to low interest yields earned on invested balances.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the periods indicated:

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
Grant revenue	\$ 382	\$ 2,128	\$ (1,746)	\$ 1,319	\$ 3,759	\$ (2,440)
Operating expenses:						
Research and development	8,442	8,963	(521)	24,182	18,068	6,114
General and administrative	3,265	2,802	463	10,169	8,977	1,192
Total operating expenses	11,707	11,765	(58)	34,351	27,045	7,306
Loss from operations	(11,325)	(9,637)	(1,688)	(33,032)	(23,286)	(9,746)
Interest income	200	7	193	262	26	236
Net loss	\$ (11,125)	\$ (9,630)	\$ (1,495)	\$ (32,770)	\$ (23,260)	\$ (9,510)

Comparison of Three Months Ended September 30, 2022 and 2021

Grant Revenue

Grant revenue was \$0.4 million and \$2.1 million for the three months ended September 30, 2022 and 2021, respectively. The decrease of \$1.7 million was primarily due to the completion of the CIRM subaward in the first quarter of 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

(in thousands)	Three Months Ended September 30,		Increase/ (Decrease)
	2022	2021	
Zilovertamab	\$ 2,359	\$ 5,176	\$ (2,817)
ONCT-534	673	90	583
ONCT-808	1,720	860	860
ONCT-216	520	739	(219)
Unallocated research and development expenses	3,170	2,098	1,072
Total research and development expenses	\$ 8,442	\$ 8,963	\$ (521)

Research and development expenses for the three months ended September 30, 2022 and 2021 were \$8.4 million and \$8.9 million, respectively, a decrease of \$0.5 million. The decrease was primarily due to a \$1.5 million decrease in direct product candidate costs and a \$1.0 million increase in unallocated expenses.

Direct expenses for zilovertamab decreased \$2.8 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily due to a decrease in manufacturing development costs.

Direct expenses for ONCT-534 increased \$0.6 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily due to an increase in preclinical activity.

Direct expenses for ONCT-808 increased \$0.9 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily due to an increase in manufacturing development costs.

Direct expenses for ONCT-216 decreased \$0.2 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily due to a decrease in clinical trial costs.

Unallocated expenses increased \$1.0 million for the three months ended September 30, 2022, compared to the three months ended September 30, 2021, primarily due to higher personnel costs, including stock-based compensation costs.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2022 and 2021 were \$3.3 million and \$2.8 million, respectively, an increase of \$0.5 million. The increase was primarily due to higher non-cash stock-based compensation and legal expenses.

Comparison of Nine Months Ended September 30, 2022 and 2021

Grant Revenue

Grant revenue for the nine months ended September 30, 2022 was \$1.3 million, compared to \$3.8 million for the nine months ended September 30, 2021. The decrease of \$2.5 million was primarily due to the completion of the CIRM subaward in the first quarter of 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

(in thousands)	Nine Months Ended September 30,		Increase/ (Decrease)
	2022	2021	
Zilovertamab	\$ 7,570	\$ 8,888	\$ (1,318)
ONCT-534	1,585	278	1,307
ONCT-808	3,920	1,465	2,455
ONCT-216	2,077	2,475	(398)
Unallocated research and development expenses	9,030	4,962	4,068
Total research and development expenses	<u>\$ 24,182</u>	<u>\$ 18,068</u>	<u>\$ 6,114</u>

Research and development expenses for the nine months ended September 30, 2022 and 2021 were \$24.2 million and \$18.1 million, respectively, an increase of \$6.1 million. The increase was primarily due to a \$2.1 million increase in direct product candidate costs and a \$4.0 million increase in unallocated expenses.

Direct expenses for zilovertamab decreased \$1.3 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, primarily due to a decrease in manufacturing development costs that was partially offset by an increase in clinical trial activity.

Direct expenses for ONCT-534 increased \$1.3 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, primarily due to an increase in preclinical activity and manufacturing development costs.

Direct expenses for ONCT-808 increased \$2.5 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, primarily due to an increase in manufacturing development costs.

Direct expenses for ONCT-216 decreased \$0.4 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, primarily due to lower clinical trial activity and manufacturing costs.

