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 MARCH 31, 2023

or

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

Commission File Number 001-36818

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**34-2037594**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
4350 La Jolla Village Drive, Suite 800, San Diego CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

(858) 550-0780
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

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, a 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of outstanding shares of the registrant's common stock as of May 4, 2023 was 24,059,460.

FORM 10-Q

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PART I FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

TRACON Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,610	$ 17,433
Prepaid and other assets	529	795
Total current assets	7,139	18,228
Property and equipment, net	47	51
Restricted cash	67	67
Other assets	1,070	1,123
Total assets	$ 8,323	$ 19,469
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,342	$ 11,107
Accrued compensation and related expenses	1,840	1,457
Long-term debt, current portion	—	9,807
Total current liabilities	14,182	22,371
Other long-term liabilities	914	969
Arbitration financing payable	4,299	3,280
Commitments and contingencies (Note 5)		
Stockholders' deficit:		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at March 31, 2023 and December 31, 2022; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 40,000,000 at March 31, 2023 and December 31, 2022; issued and outstanding shares — 24,027,891 and 23,125,250 at March 31, 2023 and December 31, 2022, respectively	24	23
Additional paid-in capital	234,319	229,737
Accumulated deficit	(245,415)	(236,911)
Total stockholders' deficit	(11,072)	(7,151)
Total liabilities and stockholders' deficit	$ 8,323	$ 19,469

See accompanying notes.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 4,969	$ 2,993
General and administrative	2,344	6,453
Total operating expenses	7,313	9,446
Loss from operations	(7,313)	(9,446)
Other expense:		
Interest expense, net	(1,188)	(26)
Other expense, net	(3)	(1)
Total other expense	(1,191)	(27)
Net loss	$ (8,504)	$ (9,473)
Net loss per share, basic and diluted	$ (0.36)	$ (0.48)
Weighted-average shares outstanding, basic and diluted	23,702,178	19,608,986

See accompanying notes.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit)
	Shares	Amount			
Balance at December 31, 2022	23,125,250	$ 23	$ 229,737	$ (236,911)	$ (7,151)
Stock-based compensation expense	—	—	484	—	484
Issuance of common stock and warrants, net of offering costs	902,641	1	4,098	—	4,099
Net loss	—	—	—	(8,504)	(8,504)
Balance at March 31, 2023	24,027,891	$ 24	$ 234,319	$ (245,415)	$ (11,072)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	19,445,903	$ 19	$ 219,471	$ (207,776)	$ 11,714
Stock-based compensation expense	—	—	548	—	548
Issuance of common stock, net of offering costs	10,389	—	—	—	—
Issuance of common stock upon cashless exercise of pre-funded warrants	170,668	1	—	—	1
Net loss	—	—	—	(9,473)	(9,473)
Balance at March 31, 2022	19,626,960	$ 20	$ 220,019	$ (217,249)	$ 2,790

See accompanying notes.

TRACON Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (8,504)	$ (9,473)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	484	548
Depreciation and amortization	4	5
Noncash interest	88	5
Amortization of debt discount	1,123	2
Lease asset amortization and liability accretion, net	7	(32)
Changes in assets and liabilities:		
Prepaid expenses and other assets	266	211
Accounts payable and accrued expenses	1,146	2,708
Accrued compensation and related expenses	383	(716)
Net cash used in operating activities	(5,003)	(6,742)
Cash flows from investing activities		
Purchase of property and equipment	—	(4)
Net cash used in investing activities	—	(4)
Cash flows from financing activities		
Repayment of long-term debt	(10,000)	(700)
Proceeds from sale of common stock and warrants, net of offering costs	4,180	14
Net cash used in financing activities	(5,820)	(686)
Change in cash, cash equivalents, and restricted cash	(10,823)	(7,432)
Cash, cash equivalents, and restricted cash at beginning of period	17,500	24,072
Cash, cash equivalents, and restricted cash at end of period	$ 6,677	$ 16,640

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization and Business

TRACON Pharmaceuticals, Inc. (TRACON or the Company) was incorporated in the state of Delaware on October 28, 2004. TRACON is a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, and utilizes its cost efficient, contract research organization (CRO) independent product development platform to partner with other life science companies to develop and commercialize innovative products in the United States.

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, TRACON Pharma Limited and TRACON Pharma International Limited, which were formed in September 2015 and January 2019, respectively, and are currently inactive. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

As of March 31, 2023, the Company has devoted substantially all its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations. The Company has incurred operating losses since inception. As of March 31, 2023, the Company had an accumulated deficit of $245.4 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it continues the development and commercialization of its product candidates and works to develop additional product candidates through research and development programs. At March 31, 2023, the Company had cash and cash equivalents of $6.7 million, of which $0.1 million is classified as restricted cash as it is pledged as collateral for the Company's obligations under its corporate headquarters facility lease. The Company's ability to execute its operating plan through 2023 and beyond depends on its ability to obtain additional funding through equity offerings, debt financings, or potential licensing and collaboration arrangements. The accompanying unaudited condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, based on the Company's current working capital, business plan, anticipated operating expenses and net losses, and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, management believes that there is substantial doubt about its ability to continue as a going concern for a period of 12 months following the date that these unaudited condensed consolidated financial statements are issued. The unaudited condensed consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company plans to continue to fund its losses from operations through its existing cash and cash equivalents, as well as through future equity offerings, debt financings, other third-party funding, and potential licensing or collaboration arrangements. In addition, the Company may fund its losses from operations through the Capital on Demand™ Sales Agreement (the Sales Agreement) the Company entered into with JonesTrading in December 2020, as amended in March 2022, pursuant to which the Company may sell, at its option, up to an aggregate of $50.0 million of the Company's common stock, $44.4 million of which remained available for sale as of March 31, 2023. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. As a result of adverse macroeconomic and geopolitical developments, such as the COVID-19 pandemic and actions taken to slow its spread, the ongoing military conflict between Ukraine and Russia, recent and potential future bank failures, actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate in the future, it may make any additional debt or equity financing more difficult, more costly, and more dilutive. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans, which could have a material adverse effect on the Company's business, operating results and financial condition, and the Company's ability to achieve its intended business objectives. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements as of March 31, 2023, and for the three months ended March 31, 2023 and 2022, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and with accounting principles generally accepted in the United States (GAAP) applicable to interim financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the audited 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. Interim results are not necessarily indicative of results for a full year or future periods. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2022, included in its Annual Report on Form 10-K filed with the SEC on March 8, 2023.

Use of Estimates

The Company's unaudited condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company's unaudited condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue, and expenses. The most significant estimates in the Company's unaudited condensed consolidated financial statements relate to expenses incurred for clinical trials. 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. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the date of this filing.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. The carrying amounts approximate fair value due to the short maturities of these investments. Cash and cash equivalents include cash in readily available checking and money market funds.

Restricted Cash

Restricted cash consists of money market funds held by the Company's financial institution as collateral for the Company's obligations under its facility lease for the Company's corporate headquarters in San Diego, California.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration 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 management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful life of the related assets, which is generally five years. Leasehold improvements are amortized over the shorter of the lease term or estimated useful life of the related assets. Repairs and maintenance costs are charged to expense as incurred.

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are recorded as other assets, accounts payable and accrued expenses, and other long-term liabilities within the unaudited condensed consolidated balance sheets. The Company currently does not have any finance leases.

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

Revenue Recognition

To date, substantially all the Company's revenue has been derived from license agreements. The terms of these arrangements included payments to the Company for the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. In accordance with Accounting Standards Codification 606, Revenue from Contracts with Customers (ASC 606), the Company performs the following five steps in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of these agreements: (i) identification of the contract(s) with a customer; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services transferred to the customer. Once a contract is determined to be within the scope of ASC 606, at contract inception the Company assesses the goods or services promised within the contract to determine those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Company evaluates whether the achievement of the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Achievement of milestones that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis and the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achieving such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its out-licensing arrangements.

The Company receives payments from its collaborators based on billing schedules established in each contract. Up-front and other payments may require deferral of revenue recognition to a future period until the Company performs its obligations under its collaboration arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Clinical Trial Expense Accruals

As part of the process of preparing the Company's unaudited condensed consolidated financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors, clinical sites, and consultants in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company's objective is to reflect the appropriate trial expenses in its unaudited condensed consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with the clinical sites and applicable personnel and outside service providers as to the progress or state of consummation of trials. During a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are dependent upon accurate reporting by clinical sites and other third-party vendors. Although the Company does not expect its estimates to differ materially from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For the three months ended March 31, 2023 and 2022, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Research and Development Costs

Research and development costs, including license fees, are expensed as incurred.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted average number of shares of common stock outstanding that are subject to repurchase. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

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):

	March 31,	
	2023	2022
Warrants to purchase common stock	8,780,245	4,633,855
Common stock options	3,116,854	2,135,560
ESPP shares	6,112	6,464
	11,903,211	6,775,879

2. Financial Instruments and Fair Value Measurements

Cash equivalents, which are classified as equity securities and restricted cash, consisted of the following (in thousands):

	March 31, 2023				December 31, 2022			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 6,348	$ —	$ —	$ 6,348	$ 10,150	$ —	$ —	$ 10,150
Classified as:								
Cash equivalents				$ 6,281				$ 10,083
Restricted cash				67				67
Total cash equivalents and restricted cash				$ 6,348				$ 10,150

At March 31, 2023 and December 31, 2022, the Company had no investments.

The carrying amounts of cash and cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long-term debt approximates its carrying value.

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 nonrecurring 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.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The fair values of the Company's assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At March 31, 2023				
Money market funds	$ 6,348	$ —	$ 6,348	$ —
At December 31, 2022				
Money market funds	$ 10,150	$ —	$ 10,150	$ —

3. Long-Term Debt

Arbitration Financing Investment Agreement

In December 2022, the Company entered into a non-recourse financing agreement (the Investment Agreement) with certain investors (collectively, the Investors) pursuant to which the Investors will pay the Company a maximum aggregate amount (Maximum Capital) equal to $30.0 million or a lesser amount based on the amount awarded (Award), if any, to the Company in connection with its ongoing arbitration proceeding (the Arbitration) with I-Mab Biopharma (I-Mab). Of the Maximum Capital, (i) $3.5 million (Initial Capital) was paid to the Company shortly after execution, (ii) 25% was to be paid to the Company within 15 business days of issuance of an Award, subject to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement, and (iii) the remainder was to be paid to the Company in tranches over a multi-year period, subject to the issuance of an Award and the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement. In connection with the execution of the Investment Agreement and funding of the Initial Capital amount, the Company paid a closing fee in the amount of 2%. In April 2023, the Company received notification of the Award resulting from the Arbitration and it was determined the Company was entitled to approximately $23.0 million. As this Award amount did not exceed the prespecified thresholds under the Investment Agreement, the Company will not receive any additional funds under the Investment Agreement such that, as of date of the Award, the Maximum Capital is equal to the Initial Capital. See Note 6 – Subsequent Events, for additional information.

Subject to and contingent on the Company's actual recovery of proceeds from an Award or any contemporaneously resolved settlements with I-Mab and following the payment of applicable attorney's fees (the Proceeds), the Company shall pay the Investors an amount (Repayment Amount) equal to the sum of (i) all amounts paid by the Investors to or on behalf of the Company pursuant to the Investment Agreement, plus (ii) a low sub-single digit to low single digit multiple calculated on each tranche of Maximum Capital actually paid by the Investors to or on behalf of the Company with the applicable multiple being based on the timing of payment from the Company and whether certain events relating to the Arbitration occur, plus (iii) a mid-teen percentage annual rate of return on the amounts set forth in clauses (i) and (ii) that begins to accrue if the amounts are not paid by the Company to the Investors within a multi-month period specified in the Investment Agreement. If the amount of Proceeds are less than the Repayment Amount, then the Company shall only be required to pay to the Investors the Proceeds recovered (other than in circumstances in which the Company accepts a settlement offer that resolves the Arbitration for an amount less than the Repayment Amount without the prior written consent of the Investors), and in the circumstance in which there are no Proceeds then the Company shall not be required to pay the Investors any Repayment Amounts and the Investors shall have no right of recourse or right of action against the Company.

The Investment Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of representations or covenants and a bankruptcy default. The Investment Agreement also contains customary covenants that require the Company to, among other things, (i) use commercially reasonable efforts to pursue its claims in connection with the Arbitration and recover amounts awarded to it in connection with an Award, (ii) pay costs and expenses in connection with enforcing an Award, (iii) keep the Investors informed regarding the Arbitration and its collection and enforcement efforts and (iv) not incur liens (other than permitted liens) on or transfer any portion of its assets related to its claims in connection with the Arbitration, any Award, the Proceeds and related assets.

If the Company fails to pay amounts owed to the Investors when due, such overdue amounts bear interest at a default rate set forth in the Investment Agreement. Upon certain remedy events, including the Company's breach of the Investment Agreement, the Investors may exercise all of their rights and remedies as set forth in the Investment Agreement and under applicable law, including, without limitation, termination of their obligations to pay additional amounts under the Investment Agreement. Pursuant to the Investment Agreement, the Company will also grant to the Investors a security interest in its interest in its claims in connection with the Arbitration, any Award, the Proceeds and related assets (Specific Collateral), as further described in the Investment Agreement, as security for the payment of the Company's obligations under the Investment Agreement.

In December 2022, the Investors funded the Initial Capital amount of $3.5 million which was recorded as arbitration financing payable on the unaudited condensed consolidated balance sheets. The carrying amount of the arbitration financing payable recorded on the unaudited condensed consolidated balance sheets is net of debt discount, including the Initial Capital closing fee, which is being amortized over the estimated term of the agreement using the effective interest method. Pursuant to the terms of the Investment Agreement, repayment of all capital amounts funded under the Investment Agreement, including the Initial Capital, and the obligation amount owed is contingent upon the Company's actual recovery of proceeds from an Award, which is uncertain. Accordingly, as of March 31, 2023, the Company has estimated an effective interest rate and term of the agreement over which the related debt discount is being amortized. The Company will re-evaluate this estimate at the end of each subsequent reporting period, with any material changes recorded prospectively using a new effective interest rate based on the updated estimate of the amount of arbitration financing payable owed as of the end of the reporting period. In the event in which there is no recovery of proceeds from an Award, the Company is not required to repay the $3.5 million Initial Capital. As of March 31, 2023 the arbitration financing payable was classified as a long-term liability as it is considered unlikely the obligation amount owed under the Investment Agreement will be settled prior to March 31, 2024.

Runway Growth Finance Corp. Loan and Security Agreement

In September 2022, the Company entered into a loan and security agreement (the RGC Loan Agreement) with Runway Growth Finance Corp. (RGC). The RGC Loan Agreement was a long-term debt facility that provided a term loan commitment in an aggregate principal amount of up to $35.0 million in three tranches: (i) a Term A loan in an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement on closing of the RGC Loan Agreement and repaid in January 2023 in connection with the Investment Agreement; (ii) a Term B loan in an aggregate principal amount of up to $15.0 million to be funded in one or more disbursements at the request of the Company on or prior to June 30, 2024, subject to certain conditions being met; and (iii) a Term C loan in an aggregate principal amount of up to $10.0 million that may be disbursed in a single disbursement in the lender's sole discretion upon the Company's request at any time from closing of the RGC Loan Agreement through and including December 31, 2024. In December 2022, the Company and RGC amended the RGC Loan Agreement (the RGC Loan Amendment) under which: (i) the Company repaid all amounts of principal and accrued but unpaid interest in respect of the Term A Loan (as defined in the RGC Loan Agreement) on January 3, 2023 without the obligation for the Company to pay the final payment fee or the prepayment fee described in the RGC Loan Agreement; (ii) on or before March 31, 2023, at the Company's request, if the Company has raised at least $25.0 million in net cash proceeds from certain equity or debt transactions (including amounts raised in connection with the Investment Agreement) prior to making such request, RGC will loan to the Company an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement; (iii) the Company will not issue an additional warrant to RGC in connection with the loan, if any, described in clause (ii) above; and (iv) RGC's security interest in Specific Collateral was subordinated to the arbitration financing Investors' security interest in the Specific Collateral. If the loan described in clause (ii) above is not made by March 31, 2023, the RGC Loan Agreement will terminate on that date, and the Company will not be obligated to pay the prepayment fee described in the RGC Loan Agreement but the final payment fee of 4.25% of the aggregate principal amount of the funded term loans as described in the RCG Loan Agreement will become immediately due and payable. All other material terms and conditions of the RGC Loan Agreement remained unchanged and the transaction was accounted for as a debt modification. On April 5, 2023, the Company and RGC amended the RGC Loan Agreement effective March 31, 2023 such that the Company would have until April 15, 2023 to raise at least $25.0 million in net cash proceeds from certain equity or debt transactions prior to making a request of RGC to redraw an aggregate principal amount of $10.0 million under the RGC Loan Agreement, which RGC may, in its sole and absolute discretion, allow or deny. On April 20, 2023, the Company and RGC amended the RGC Loan Agreement effective April 15, 2023 to extend the time period described in the foregoing sentence from April 15, 2023 to April 28, 2023. The Company did not redraw the $10.0 million under the RGC Loan Agreement, as amended, by April 28, 2023, resulting in the RGC Loan Agreement terminating and the final payment fee becoming immediately due and payable on that date.

In connection with the funding of the Term A loan, the Company issued RGC warrants to purchase 150,753 shares of its common stock (the RGC Term A Warrants) at an exercise price of $1.99 per underlying share of the Company's common stock. The RGC Term A Warrants are fully exercisable in whole or in part at the option of the holder, payable in cash or on a cashless basis according to the formula set forth in the RGC Term A Warrants, and expire September 2, 2032. The fair value of the warrant at the grant date was determined utilizing a Black-Scholes pricing model, recorded as a component of the total debt discount and stockholders' deficit within additional paid-in capital on the unaudited condensed consolidated balance sheets, and will be amortized to interest expense using the effective interest method over the term of the debt.

Long-term debt and unamortized debt discount balances associated with the RGC Loan Agreement were as follows (in thousands):

	March 31, 2023	December 31, 2022
Long-term debt	$ —	$ 10,000
Less debt discount, net of current portion	—	—
Long-term debt, net of debt discount	—	10,000
Less current portion of long-term debt	—	(10,000)
Long-term debt, net of current portion	$ —	$ —
Current portion of long-term debt	$ —	$ 10,000
Current portion of debt discount	—	(193)
Current portion of long-term debt, net	$ —	$ 9,807

Future minimum principal and interest payments under the RGC Loan Agreement, including the final payment, as of March 31, 2023 are as follows (in thousands):

Remaining 2023	$ 425
	425
Less interest and final payment	(425)
Long-term debt	$ —

Silicon Valley Bank Loan and Security Agreement

In May 2018, the Company entered into a third amendment to its Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2018 Amended SVB Loan) under which the Company borrowed $7.0 million, all of which was immediately used to repay the Company's then existing loan with SVB.

The 2018 Amended SVB Loan matured in June 2022 and in accordance with its terms, the Company paid a final payment of $0.3 million associated with the payoff of the 2018 Amended SVB Loan. In August 2022, the Company terminated the 2018 Amended SVB Loan.

At March 31, 2023, the Company had the following exercisable outstanding warrants for the purchase of common stock issued in connection with the Company's loan agreements with SVB:

Expiration	Number of shares	Exercise price
November 14, 2023 through June 4, 2024	3,874	$ 77.40
January 25, 2024	4,669	$ 51.40
May 3, 2025	5,363	$ 26.10
	13,906	

4. Commitments and Contingencies

License Agreements

The Company has entered into various license agreements pursuant to which the Company acquired licenses to certain intellectual property. The agreements generally required an upfront license fee and, in some cases, reimbursement of patent costs. Additionally, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each license agreement is generally cancelable by the Company, given appropriate prior written notice. At March 31, 2023, potential future milestone payments under these agreements totaled an aggregate of $9.6 million.