Unallocated expenses increased \$4.0 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, primarily due to higher personnel costs, including stock-based compensation costs.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2022 and 2021 were \$10.2 million and \$9.0 million, respectively, an increase of \$1.2 million. The increase was primarily due to higher personnel costs and corporate expenses which were partially offset by lower legal costs.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of September 30, 2022, we had an accumulated deficit of \$146.9 million and anticipate that we will continue to incur net losses for the foreseeable future. As of September 30, 2022, we had \$70.6 million in cash and cash equivalents and no debt. We believe we have sufficient cash to fund our projected operating requirements for at least twelve months from the filing date of this Quarterly Report. We expect our operating expenses to continue to be substantial for the foreseeable future and, as a result, we will need additional capital to fund our operations, which we may obtain through a combination of public or private equity or debt offerings or other sources, including potential collaborations, strategic alliances and other similar arrangements.

In December 2021, we entered into an at-the-market Sales Agreement, or the Sales Agreement, with Jefferies LLC, providing for the sale of up to \$50.0 million of our common stock from time to time in “at-the-market” offerings under an existing shelf registration statement. During the three and nine months ended September 30, 2022, we sold 3,363,005 and 6,084,321 shares of common stock for net proceeds of \$3.7 million and \$7.6 million, respectively.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

(in thousands)	Nine Months Ended September 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (27,702)	\$ (19,973)
Financing activities	7,565	616
Net decrease in cash and cash equivalents	\$ (20,137)	\$ (19,357)

Operating Activities

Net cash used in operating activities was \$27.7 million and \$20.0 million for the nine months ended September 30, 2022 and 2021, respectively. The increase in cash used in operations was primarily attributable to the development and manufacturing activities associated with the clinical programs and higher personnel costs. The net cash used in operating activities during the nine months ended September 30, 2022 was primarily due to our net loss of \$32.8 million adjusted for \$5.8 million of non-cash charges, primarily for stock-based compensation, and a \$0.7 million change in operating assets and liabilities. Net cash used in operating activities during the nine months ended September 30, 2021 was primarily due to our net loss of \$23.3 million adjusted for \$4.3 million of non-cash charges, primarily for stock-based compensation, and a \$1.0 million change in operating assets and liabilities.

Investing Activities

No cash was used or provided by investing activities for the nine months ended September 30, 2022 and 2021.

Financing Activities

Net cash provided by financing activities was \$7.6 million and \$0.6 million for the nine months ended September 30, 2022 and 2021, respectively. The net cash provided during 2022 resulted from proceeds received from the sale of common stock under the ATM program and the net cash provided during 2021 was primarily due to cash received from the exercise of common stock options and warrants.

Operating Capital Requirements

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the research and development of, and seek regulatory approvals for, our product candidates and conduct additional research and development activities. Our product candidates have not yet achieved regulatory approval and we may not be successful in achieving commercialization of our product candidates.

We believe that our existing cash and cash equivalents will be sufficient to fund our operations into the first half of 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a

forward-looking statement that involves risks and uncertainties, and actual results could vary materially. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish the sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research and development of our product candidates, and we may be forced to seek additional funds sooner than expected to pursue our research and development activities. We expect to finance our capital requirements in the foreseeable future through a combination of the sale of public or private equity or debt securities, government funding, or other sources, including potentially collaborations, licenses and other similar arrangements. There can be no assurance that we will be able to obtain any sources of financing on acceptable terms, or at all. To the extent that we can raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. Any of these events could significantly harm our business, operations, financial condition and prospects.

Our forecast of the period of time through which our existing cash and cash equivalents and investments will be adequate to support our operations is a forward-looking statement and involves significant risks and uncertainties. We have based this forecast on assumptions that may prove to be wrong, and actual results could vary materially from our expectations, which may adversely affect our capital resources and liquidity. We could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of our clinical trials of zilovetamab, and preclinical studies or clinical trials of our ROR1 CAR T and DAARI product candidates or additional indications of our current product candidates as well as other product candidates that we may choose to pursue in the future;
- the costs incurred as a result of the COVID-19 pandemic, including preclinical, manufacturing and clinical trial delays;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs of obtaining ibrutinib, for which we currently obtain supply at no cost under our agreement with Pharmacylics LLC to conduct our clinical trials of zilovetamab;
- the costs and capacity for third-party process development and manufacturing, including for CAR T and lentivirus;
- the costs, timing and outcome of seeking and obtaining worldwide regulatory approvals for our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs associated with hiring additional personnel, CROs and consultants as our preclinical and clinical activities increase;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities for, and the pricing and reimbursement of, any products for which we may receive regulatory approval;
- the terms and timing of establishing and maintaining potential collaborations, strategic alliances and other similar arrangements, including milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future; and
- costs associated with any products or technologies that we may in-license or acquire.

If we cannot continue or expand our research and development operations, or otherwise capitalize on our business opportunities, because we lack sufficient capital, our business, operations, financial condition and prospects could be materially adversely affected.