5. Stockholders' Deficit

Sale of Common Stock and Pre-Funded Warrants

In March 2023, the Company issued and sold 174,508 shares of its common stock at a purchase price of $1.38 per share and pre-funded warrants to purchase 2,013,999 shares of its common stock at a purchase price of $1.37 per share of underlying common stock with an exercise price of $0.01 per share of underlying common stock (the 2023 Pre-Funded Warrants) for net proceeds of approximately $3.0 million in a private placement (the Private Placement) with an accredited institutional healthcare-focused fund. In accordance with their terms, the 2023 Pre-Funded Warrants may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99% of the shares of the Company's common stock outstanding immediately after giving effect to such exercise, unless approval by the Company's stockholders is obtained as required under the Nasdaq listing standards, including Nasdaq Listing Rules 5635(b) and (d). At the Company's 2023 Annual Meeting held on April 19, 2023, stockholder approval, in accordance with applicable rules of the Nasdaq Stock Market, was obtained for the issuance of shares of common stock upon the potential future exercise of certain outstanding warrants held by this accredited institutional healthcare-focused fund, including the 2023 Pre-Funded Warrants, that would result in it and its affiliates owning in excess of 19.99% of the shares of common stock outstanding immediately after giving effect to such exercise. The 2023 Pre-Funded Warrants were recorded as a component of stockholders' deficit within additional paid-in capital on the unaudited condensed consolidated balance sheets.

At-The-Market Issuance Sales Agreement

In December 2020, as amended in March 2022, the Company entered into a Capital on Demand™ Sales Agreement (the Sales Agreement) with JonesTrading, pursuant to which it may sell from time to time, at its option, up to an aggregate of $50.0 million of the Company's common stock through JonesTrading, as sales agent or principal, $44.4 million of which remains available for sale as of March 31, 2023. Sales of the Company's common stock made pursuant to the Sales Agreement with JonesTrading, if any, will be made on the Nasdaq Capital Market under the Company's effective registration statement on Form S-3, subject to limitations on the amount of securities the Company may sell pursuant to its effective registration statement on Form S-3 within any 12-month period, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, the Company may also sell shares of its common stock through JonesTrading, on the Nasdaq Capital Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading will use its commercially reasonable efforts to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is required to pay JonesTrading 2.5% of gross proceeds for the common stock sold through the Sales Agreement.

Equity Plan Activity

During the three months ended March 31, 2023, the Company issued no shares of common stock upon the exercise of outstanding stock options and upon the vesting of restricted stock units. During the three months ended March 31, 2023, the Company issued 0 shares of common stock in connection with the employee stock purchase plan (the ESPP). During the year ended December 31, 2022, the Company issued no shares of common stock upon the exercise of outstanding stock options, no shares of common stock upon the vesting of restricted stock units, and 56,261 shares of common stock in connection with the ESPP.

Common Stock Warrants

As of March 31, 2023, the Company had the following outstanding warrants for the purchase of common stock:

Expiration	Number of shares	Exercise price
November 14, 2023 through June 4, 2024	3,874	$ 77.40
January 25, 2024	4,669	$ 51.40
March 27, 2024	1,369,602	$ 27.00
May 3, 2025	5,363	$ 26.10
August 27, 2030	1,889,513	$ 0.01
August 31, 2030	1,137,454	$ 0.01
June 21, 2032	2,205,018	$ 0.01
September 2, 2032	150,753	$ 1.99
March 10, 2033	2,013,999	$ 0.01
	8,780,245	

During the three months ended March 31, 2023, the Company issued no shares of its common stock upon the exercise of pre-funded warrants. During the three months ended March 31, 2022, the Company issued 170,668 shares of its common stock upon the cashless exercise of 176,554 pre-funded warrants.

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	3.4%	1.7%
Expected volatility	89.9%	89.0%
Expected term (in years)	6.3	6.3
Expected dividend yield	—%	—%

Stock compensation expense for the ESPP was immaterial for the three months ended March 31, 2023 and 2022.

The allocation of stock-based compensation expense was as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 227	$ 200
General and administrative	257	348
	$ 484	$ 548

6. Subsequent Events

Arbitration Award

The Company was previously developing TJ004309, also known as TJD5 or uliledlimab, a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate to the immunosuppressive metabolite adenosine, in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that the Company entered into in November 2018 (the TJ004309 Agreement). The Company also entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) with I-Mab in November 2018 which allowed for the development of up to five of I-Mab's proprietary bispecific antibody product candidates to be nominated by I-Mab within a five-year period for development and commercialization in North America, with the option to opt-in and acquire product rights outside of Greater China and Korea prior to completing the first pivotal clinical trial for any bispecific product candidate.

As previously disclosed, in June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal seated in New York City (the Tribunal) after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations under the TJ004309 Agreement and the Bispecific Agreement. In April 2023, the Company received notification from the Tribunal of the final award to the Company. The Tribunal found in favor of the Company for certain claims. As a result, the Tribunal declared the Phase 1 clinical trial of TJ004309 Agreement "Complete," as that term is defined in the TJ004309 Agreement as of January 2022. The Tribunal also determined that the Company is entitled to approximately $23.0 million, which includes the $9.0 million prespecified termination fee payable by I-Mab under the TJ004309 Agreement, plus interest, and certain of the Company's legal fees, costs and disbursements incurred in connection with the arbitration. The Company is entitled to a high single digit interest rate on the award. Pursuant to the arbitration award, the TJ004309 Agreement and the Bispecific Agreement have been terminated. The decision by the Tribunal is final and binding on the parties.

Lincoln Park Capital Fund, LLC (Lincoln Park) Common Stock Purchase Agreement

On May 8, 2023, the Company and Lincoln Park entered into a common stock purchase agreement (the Lincoln Park Purchase Agreement), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Lincoln Park is committed to purchase up to an aggregate of $26.0 million of the Company's shares of common stock from time to time and at the Company's sole discretion over the term of the Lincoln Park Purchase Agreement. In consideration for entering into the Lincoln Park Purchase Agreement, concurrently with the execution of the Lincoln Park Purchase Agreement, the Company issued to Lincoln Park 599,216 shares of its common stock as a commitment fee. Concurrently with entering into the Lincoln Park Purchase Agreement, the Company also entered into a Registration Rights Agreement in which the Company agreed to file one or more registration statements as permissible and necessary to register under the Securities Act for resale of the shares of its common stock that may be issued to Lincoln Park under the Lincoln Park Purchase Agreement. Additionally, Lincoln Park is committed to purchase upon the Company's request up to $1.0 million of shares of the Company's common stock of the $26.0 million aggregate committed amount on the commencement date (as that term is defined in the Lincoln Park Agreement).

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, timing of future events and future financial performance, includes forward-looking statements that are based upon current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Quarterly Report for a discussion of important factors that could cause our actual results and the timing of selected events to differ materially from those described in or implied by the forward-looking statements contained in this Quarterly Report. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report or to reflect actual outcomes.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and utilizing our cost efficient, contract research organization (CRO) independent product development platform to partner with other life science companies to develop and commercialize innovative products in the United States.

In December 2019, we entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb) administered by rapid subcutaneous injection for the treatment of sarcoma in North America. The ENVASARC Phase 2 pivotal trial (the ENVASARC trial) is enrolling a total of 160 patients at 600mg of envafolimab, with 80 patients enrolling at 600mg of envafolimab every three weeks in cohort C, and 80 patients enrolling at 600mg of envafolimab every three weeks in combination with Yervoy® at 1mg/kg every three weeks for four doses in cohort D, in the sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS). Nine of 80 responses by blinded independent central review (BICR) in either cohort are needed to satisfy the primary objective of the trial which is to statistically exceed the known 4% objective response rate (ORR) of Votrient® (pazopanib), the only U.S. Food and Drug Administration (FDA)-approved treatment for patients with refractory UPS or MFS. Achieving the primary endpoint of exceeding the known 4% ORR could be the basis for accelerated approval of envafolimab by the FDA as a single agent and/or in combination with Yervoy. The trial will provide at least 86% power to demonstrate the lower bound of the 95% confidence interval is greater than 5% in each cohort, which would be greater than the 4% ORR of Votrient reported in soft tissue sarcoma in its package insert. Votrient is the only approved treatment for refractory soft tissue sarcoma, which includes UPS and MFS.

In December 2022, we announced the IDMC recommended continued accrual as planned in both cohorts at the first planned interim efficacy analysis. The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The double-digit ORR assessed by BICR in each cohort exceeded the prespecified futility rule that required at least one response among the initial 18 patients enrolled at 600mg into each cohort. Envafolimab monotherapy (cohort C) and in combination with Yervoy (cohort D) was well tolerated, with only a single related serious adverse event reported in 36 patients. A second interim efficacy analysis is planned following the 12-week efficacy scan in the 92nd dosed patient, to allow for determination of the preliminary ORR, which we expect in the third quarter of 2023 as the ENVASARC trial has enrolled more than 92 patients to date. There must be at least three responses among the initial 46 patients enrolled at 600mg into each cohort to continue enrollment in that cohort per the futility rule of the trial. An additional ad hoc analysis by the IDMC, as required by the IDMC Charter that requires a review of safety and efficacy data at a minimum of every six months, is planned for the second quarter of 2023. This review will not invoke a formal futility rule and will not include central review of all available scans.

In September 2022, we announced that the FDA had granted us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy. We are also eligible to apply for breakthrough therapy designation based on data from the ENVASARC clinical trial. We expect to complete enrollment by the end of 2023, have final response assessment data including duration of response in all patients from the ENVASARC trial in mid-2024, and, assuming positive data, to submit a biologics license application (BLA) to the FDA seeking accelerated approval in 2024. At any time that we reach nine responses in each cohort and meet the endpoint, we expect to discuss the submission process with the FDA.

Our other clinical stage oncology product candidates include YH001, which is a monospecific investigational cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody, that we licensed from Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen) in October 2021, and TRC102, which is a small molecule that has been studied in Phase 1 and Phase 2 trials for the treatment of mesothelioma, lung cancer, glioblastoma and solid tumors.

YH001 is an investigational humanized CTLA-4 IgG1 monoclonal antibody that completed dosing in two Phase 1 trials sponsored by Eucure for the treatment of various cancer indications. CTLA-4 is a protein expressed on T-cells and expressed at high levels specifically on regulatory T-cells that act as a checkpoint to inhibit effector T-cell immune responses to cancer cells. The CTLA-4 inhibitor Yervoy (ipilimumab) marketed by BMS has been approved as a single agent in melanoma and approved in combination with other therapies in multiple indications including non-small cell lung cancer, renal cell carcinoma (RCC) and microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer. Data from the Phase 1 dose escalation trial in Australia of YH001 in combination with the PD-1 antibody, toripalimab, were presented at the American Society of Clinical Oncology 2022 Annual Meeting. YH001 was well tolerated up to 4 mg/kg when combined with toripalimab in the 24 patients as of the December 31, 2021 data cut-off date. The Phase 1 dose escalation trial in China of YH001 as a single agent, recently completed enrollment and determined a recommended Phase 2 dose. We expect data to be presented in the second half of 2023. No CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma.

In August 2022, we announced that the FDA had approved the Investigational New Drug (IND) application for the initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin, an approved treatment for soft tissue sarcoma, for the treatment of sarcoma patients and in December 2022, we initiated dosing in the Phase 1/2 clinical trial. The Phase 1/2 trial will assess the safety and efficacy of the triplet combination of YH001, envafolimab and doxorubicin in the common sarcoma subtypes of leiomyosarcoma and dedifferentiated liposarcoma, and we expect Phase 1 data in the second half of 2023. In addition, the trial will assess the safety and efficacy of the doublet combination of YH001 and envafolimab in patients with the rare sarcoma subtypes of alveolar soft part sarcoma and chondrosarcoma. Additionally, we plan to initiate trials of YH001 as a single agent or in combination with immunotherapies in other tumor types.

TRC102 is a small molecule in clinical development to reverse resistance to specific chemotherapeutics by inhibiting DNA base excision repair (BER). In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and we believe promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy for the treatment of cancer patients. TRC102 has been studied in Phase 1 or Phase 2 trials in mesothelioma patients in combination with the approved chemotherapeutic Alimta® (pemetrexed), in glioblastoma, ovarian cancer, lung and colorectal cancer patients in combination with the approved chemotherapeutic Temodar® (temozolomide) and in lung cancer patients in combination with the approved chemotherapeutics Alimta and cisplatin as well as external beam radiation (i.e., chemoradiation). All current TRC102 trials are sponsored and funded by the National Cancer Institute (NCI). We retain global rights to develop and commercialize TRC102 in all indications. In October 2020, we received orphan drug designation (ODD) from the FDA for TRC102 for the treatment of patients with malignant glioma, including glioblastoma. O6-methylguanine DNA methyltransferase (MGMT) deficiency is observed in about one-third of glioblastoma patients, and a prior study of Temodar and TRC102 reported at the Society for Neuro-Oncology in 2018 demonstrated that two MGMT deficient glioblastoma patients had prolonged survival when treated with Temodar and TRC102 after progressing previously on Temodar and radiation therapy. A December 2020 publication in Cancer Cell also demonstrated Temodar and TRC102 were active in MGMT deficient patients with colorectal cancer. Based on these data, we believe a trial in first line glioblastoma patients of Temodar, radiation therapy and TRC102 is warranted and are discussing further development with investigators at this time. In addition, based on data presented at the ASCO 2020 virtual meeting that the combination of chemoradiation and TRC102 produced objective responses in all 15 evaluable patients with advanced localized lung cancer treated in a Phase 1 trial, in January 2022, the NCI initiated a randomized Phase 2 trial of chemoradiation with or without TRC102, followed by consolidative durvalumab treatment. The primary objective is to improve the 56% one-year progression free survival (PFS) rate with current standard of care to 75% with current standard of care plus TRC102. The trial began enrollment in June 2022 and is expected to be complete in 2025.

The following table summarizes key information regarding ongoing and planned development of our clinical stage product candidates:

	Phase	Data Expected
Envafolimab		
Soft Tissue Sarcoma (UPS and MFS)	Pivotal Phase 2	Interim Data – Q2 and Q3 2023 Final Data – mid-2024
Envafolimab + YH001		
Multiple Soft Tissue Sarcoma Subtypes	Phase 1/2 (planned)	Second half of 2023 and 2024
TRC102		
Lung Cancer	Randomized Phase 2	2025

We utilize a CRO-independent product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance, product development and regulatory affairs groups manage significant aspects of our clinical trials with internal resources. We use these internal resources to reduce the costs associated with utilizing CROs to conduct clinical trials. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which can expedite patient enrollment and improve the quality of patient data as compared to a CRO-managed model. We have leveraged this platform in all of our sponsored clinical trials. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees through license agreements with Eucure and Biocytogen, 3D Medicines and Alphamab, and Janssen. We continue to evaluate life science companies that would benefit from a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise. We believe we will continue to be recognized as a preferred U.S. clinical development partner through a cost- and risk-sharing partnership structure, which may include U.S. commercialization.

Our goal is to be a leader in the development of targeted therapies for patients with cancer and other diseases of high unmet medical need.

Since our inception in 2004, we have devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials, in-licensing related intellectual property, providing general and administrative support for these operations, and protecting our intellectual property. To date, we have not generated any revenue from product sales and instead, have funded our operations from the sales of equity securities, payments received in connection with our collaboration agreements, and commercial bank debt. At March 31, 2023, we had cash and cash equivalents totaling $6.7 million, of which $0.1 million is pledged as collateral for our obligations under our corporate headquarters facility lease.

We do not own or operate, nor do we expect to own or operate, facilities for product manufacturing, storage, distribution or testing. We contract with third parties or our collaboration partners for the manufacture of our product candidates and we intend to continue to do so in the future.

We have incurred losses from operations in each year since our inception. Our net losses were $8.5 million and $9.5 million for the three months ended March 31, 2023 and 2022, respectively. At March 31, 2023, we had an accumulated deficit of $245.4 million.

We expect to continue to incur significant expenses and operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our current level of research and development expenses to remain relatively constant for the remainder of 2023 as we:

- continue to enroll the ENVASARC trial and the Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes;
- continue our research and development efforts;
- in-license additional product candidates for development and commercialization; and
- seek regulatory approvals for product candidates that successfully complete clinical trials.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more product candidates, which we expect will take a number of years. If we obtain regulatory approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, and distribution. Accordingly, we will need to raise substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts, developments under our collaboration agreements, including whether and when we receive milestone and other potential payments, and the timing and nature of the regulatory approval process for product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Further, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. As a result of adverse macroeconomic and geopolitical developments, such as the COVID-19 pandemic and actions taken to slow its spread, the ongoing military conflict between Ukraine and Russia, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop product candidates.

Collaboration and License Agreements

Collaboration Agreement with 3D Medicines and Alphamab

In December 2019, we, 3D Medicines, and Alphamab entered into the Envafolimab Collaboration Agreement for the development of envafolimab, an investigational PD-L1 sdAb, or nanobody, administered by rapid subcutaneous injection, for the treatment of sarcoma in North America.

Pursuant to the Envafolimab Collaboration Agreement, we were granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. We are responsible for conducting and will bear the costs of any Phase 1, Phase 2, and Phase 3 or post-approval clinical trial in North America for envafolimab in the indications of refractory and first line treatment of sarcoma. 3D Medicines and Alphamab are responsible for conducting and will bear the costs of investigational new drug (IND)-enabling studies (other than those specific to the sarcoma indication) and the preparation of the chemistry, manufacturing and controls (CMC) activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than sarcoma.

We will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than sarcoma and launched in North America, or (b) envafolimab is first approved in North America for sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, or licensee, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, we have the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we elect and 3D Medicines and Alphamab agree for us to not co-market envafolimab for sarcoma in North America, then 3D Medicines and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities.

If we have the responsibility for commercialization under the Envafolimab Collaboration Agreement, we will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Envafolimab Collaboration Agreement, we will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if we have elected to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if we have chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without our written consent and the parties must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1 in sarcoma.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event we elect, or a joint steering committee (JSC) determines, to cease further development or commercialization of envafolimab, or if we fail to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and do not cure such failure within a specified time period, then our rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

Collaboration Agreement with Eucure and Biocytogen

In October 2021, we, Eucure and Biocytogen entered into a collaborative development and commercialization agreement (the YH001 Collaboration Agreement) for the development of YH001, a monospecific investigational CTLA-4 antibody. Pursuant to the YH001 Collaboration Agreement, we were granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including sarcoma, microsatellite stable colorectal cancer, RCC, and K-ras positive non-small cell lung cancer (collectively, the Initial Indications) or one or more of bladder cancer, endometrial cancer, and melanoma as substitute indications, which may be substituted for Initial Indications at our discretion (each upon such substitution, a Substitute Indication). We are responsible for, and will bear the costs of, preparing and filing all regulatory submissions and conducting any Phase 1, Phase 2, Phase 3, or post-approval clinical trials in North America for YH001 in the Initial Indications and potentially the Substitute Indications, while Eucure is responsible for conducting, and will bear the costs of, the preparation of CMC activities for YH001. Eucure has agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, YH001 to us for clinical trials pursuant to the terms of a clinical supply and quality agreement that will be separately negotiated and agreed in good faith between the parties.

Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product. During a specified period, we have the option, subject to Eucure's prior written approval, to expand the license to include the development and commercialization of YH001 for the treatment, through administration by intravenous or subcutaneous means, of all human and veterinary therapeutic indications in North America for a payment to Eucure in the low single digit millions (the Company Option).

Pursuant to the YH001 Collaboration Agreement, we granted Eucure an irrevocable, perpetual, royalty-free, exclusive license, with the right to grant sublicenses to develop, register, sell, offer to sell, have sold, market and distribute YH001 in all territories outside of North America as well as within North America for all indications other than the Initial Indications and the Substitute Indications.

We will be responsible for commercializing YH001 in North America, including booking of sales revenue in the Initial and Substitute Indications. We will owe Eucure escalating double digit royalties on net sales of YH001 in North America ranging from the mid-twenties to mid-double digits; provided that until the end of the first full calendar year following the first commercial sale of YH001, royalties will range from the lower double digits to the mid-double digits. If sales of YH001 exceed a pre-determined sales threshold in the first full year of sales following first commercial sale, we will owe a milestone to Eucure in the high single digit millions. Payment obligations under the YH001 Collaboration Agreement continue on a country-by-country basis until the latest of (i) expiration of the last to expire licensed patent covering YH001, (ii) expiration of marketing or regulatory exclusivity covering YH001 and (iii) 10 years from the first commercial sale of YH001 in such country in North America. Eucure has agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, YH001 to us at cost plus a low double-digit markup for commercial sales pursuant to the terms of a commercial supply and quality agreement that will be separately negotiated and agreed in good faith between the parties within 180 days prior to the anticipated first commercial sale in North America.