In April 2021, our Form S-3 registration statement became effective. Future sales of our common stock, if any, will depend on a variety of factors including, but not limited to, the expected timing for achieving key milestones, including initiating, completing and announcing results of clinical trials of zilovetamab, announcing the first-in-human dosing of ONCT-808, our lead cell therapy product candidate targeting ROR1 which is currently in preclinical development, and advancing ONCT-534, our DAARI preclinical product candidate, prevailing market conditions, the trading price of our common stock and our capital needs. There can be no

assurance that we will be successful in consummating future sales of our securities based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

In December 2021, we entered into an Open Market Sales AgreementSM, or the Sales Agreement, pursuant to which we are able to offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$50.0 million. We have no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. Through September 30, 2022, we have sold 6,084,321 shares of common stock for net proceeds of \$7.6 million, net of commissions, under the Sales Agreement.

Contractual Obligations and Commitments

We are party to a number of license agreements, pursuant to which we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements. As of September 30, 2022, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. See Note 4 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for a description of these agreements.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period and, therefore, are cancelable contracts.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of the financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods.

Our estimates are based on our historical experience, trends and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We consider our critical accounting policies and estimates to be related to research and development expenses and accruals, and revenue recognition. There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2022, from those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies & Estimates," included in our Annual Report on Form 10-K for the year ended December 31, 2021.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports we file and submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, who serve as our principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the specific factors discussed below, as well as all other information included in this Quarterly Report on Form 10-Q, including our financial statements, the notes thereto and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these known or unknown risks might cause you to lose all or part of your investment in our securities.

There have been no material changes to the risk factors included in “Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Form	Incorporation by Reference		Filing Date
			File no.	Exhibit No.	
3.1	Restated Certificate of Incorporation of the Registrant dated February 6, 2004 (“Restated Certificate”)	S-3	333-127175	4.1	4-Aug-05
3.1.1	Certificate of Amendment of Restated Certificate dated May 6, 2011	8-K	000-50549	3.2	6-May-11
3.1.2	Certificate of Amendment of Restated Certificate dated May 6, 2014	8-K	000-50549	3.3	9-May-14
3.1.3	Certificate of Amendment of Restated Certificate dated May 6, 2015	10-Q	000-50549	3.4	11-May-15
3.1.4	Certificate of Amendment of Restated Certificate dated December 5, 2016	8-K	000-50549	3.1	5-Dec-16
3.1.5	Certificate of Amendment of Restated Certificate dated June 7, 2019 related to the Reverse Stock Split of the Registrant	8-K	000-50549	3.1	10-Jun-19
3.1.6	Certificate of Amendment of Restated Certificate dated June 7, 2019 related to the Name Change of the Registrant	8-K	000-50549	3.2	10-Jun-19
3.1.7	Certificate of Amendment of Restated Certificate dated May 25, 2021	8-K	000-50549	3.1	28-May-21
3.2	Amended and Restated Bylaws of the Registrant	8-K	000-50549	3.3	10-Jun-19
4.1	Specimen of Common Stock Certificate	10-Q	000-50549	4.2	9-Aug-19
4.2	Form of Common Stock Warrant, issued by Registrant pursuant to the Purchase Agreement dated September 25, 2017, between Registrant and the purchasers identified in Exhibit A therein	S-3	333-221040	4.9	20-Oct-17
4.3	Form of Warrant to purchase shares of Series B-2 Preferred Stock of Registrant	S-4	333-230758	4.11	8-Apr-19
4.3.1	Form of Amendment to Warrant to Purchase shares of Series B-2 Preferred Stock of Private Oncternal	10-Q	000-50549	4.1	9-Aug-19
4.4	Form of Common Stock Warrant, issued by Registrant pursuant to the Securities Purchase Agreement dated May 19, 2020, between the Registrant and the purchasers signatory thereto (“May 2020 Purchase Agreement”)	8-K	000-50549	4.1	21-May-20
4.5	Form of Placement Agent Warrant, issued by Registrant pursuant to the May 2020 Purchase Agreement	8-K	000-50549	4.2	21-May-20
4.6	Form of Common Stock Warrant, issued by Registrant pursuant to the Securities Purchase Agreement dated July 17, 2020, between the Registrant and the purchasers signatory thereto (the “July 2020 Purchase Agreement”)	8-K	000-50549	4.1	21-Jul-20
4.7	Form of Placement Agent Warrant, issued by Registrant pursuant to the July 2020 Purchase Agreement.	8-K	000-50549	4.2	21-Jul-20
4.8	Form of Underwriter Warrant, issued by Registrant pursuant to the Amended and Restated Underwriting Agreement dated August 27, 2020, between the Registrant and H.C. Wainwright & Co., LLC (“H.C. Wainwright”).	8-K	000-50549	4.1	31-Aug-20