Pursuant to the YH001 Collaboration Agreement, each party agreed that during the term of the YH001 Collaboration Agreement, it would not develop, manufacture, commercialize or license from any third party a monospecific inhibitor to CTLA-4.

The term of the YH001 Collaboration Agreement continues until the earlier of (i) the date that the parties cease further development and commercialization of YH001 in North America or (ii) on a country-by-county basis, the expiration of the royalty obligations in such country. The YH001 Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to YH001. In the event of a termination of the YH001 Collaboration Agreement, other than by us as a result of Eucure's material uncured breach or bankruptcy, (i) our license shall terminate and (ii) we would be obligated to grant Eucure an irrevocable, perpetual, royalty-free, non-exclusive license with the right to grant sublicenses under its rights in all development data and intellectual property to develop, register, sell, offer to sell, have sold, market and distribute YH001 in North America. In the event of a termination of the YH001 Collaboration Agreement by us as a result of Eucure's material uncured breach or bankruptcy, the license shall continue in the Initial Indications in North America, provided that (i) such license shall remain exclusive during the royalty term and non-exclusive thereafter; (ii) we shall have the right to have YH001 manufactured for its development and commercialization requirements in the Initial Indications in North America; and (iii) the license shall terminate in the event of an uncured material breach by us of any provision (including payment obligations) that survives termination of the YH001 Collaboration Agreement. In the event the YH001 Collaboration Agreement terminates for safety reasons related to YH001, by mutual agreement of the parties or by Eucure in the event of an uncured material breach or bankruptcy by us, then our rights and obligations under the YH001 Collaboration Agreement will revert to Eucure. In the event Eucure does not approve the Company Option, we may terminate the YH001 Collaboration Agreement for convenience with a 30-day notice to Eucure, provided that such termination is given within 12 months of the effective date of the YH001 Collaboration Agreement (the Company Option Termination). In the event of a Company Option Termination, Eucure would be obligated to reimburse us for all costs and expenses that we incurred in performing the development activities.

License Agreement with Case Western

Under our license agreement with Case Western, we may be required to pay up to an aggregate of approximately $9.8 million in milestone payments, of which $0.7 million relates to the initiation of certain development activities ($0.2 million of which has been paid) and approximately $9.1 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If products utilizing certain intellectual property licensed from Case Western (the TRC102 Technology) are successfully commercialized, we will be required to pay Case Western a single-digit royalty on net sales, subject to adjustments in certain circumstances. Beginning on the earlier of a specified number of years from the effective date of the agreement and the anniversary of the effective date following the occurrence of a specified event, we will be required to make a minimum annual royalty payment of $75,000, which will be credited against our royalty obligations. In the event we sublicense any of our rights under the agreement relating to the TRC102 Technology, we will be obligated to pay Case Western a portion of certain fees we may receive under the sublicense. Our royalty obligations will continue on a country-by-country basis through the later of the expiration of the last valid claim under the TRC102 Technology or 14 years after the first commercial sale of a product utilizing the TRC102 Technology in a given country.

Financial Operations Overview

Research and Development Expenses

Research and development expenses consist of costs associated with the preclinical and clinical development of product candidates. These costs consist primarily of:

- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and development functions;
- costs incurred under clinical trial agreements with investigative sites;
- costs to acquire preclinical study and clinical trial materials;
- costs associated with conducting our preclinical, development and regulatory activities, including fees paid to third party professional consultants, service providers and our scientific advisory board;
- payments related to licensed products and technologies; and
- facilities, depreciation and other expenses, including allocated expenses for rent and maintenance of facilities.

Research and development costs, including third party costs reimbursed in connection with our collaboration agreements, are expensed as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

The following table summarizes our research and development expenses by product candidate for the periods indicated.

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Third-party research and development expenses:		
Envafolimab	$ 2,094	$ 1,470
YH001	1,422	21
TRC102	—	94
TJ004309	—	187
Total third-party research and development expenses	3,516	1,772
Unallocated expenses	1,453	1,221
Total research and development expenses	$ 4,969	$ 2,993

Unallocated expenses consist primarily of our internal personnel and facility related costs.

We expect our current level of research and development expenses to remain relatively consistent for the remainder of 2023 as we continue enrollment of the ENVASARC trial and the Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

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 product candidates due to the inherently unpredictable nature of preclinical and clinical development. 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 as to 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.

The costs of clinical trials to us and the timing of such costs may vary significantly based on factors such as:

- the extent to which costs for comparator drugs are borne by third parties;
- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the effects of macroeconomic and geopolitical developments;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate; and
- the extent to which costs are borne by third parties such as the NCI.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include legal services, including those associated with the TJ004309 Agreement and Bispecific Agreement arbitration, insurance, occupancy costs, accounting services, and the cost of various consultants.

We anticipate that our general and administrative expenses will remain relatively consistent for the remainder of 2023; however, there may be increases to the extent we have to expend additional legal fees in connection with enforcing and collecting the arbitration award announced in April 2023 from I-Mab.

Other Expense

In 2023, other expense primarily consists of interest related to our arbitration financing agreement. In 2022, other expense primarily consists of interest related to our loan agreements with SVB, which was terminated in June 2022, and RGC offset in part by interest income from our cash equivalents and investing activities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and on various other factors that we believe to be 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. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies Involving Management Estimates and Assumptions*," included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		
	2023	2022	Change
	(in thousands)		
Research and development expenses	$ 4,969	$ 2,993	$ 1,976
General and administrative expenses	2,344	6,453	(4,109)
Total other expense	(1,191)	(27)	(1,164)

Research and development expenses. Research and development expenses were $5.0 million and $3.0 million for the three months ended March 31, 2023 and 2022, respectively. The increase of $2.0 million was primarily due to envafolimab drug product purchased in 2023 for clinical trials. We expect research and development expenses to remain relatively consistent in future periods with our continued enrollment of the ENVASARC trial and the Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

General and administrative expenses. General and administrative expenses were $2.3 million and $6.5 million for the three months ended March 31, 2023 and 2022, respectively. The decrease of $4.1 million was primarily due to legal expenses incurred in 2022 in connection with the arbitration proceeding of our dispute with I-Mab regarding the TJ004309 Agreement and Bispecific Agreement. We expect general and administrative expenses to remain relatively consistent in future periods, however, there may be increases to the extent we must expend additional legal fees in connection with enforcing and collecting the arbitration award announced in April 2023 from I-Mab.

Total other expense. Total other expense was $1.2 million for the three months ended March 31, 2023, and $27,000 for the three months ended March 31, 2022. The increase of $1.2 million was primarily due to noncash interest related to the arbitration financing agreement entered into in December 2022.

Liquidity and Capital Resources

Our sources of cash liquidity include our cash and cash equivalents. We believe that our cash and cash equivalents as of March 31, 2023, will be sufficient to fund the current requirements of working capital and other financial commitments, including our arbitration financing and operating lease obligations, into the third quarter of 2023, and with the amounts we expect to recover from I-Mab pursuant to the arbitration award announced in April 2023, if received, into early 2024. Based on our current business plan, we believe that there is substantial doubt as to whether our existing cash and cash equivalents will be sufficient to meet our obligations as they become due within one year from the date the accompanying unaudited condensed consolidated financial statements are issued.

We may fund our future liquidity needs by selling shares of our common stock under our existing Capital on Demand™ sales agreement with JonesTrading Institutional Services LLC (JonesTrading). In addition, we periodically consider various other financing alternatives, including debt financings, in order to meet our liquidity needs and may, from time to time, seek to take advantage of favorable interest rate environments, if any, or other market conditions.

We have incurred losses and negative cash flows from operations since our inception. As of March 31, 2023, we had an accumulated deficit of $245.4 million, and we expect to continue to incur net losses for the foreseeable future. We expect our current level of research and development expenses to remain relatively consistent for the remainder of 2023 due to the continued enrollment of the ENVASARC trial and the Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes. Given we do not anticipate any revenues from product sales in the foreseeable future, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third-party funding, and licensing or collaboration arrangements.

Arbitration Award

As previously disclosed, in June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal seated in New York City (the Tribunal) after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations under the two separate strategic collaboration and clinical trial agreements we entered into with I-Mab in November 2018 for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ004309 Agreement), as well as up to five proprietary bispecific antibodies (the Bispecific Agreement) currently under development by I-Mab. In April 2023, we received notification from the Tribunal of the final award to us. The Tribunal found in favor of us for certain claims. As a result, the Tribunal declared the Phase 1 clinical trial of TJ004309 Agreement "Complete," as that term is defined in the TJ004309 Agreement as of January 2022. The Tribunal also determined that we are entitled to approximately $23.0 million, which includes the $9.0 million prespecified termination fee payable by I-Mab under the TJ004309Agreement, plus interest, and certain of our legal fees, costs and disbursements incurred in connection with the arbitration. We are entitled to a high single digit interest rate on the award. Pursuant to the arbitration award, the TJ004309 Agreement and the Bispecific Agreement have been terminated. The decision by the Tribunal is final and binding on the parties.

Arbitration Financing Investment Agreement

In December 2022, we entered into a non-recourse financing agreement (the Investment Agreement) with certain investors (collectively, the Investors) pursuant to which the Investors will pay us a maximum aggregate amount (Maximum Capital) equal to $30.0 million or a lesser amount based on the amount awarded (Award), if any, to us in connection with our ongoing arbitration proceeding with I-Mab (the Arbitration). Of the Maximum Capital, (i) $3.5 million (Initial Capital) was paid to us shortly after execution, (ii) 25% was to be paid to us within 15 business days of issuance of an Award, subject to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement, and (iii) the remainder was to be paid to us in tranches over a multi-year period, subject again to the issuance of an Award and the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement. In connection with the execution of the Investment Agreement and funding of the Initial Capital amount, we paid a closing fee in the amount of 2%. In April 2023, we received notification of the Award resulting from the Arbitration and it was determined we were entitled to approximately $23.0 million, which includes the $9.0 million prespecified termination fee payable by I-Mab under the TJ004309 Agreement, plus interest, and certain of the Company's legal fees, costs and disbursements incurred in connection with the arbitration. As this Award amount did not exceed the prespecified thresholds under the Investment Agreement, we will not receive any additional funds under the Investment Agreement such that, as of the date of the Award, the Maximum Capital is equal to the Initial Capital.

Subject to and contingent on our actual recovery of proceeds from an Award or any contemporaneously resolved settlements with I-Mab and following the payment of applicable attorney's fees (the Proceeds), we shall pay the Investors an amount (Repayment Amount) equal to the sum of (i) all amounts paid by the Investors to or on behalf of us pursuant to the Investment Agreement, plus (ii) a low sub-single digit to low single digit multiple calculated on each tranche of Maximum Capital actually paid by the Investors to or on behalf of us with the applicable multiple being based on the timing of payment from us and whether certain events relating to the Arbitration occur, plus (iii) a mid-teen percentage annual rate of return on the amounts set forth in clauses (i) and (ii) that begins to accrue if the amounts are not paid by us to the Investors within a multi-month period specified in the Investment Agreement. If the amount of Proceeds are less than the Repayment Amount, then we shall only be required to pay to the Investors the Proceeds recovered (other than in circumstances in which we accept a settlement offer that resolves the Arbitration for an amount less than the Repayment Amount without the prior written consent of the Investors), and in the circumstance in which there are no Proceeds then we shall not be required to pay the Investors any Repayment Amounts and the Investors shall have no right of recourse or right of action against us.

The Investment Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of representations or covenants and a bankruptcy default. The Investment Agreement also contains customary covenants that require us to, among other things, (i) use commercially reasonable efforts to pursue its claims in connection with the Arbitration and recover amounts awarded to it in connection with an Award, (ii) pay costs and expenses in connection with enforcing an Award, (iii) keep the Investors informed regarding the Arbitration and its collection and enforcement efforts and (iv) not incur liens (other than permitted liens) on or transfer any portion of our assets related to our claims in connection with the Arbitration, any Award, the Proceeds and related assets.

If we fail to pay amounts owed to the Investors when due, such overdue amounts bear interest at a default rate set forth in the Investment Agreement. Upon certain remedy events, including our breach of the Investment Agreement, the Investors may exercise all of their rights and remedies as set forth in the Investment Agreement and under applicable law, including, without limitation, termination of their obligations to pay additional amounts under the Investment Agreement. Pursuant to the Investment Agreement, we will also grant to the Investors a security interest in our interest in our claims in connection with the Arbitration, any Award, the Proceeds and related assets (Specific Collateral), as further described in the Investment Agreement, as security for the payment of our obligations under the Investment Agreement.

As of March 31, 2023, the $3.5 million Initial Capital was funded. The arbitration financing arrangement is a non-recourse financing agreement whereby repayment of all capital amounts funded under the Investment Agreement, including the Initial Capital, and the amount that which is required to be repaid is contingent upon our actual recovery of proceeds from an Award. In the event in which there is no recovery of proceeds from an Award, we are not required to repay the $3.5 million Initial Capital.

Runway Growth Finance Corp. Loan and Security Agreement

In September 2022, we entered into a loan and security agreement (the RGC Loan Agreement) with Runway Growth Finance Corp. (RGC). The RGC Loan Agreement was a long-term debt facility that provided a term loan commitment in an aggregate principal amount of up to $35.0 million in three tranches: (i) a Term A loan in an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement on closing of the RGC Loan Agreement and repaid in January 2023 in connection with the Investment Agreement; (ii) a Term B loan in an aggregate principal amount of up to $15.0 million to be funded in one or more disbursements at our request on or prior to June 30, 2024, subject to certain conditions being met; and (iii) a Term C loan in an aggregate principal amount of up to $10.0 million that may be disbursed in a single disbursement in the lender's sole discretion upon our request at any time from closing of the RGC Loan Agreement through and including December 31, 2024. In December 2022, we and RGC amended the RGC Loan Agreement under which: (i) we repaid all amounts of principal and accrued but unpaid interest in respect of the Term A Loan (as defined in the RGC Loan Agreement) on January 3, 2023 without the obligation for us to pay the final payment fee or the prepayment fee described in the RGC Loan Agreement; (ii) on or before March 31, 2023, at our request, if we have raised at least $25.0 million in net cash proceeds from certain equity or debt transactions (including amounts raised in connection with the Investment Agreement) prior to making such request, RGC will loan to us an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement; (iii) we will not issue an additional warrant to RGC in connection with the loan, if any, described in clause (ii) above; and (iv) RGC's security interest in Specific Collateral was subordinated to the arbitration financing Investors' security interest in the Specific Collateral. If the loan described in clause (ii) above is not made by March 31, 2023, the RGC Loan Agreement will terminate on that date, and we will not be obligated to pay the prepayment fee described in the RGC Loan Agreement but the final payment fee of 4.25% of the aggregate principal amount of the funded term loans as described in the RCG Loan Agreement will become immediately due and payable. All other material terms and conditions of the RGC Loan Agreement remained unchanged. On April 5, 2023, we and RGC amended the RGC Loan Agreement effective March 31, 2023 such that we would have until April 15, 2023 to raise at least $25.0 million in net cash proceeds from certain equity or debt transactions prior to making a request of RGC to redraw an aggregate principal amount of $10.0 million under the RGC Loan Agreement, which RGC may, in its sole and absolute discretion, allow or deny. On April 20, 2023, we and RGC amended the RGC Loan Agreement effective April 15, 2023 to extend the time period described in the foregoing sentence from April 15, 2023 to April 28, 2023. As of March 31, 2023, the total outstanding balance owed under the RGC Loan Agreement was $0. We did not redraw the $10.0 million as of April 28, 2023, resulting in the RGC Loan Agreement terminating and the final payment fee becoming immediately due and payable on that date, which we subsequently paid. As of the date of this report, we owe no other amounts under the RGC Loan Agreement.

In connection with the funding of the Term A loan, we issued RGC warrants to purchase 150,753 shares of our common stock (the RGC Term A Warrants) at an exercise price of $1.99 per underlying share of our common stock. The RGC Term A Warrants are fully exercisable in whole or in part at the option of the holder, payable in cash or on a cashless basis according to the formula set forth in the RGC Term A Warrants, and expire September 2, 2032.

Common Stock and Pre-Funded Warrants Offerings

In March 2023, we issued and sold 174,508 shares of our common stock at a purchase price of $1.38 per share and pre-funded warrants to purchase 2,013,999 shares of our common stock at a purchase price of $1.37 per share of underlying common stock with an exercise price of $0.01 per share of underlying common stock (the 2023 Pre-Funded Warrants) for net proceeds of approximately $3.0 million in a private placement (the Private Placement) with an accredited institutional healthcare-focused fund. In accordance with their terms, the 2023 Pre-Funded Warrants may not be exercised if the holder's ownership of our common stock would exceed 19.99% of the shares of our common stock outstanding immediately after giving effect to such exercise.

In June 2022, we issued and sold 841,989 shares of our common stock at a purchase price of $1.32 per share and pre-funded warrants to purchase 2,205,018 shares of our common stock at a purchase price of $1.31 per share of underlying common stock with an exercise price of $0.01 per share of underlying common stock (the 2022 Pre-Funded Warrants) for net proceeds of approximately $3.9 million in a registered direct offering (the Offering) with an accredited institutional healthcare-focused fund. In accordance with their terms, the 2022 Pre-Funded Warrants may not be exercised if the holder's ownership of our common stock would exceed 19.99% of the shares of our common stock outstanding immediately after giving effect to such exercise. In connection with the Offering, we amended two existing pre-funded warrants to purchase shares of our common stock held by the same institutional healthcare-focused fund to extend the exercise periods and to permit exercise in excess of a similar 19.99% limit following approval of our stockholders of such exercise.

At our 2023 Annual Meeting held on April 19, 2023, stockholder approval, in accordance with applicable rules of the Nasdaq Stock Market, was obtained for the issuance of shares of common stock upon the potential future exercise of certain outstanding warrants held by such accredited institutional healthcare-focused fund that would result in it and its affiliates owning in excess of 19.99% of the shares of common stock outstanding immediately after giving effect to such exercise.

ATM Facility

In December 2020, as amended in March 2022, we entered into a Capital on Demand™ Sales Agreement (the Sales Agreement) with JonesTrading pursuant to which we could sell from time to time, at our option, up to an aggregate of $50.0 million of shares of our common stock through JonesTrading, as sales agent or principal, $44.4 million of which remains available for sale as of March 31, 2023. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Capital Market under our effective registration statement on Form S-3 subject to limitations on the amount of securities the Company may sell pursuant to its effective registration statement on Form S-3 within any 12 month period, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through JonesTrading, on the Nasdaq Capital Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading will use its commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are required to pay JonesTrading 2.5% of gross proceeds from the common stock sold through the Sales Agreement.

Operating Lease Obligations

Our operating lease obligations relate to our corporate headquarters in San Diego, California, which expires in April 2027. As of March 31, 2023, future minimum lease payments under this lease were $0.3 million and $0.6 million for each of the next 12 and 24 months, respectively.

Other Obligations

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

Cash Flows

The following table summarizes our net cash flow activity for each of the periods set forth below:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (5,003)	$ (6,742)
Investing activities	—	(4)
Financing activities	(5,820)	(686)
Change in cash, cash equivalents, and restricted cash	$ (10,823)	$ (7,432)

Operating activities. Net cash used in operating activities was $5.0 million and $6.7 million for the three months ended March 31, 2023 and 2022, respectively, and was primarily due to our net loss and changes in our working capital, partially offset by non-cash charges including stock-based compensation.

Investing activities. Net cash used in investing activities was $0 and $4,000 for the three months ended March 31, 2023 and 2022, respectively.

Financing activities. Net cash used in financing activities was $5.8 million for the three months ended March 31, 2023 and primarily resulted from our repayment of $10.0 million to RGC under the RGC Loan Agreement, as amended, partially offset by $4.2 million in net proceeds from sales of common stock and pre-funded warrants. Net cash used in financing activities was $0.7 million for the three months ended March 31, 2022 and primarily resulted from repayments on borrowings under our SVB loan agreement.