4.9	<u>Form of Underwriter Warrant, issued by Registrant pursuant to the Amended and Restated Underwriting Agreement dated November 17, 2020, between the Registrant and H.C. Wainwright</u>	8-K	000-50549	4.1	19-Nov-20
4.10	<u>Form of Underwriter Warrant, issued by Registrant pursuant to the Amended and Restated Underwriting Agreement dated December 9, 2020, between the Registrant and H.C. Wainwright</u>	8-K	000-50549	4.1	11-Dec-20
10.1*†	<u>First Amendment to the Amended and Restated License Agreement Between the University of Tennessee Research Foundation and the Registrant dated August 22, 2022</u>				
31.1*	<u>Certification of Chief Executive Officer of the Registrant, as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>				
31.2*	<u>Certification of Chief Financial Officer of the Registrant, as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>				
32.1‡	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>				
32.2‡	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>				
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* Filed herewith

‡ Furnished herewith

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

[*] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.**

FIRST AMENDMENT TO THE AMENDED AND RESTATED LICENSE AGREEMENT BETWEEN THE UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION AND ONCTERNAL THERAPEUTICS, INC.

This First Amendment to the Amended and Restated License Agreement Between the University of Tennessee Research Foundation and Oncternal Therapeutics, Inc. (“First Amendment”), effective as of the latest date of signing below, between the University of Tennessee Research Foundation, having an office at 910 Madison Avenue, Suite 827, Memphis TN 38163 (“UTRF”) and Oncternal Therapeutics, Inc., a company organized and existing under the laws of California and having its principal place of business at 12230 El Camino Real, Suite 300 San Diego, CA 92130 (“LICENSEE”), herein after referred to as the “Parties.”

BACKGROUND

WHEREAS, UTRF and LICENSEE entered into the Amended and Restated License Agreement between University of Tennessee Research Foundation and Oncternal Therapeutics, Inc. (“Agreement”) having an Effective Date of March 9, 2022;

WHEREAS, the Parties desire to amend the Agreement to include additional invention disclosures within Article 1.6 and to update the table of Licensed Patents in Appendix A;

NOW, THEREFORE, the Parties hereto agree as follows:

ARTICLE 1AMENDMENT

1.1Article 1.6 is amended to read as follows:

1.6 “Invention Disclosure” means the UTRF file numbers:

- (a) [***].
- (b) [***].
- (c) [***].
- (d) [***].
- (e) [***].
- (f) [***].
- (g) [***].
- (h) [***].

(i) [***].

1.2 Delete Appendix A in the Agreement in its entirety and replace with the Appendix A attached to this First Amendment.

1.3 ALL OTHER PROVISIONS of the Agreement shall remain in full force and effect.

ARTICLE 2 MISCELLANEOUS

2.1 This First Amendment is entered into in the State of Tennessee and shall be construed, interpreted and applied in accordance with the laws of the State of Tennessee without giving effect to any conflict of laws provisions thereof.

2.2 The Parties hereto acknowledge that this First Amendment together with the Agreement sets forth the entire understanding and agreement hereto as to the subject matter thereof and supersedes all prior understandings and agreements.

2.3 The provisions of this First Amendment are severable, and in the event that any provision shall be determined to be invalid or unenforceable under any controlling body of the law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

IN WITNESS WHEREOF, the Parties execute this First Amendment by their duly authorized representatives and acknowledge that they understand and agree to be bound by its terms and conditions.

UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION
("UTRF")

Signature: /s/ Stacey Patterson

Name: Stacey Patterson

Title: President

Date: 8/20/2022

ONCTERNAL THERAPEUTICS, INC.
("LICENSEE")

Signature: /s/ James Breitmeyer

Name: James Breitmeyer

Title: President & CEO

Date: 8/22/2022

APPENDIX A

[*]**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James B. Breitmeyer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oncternal Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ James B. Breitmeyer
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 3, 2022

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Richard G. Vincent, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oncternal Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Richard G. Vincent

Chief Financial Officer
(Principal Financial Officer)

Dated: November 3, 2022

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Oncternal Therapeutics, Inc. (the "Company") for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James B. Breitmeyer, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James B. Breitmeyer

President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 3, 2022

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Oncternal Therapeutics, Inc. (the “Company”) for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Richard G. Vincent, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Richard G. Vincent

Chief Financial Officer
(Principal Financial Officer)

Dated: November 3, 2022

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