Funding Requirements

At March 31, 2023, we had cash and cash equivalents totaling $6.7 million, of which $0.1 million is pledged as collateral for our obligations under our corporate headquarters facility lease. We believe that our cash and cash equivalents as of March 31, 2023, will be sufficient to fund the current requirements of working capital and other financial commitments, including our arbitration financing and operating lease obligations, into the third quarter of 2023, and with the amounts we expect to recover from I-Mab pursuant to the arbitration award announced in April 2023, if received, into early 2024. We will need additional funding to complete the development and commercialization of our product candidates or those of our partners. In addition, we may evaluate in-licensing and acquisition opportunities to gain access to new product candidates that fit with our strategy. Any such transaction will likely increase our future funding requirements. These uncertainties raise substantial doubt about our ability to continue as a going concern for a period of 12 months following the date that the accompanying unaudited condensed consolidated financial statements were issued.

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. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- our ability to initiate, and the progress and results of, our ongoing and planned clinical trials;
- the ability and willingness of our collaboration partners and licensees to continue clinical development of product candidates;
- our ability to enter into and maintain our collaborations;
- our ability to achieve, and our obligations to make, milestone payments under our collaboration and license agreements;
- the costs and timing of procuring supplies of product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of our product candidates;
- the extent to which adverse macroeconomic and geopolitical developments, including as a result of recent and potential future bank failures, the COVID-19 pandemic, delay our clinical development activities or those of our collaborators;
- the costs, timing and outcome of regulatory review of product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we or any of our partners, including Eucure and Biocytogen or 3D Medicines and Alphamab, may receive marketing approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidates for which we receive marketing approval and do not partner for commercialization; and
- the extent to which we acquire or in-license other products and technologies.

Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and licensing arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. As a result of adverse macroeconomic and geopolitical developments, such as the COVID-19 pandemic and actions taken to slow its spread, the ongoing military conflict between Ukraine and Russia, recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans or programs which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified and pursuant to the requirements of the Securities and Exchange Commission's (SEC) rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (who are our principal executive officer and principal financial officer, respectively), to allow for timely decisions regarding required disclosures. In designing and evaluating the 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 the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) promulgated under the Exchange Act, we carried out an evaluation, with the participation of our management, including our Chief Executive Officer and Chief Financial Officer (who are our principal executive officer and principal financial officer, respectively), of the effectiveness of our disclosure controls and procedures as of March 31, 2023, the end of the period covered by this Quarterly Report. Based upon the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Except with respect to our dispute and related proceedings with I-Mab referenced below, we are not currently a party to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. For a description of our dispute and related proceedings with I-Mab, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 2 of this Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, together with the other information contained in this Quarterly Report and in our other public filings with the SEC. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Summary of Risk Factors

Our business is subject to numerous risks, as more fully described immediately below. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

- We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.
- We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts. There is substantial doubt as to our ability to continue as a going concern.
- Unfavorable U.S. and global economic conditions could adversely affect our business, financial condition or results of operations.
- We are heavily dependent on the success of our lead clinical stage product candidate envafolimab. We cannot give any assurance that envafolimab will successfully complete clinical development or receive regulatory approval, which is necessary before it can be commercialized.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.
- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.
- The regulatory approval processes of the U.S. Food and Drug Administration (FDA), and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We depend in part on NCI and other third-party sponsors to advance clinical development of TRC102. If these third-party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

- We are dependent on our corporate partners for the advancement of our product candidates. Specifically, we are dependent on 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) with respect to certain aspects of our development of envafolimab for sarcoma in North America. Similarly, we are dependent on Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen) with respect to certain aspects of our development of YH001 in North America. The failure to maintain these collaboration agreements, the failure of our corporate partners to perform their obligations under the agreements, or the actions of our corporate partners or their other partners with respect to envafolimab and YH001 in other indications or outside North America could negatively impact our business.
- We may not be able to protect our intellectual property rights throughout the world.
- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.*

We are a clinical stage biopharmaceutical company with limited operating history. All the product candidates we are developing will require substantial additional development time and resources before we or our partners would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred losses from operations in each year since our inception, including net losses of $8.5 million and $9.5 million for the three months ended March 31, 2023 and 2022, respectively. At March 31, 2023, we had an accumulated deficit of $245.4 million.

We expect to continue to incur substantial expenses as we expand our development activities and advance our clinical programs. To become and remain profitable, we or our partners must succeed in developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations.

We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts. There is substantial doubt as to our ability to continue as a going concern.*

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our current level of research and development expenses to remain relatively consistent for the remainder of 2023 due to the continued enrollment of the ENVASARC trial and the Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes, however this is based on our current expectations which are subject to change.

At March 31, 2023, we had cash and cash equivalents totaling $6.7 million, of which $0.1 million is pledged as collateral for our obligations under our corporate headquarters facility lease. Based upon our current operating plan, we believe that our cash and cash equivalents as of March 31, 2023, will be sufficient to fund the current requirements of working capital and other financial commitments, including our arbitration financing and operating lease obligations, into the third quarter of 2023, and with the amounts we expect to recover from I-Mab pursuant to the arbitration award announced in April 2023, if received, into early 2024. We will need additional funding to complete the development and commercialization of product candidates, including envafolimab and YH001. In addition, in December 2019 we entered into a collaboration and clinical trial agreement with 3D Medicines and Alphamab, and in October 2021 we entered into a collaborative development and commercialization agreement with Eucure and Biocytogen. Under these agreements, we are responsible for various portions of the costs to conduct clinical trials, among other development obligations. We will need additional funds to advance the development of these programs and meet our cost-sharing obligations, and these requirements may be substantial depending on how many programs are selected for development and the stage of development each program reaches. Our ability to utilize the amounts awarded to us in April 2023 in connection with our arbitration with I-Mab are subject to the risks associated with recovery of any award or judgment, including, without limitation, that I-Mab may be unable to pay the award or may not timely pay the award. The failure of I-Mab to pay or timely pay the award could adversely affect our ability to operate our business and our financial results. As more fully discussed in Note 1 to the unaudited condensed consolidated financial statements included in this Quarterly Report, the uncertainties around our ability to obtain additional funding raise substantial doubt regarding our ability to continue as a going concern for a period of 12 months following the date these accompanying unaudited condensed consolidated financial statements were issued.

Regardless of our expectations, changing circumstances beyond our control, including the effects of adverse macroeconomic and geopolitical developments, such as the COVID-19 pandemic, recent and potential future bank failures, rising inflation rates and the ongoing conflict between Ukraine and Russia may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties or we could encounter difficulties obtaining clinical trial material or other supplies that could increase our development costs more than we expect. In addition, we may incur further legal expenses in connection with enforcing and collecting the arbitration award announced in April 2023, and we may not be successful in enforcing and collecting the awarded amount. If we do take action to enforce and collect the arbitration award, such action could take significant time and expenses and divert our management's attention and resources, which would adversely affect our ability to operate our business and our financial results. In any event, we will require additional capital prior to completing clinical development, filing for regulatory approval, or commercializing any product candidates.

In December 2020, as amended in March 2022, we entered into a Sales Agreement with JonesTrading pursuant to which we could sell from time to time, at our option, up to an aggregate of $50.0 million of shares of our common stock through JonesTrading, as sales agent or principal, $44.4 million of which remains available for sale as of March 31, 2023. While the Sales Agreement provides us with an additional option to raise capital through issuances and sales of our common stock, there can be no guarantee that we will be able to sell shares under the Sales Agreement in the future, or that any sales will generate sufficient proceeds to meet our capital requirements. In particular, JonesTrading is under no obligation to sell any shares of our common stock that we may request to be sold under the Sales Agreement from time to time. If sales are made under the Sales Agreement, our existing stockholders may experience dilution and such sales, or the perception that such sales are or will be occurring, may cause the trading price of our common stock to decline.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. As a result of adverse macroeconomic and geopolitical developments, such as recent and potential future bank failures, the COVID-19 pandemic and actions taken to slow its spread, ongoing military conflict between Ukraine and Russia, actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate further, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or are forced to delay our planned drug development efforts due to lack of financing, it would have a material adverse effect on our business, financial condition, operating results and prospects.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to Clinical Development and Regulatory Approval of Product Candidates

If the response rate of envafolimab as a single agent or in combination with ipilimumab in UPS/MFS is not significantly higher than existing therapies, our strategy of pursuing accelerated approval of envafolimab on ORR as the primary endpoint could delay or prevent the approval of envafolimab in UPS/MFS.

We are initially developing envafolimab in refractory UPS/MFS, where the PD-(L)1 inhibitors given as single agents or in combination with ipilimumab demonstrated response rates which were significantly higher than the response rate demonstrated by the approved treatment Votrient or chemotherapy in UPS/MFS. If the response rate of envafolimab as a single agent or in combination with ipilimumab in UPS/MFS is not significantly higher than Votrient or other chemotherapy, our strategy of pursuing accelerated approval of envafolimab on ORR as the primary endpoint will be unlikely to succeed, which could delay or prevent the approval of envafolimab in UPS/MFS.

Our plan to develop envafolimab in combination with ipilimumab and YH001 in combination with envafolimab exposes us to additional risks.

We intend to develop envafolimab in combination with ipilimumab and to develop YH001 in combination with envafolimab, and may in the future develop other product candidates in combination with other approved therapies or therapies in development. Patients may not be able to tolerate envafolimab or any of our other product candidates in combination with ipilimumab, YH001 or other therapies or dosing of envafolimab in combination with ipilimumab, YH001 or other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.*

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Even if product candidates demonstrate favorable results in ongoing or planned Phase 1 and 2 clinical trials, many product candidates fail to show desired safety and efficacy traits in late-stage clinical trials despite having progressed through earlier trials. In addition to the potential lack of safety or efficacy of product candidates, clinical trial failures may result from a multitude of factors including flaws in trial design, manufacture of clinical trial material, dose selection and patient enrollment criteria, or differences in determination of progression events by investigators compared to central radiographic reviewers. With respect to envafolimab and YH001, while results of trials conducted by others outside of the United States have been promising, they may not be predictive of results in U.S. trials due to differences in trial design, target indications, patient populations, availability of alternative treatments and other factors. Based upon the recommendation of the IDMC following an interim analysis of data from the ENVASARC trial, we have proceeded in the trial using a dose of envafolimab that is twice the dose administered to the first patients in the trial. While dosing at higher levels has shown promising results in other trials outside of the United States, we cannot be certain that we will observe similar results in the ENVASARC trial, including whether the higher dose will result in tolerability issues that were not encountered with the lower dose. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. If patients drop out of our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, or if our trials are otherwise disrupted due to adverse macroeconomic and geopolitical developments, such as recent and potential future bank failures, the ongoing military conflict between Ukraine and Russia, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our stock price would be materially and adversely affected.

Interim, topline and preliminary data from preclinical studies and clinical trials may change as more data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

We and our collaboration partners publicly disclose from time to time, interim, topline or preliminary data from preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as more data become available. We and our collaboration partners may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We and our collaboration partners also make assumptions, estimations, calculations and conclusions as part of the analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, the manner in which clinical data and results are reported may differ depending on the jurisdiction in which a trial is conducted or between us and our collaboration partners. As a result, the interim, topline or preliminary results that we or our collaboration partners report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the previously published preliminary data. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects.

From time to time, we or our collaboration partners may also disclose interim data from clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us, our collaboration partners, or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, our company in general and our common stock. In addition, the information we or our collaboration partners choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we or our collaboration partners determine to be material or otherwise appropriate information to include in such disclosure, and any information we or our collaboration partners determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that is reported for our product candidates differ from future or more comprehensive data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.*

We may experience delays in clinical trials of product candidates. Our ongoing and planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- adverse findings in toxicology studies, including chronic toxicology studies;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in enrollment caused by the availability of alternative treatments;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays in our ability to acquire sufficient supply of clinical trial materials.

For example, the FDA may require additional or different data in order to move forward with a BLA submission for envafolimab for patients with local advanced, unresectable or metastatic UPS and MFS, which could ultimately delay regulatory approval and could have a material adverse effect on our business.

In addition, adverse macroeconomic and geopolitical developments have impacted clinical trials broadly, including our own with some sites pausing enrollment or not completing all assessments specified in the protocol, and some patients choosing not to enroll or continue participating in ongoing trials. We and our collaborators may continue to experience delays in site initiation and patient enrollment, failures to comply with trial protocols, delays in the manufacture of product candidates for clinical testing, supply chain disruptions and other difficulties in starting or competing our clinical trials due to macroeconomic and geopolitical developments.

If initiation or completion of our ongoing or planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize product candidates could be materially harmed, which could have a material adverse effect on our business.

Our product candidates or those of our partners may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events (AEs) caused by product candidates or other potentially harmful characteristics of product candidates could cause us, our partners, including Eucure, Biocytogen, 3D Medicines, Alphamab or the NCI, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

Envafolimab has produced AEs consistent with other inhibitors of the PD-L1 and PD-1 pathways, including rare fatal immune related toxicities. Only a single related serious adverse event was reported in 36 patients in the ENVASARC interim efficacy data review in December 2022. Based on the August 9, 2021 data cutoff from the YH001 Phase 1 dose escalation clinical trial being conducted in Australia, no dose limiting toxicities had occurred and a single related serious adverse event of grade 3 colitis was reported, which led to treatment discontinuation. Phase 1 or Phase 2 clinical trials of TRC102 conducted to date have generated AEs related to the trial drug, some of which have been serious. The most common AE identified in our clinical trials of TRC102 has been anemia. There can be no assurance that AEs associated with product candidates will not be observed. As is typical in drug development, we have a program of ongoing toxicology studies in animals for clinical stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities.

Further, if any approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression-free survival, the agency may later require us to demonstrate overall survival, which would greatly extend the time and increase the capital required to complete clinical development. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of product candidates may not be sufficient to support the submission of a BLA or a New Drug Application (NDA), or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates or those of our partners.

We have not previously submitted a marketing application, or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any product candidates will be successful in clinical trials or receive regulatory approval. Further, product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such product candidates, if approved.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review and approve proposed clinical trials or new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign and domestic inspections of manufacturing facilities. In July 2020, the FDA restarted on-site inspections on a risk-based basis. Regulatory authorities outside the United States have and may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may attempt to secure approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek accelerated approval for one or more of our product candidates, including envafolimab in UPS/MFS. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. In addition, the FDA currently requires pre-approval of promotional materials for accelerated approval products, once approved.

If we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA could require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may not receive fast track designation for our product candidates from the FDA, or fast track designation may not actually lead to a faster development or regulatory review or approval process.

Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. While the FDA did grant us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy, it has broad discretion whether or not to grant this designation for our other product candidates. Even if we believe another particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. Further, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may be unsuccessful in our efforts to obtain orphan drug designations (ODDs) from the FDA for product candidates, and even if these designations are obtained, we may not ultimately realize the potential benefits of ODD.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 people in the United States, or a patient population of greater than 200,000 people in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years.

In June 2021, we received ODD for envafolimab for the treatment of soft tissue sarcoma subtypes and in October 2020, the FDA granted ODD for TRC102 for the treatment of patients with malignant glioma, including glioblastoma and in June 2021, we received ODD for envafolimab for the treatment of soft tissue sarcoma subtypes. Generally, if a drug with an ODD subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same orphan designated indication for that time period. The applicable period is seven years in the United States, which may be extended by six months, in the case of product candidates that have complied with the respective regulatory agency's agreed upon pediatric investigation plan. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, even after a drug is granted orphan exclusivity and approved, the FDA can subsequently approve another drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, if an orphan designated product receives marketing approval for an indication broader than or different from what is designated, such product may not be entitled to orphan exclusivity. Even though the FDA has granted ODD, if we receive approval for a modified or different indication, our current orphan designations may not provide us with exclusivity.

ODD does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn, and other product candidates may obtain approval before us and receive orphan drug exclusivity, which could block us from entering the market. For example, 3D Medicines has U.S. ODD for envafolimab for the treatment of BTC, an indication that is outside the scope of our current license agreement with 3D Medicines.

Orphan drug exclusivity also may not effectively protect us from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions before the expiration of any orphan drug exclusivity period.

If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to generic competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity.

Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma subtypes, such designation may not be granted, and even if granted this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that envafolimab will receive marketing approval in the United States.

A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma, we may not be granted such designation and even if designated this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that envafolimab will receive marketing approval in the United States. In addition, if granted breakthrough therapy designation, the FDA may later decide that envafolimab no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as studies or trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we would intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates or those of our partners will be harmed.

Even if we receive regulatory approval of product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates.

Any product candidates for which we receive regulatory approvals will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy (REMS) in order to approve product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with regulatory requirements for current good manufacturing practices (cGMPs), and current good clinical practices (cGCPs), for any clinical trials that we conduct post-approval. Although physicians, in the practice of medicine, may prescribe an approved drug for unapproved indications, pharmaceutical companies are prohibited from promoting uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses of approved pharmaceutical products, and a company that is found to have improperly promoted off-label may be subject to significant liability. Later discovery of previously unknown problems with product candidates, including AEs of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of existing approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Our Reliance on Third Parties

We and our partners rely on third party manufacturers to make product candidates, and any failure by a third party manufacturer may delay or impair our ability to complete clinical trials or commercialize our product candidates.

Manufacturing drugs and biologics is complicated and is tightly regulated by regulatory authorities, including the FDA and foreign equivalents. We currently rely on third party manufacturers to supply us with drug substance for preclinical and clinical trials. Moreover, the market for contract manufacturing services for drug products is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide tight capacity, we may not be able to access the required capacity on a timely basis or on commercially viable terms, which could result in delays in initiating or completing clinical trials or our ability to apply for or receive regulatory approvals.

We rely on other third parties for drug substance and to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, there can be no guarantee that lack of clinical supplies will not force us or our partners to delay or terminate any ongoing or planned clinical trials.

We expect to continue to rely on third party manufacturers for any drug required for commercial supply and do not intend to build our own manufacturing capability. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is costly, time consuming and subject to potential difficulties and delays. With respect to envafolimab, pursuant to the Envafolimab Collaboration Agreement, 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. With respect to YH001, Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to us for clinical trials pursuant to the terms of a clinical supply and quality agreement to be separately negotiated, but we cannot guarantee that we will successfully negotiate and enter into the contemplated clinical supply and quality agreement or do so on commercially favorable terms.

We do not have any long-term supply agreements for the manufacture of product candidates and cannot guarantee that any third party manufacturer would be willing to continue supplying drug product for clinical trials or commercial sale at a reasonable cost or at all. In addition, manufacturing agreements are often subject to early termination by the third party manufacturer under certain circumstances.

The facilities used by our current or future third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for product candidates, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both drug substances and finished drug products. If our third party manufacturers or those of our collaborators cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may experience delays in initiating planned clinical trials and we may not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize product candidates.

We depend in part on NCI and other third party sponsors to advance clinical development of TRC102. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

NCI is currently sponsoring and funding multiple clinical trials involving TRC102. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of TRC102 depends in part on the continued sponsorship and funding of clinical trials by these organizations, as our resources and capital would not be sufficient to conduct these trials on our own. None of these third party sponsors are obligated to continue sponsorship or funding of any clinical trials involving our product candidates and could stop their support at any time. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

Even if these third party sponsors continue to sponsor and fund clinical trials of our product candidates, our reliance on their support subjects us to numerous risks. For example, we have limited control over the design, execution or timing of their clinical trials and limited visibility into their day-to-day activities, including with respect to how they are providing and administering our product candidates. If a clinical trial sponsored by a third party has a failure due to poor design of the trial, errors in the way the clinical trial is executed or for any other reason, or if the sponsor fails to comply with applicable regulatory requirements or if there are errors in the reported data, it could represent a major set-back for the development and approval of our product candidates, even if we were not directly involved in the trial and even if the clinical trial failure was not related to the underlying safety or efficacy of the product candidate. In addition, these third party sponsors could decide to de-prioritize clinical development of our product candidates in relation to other projects, which could adversely affect the timing of further clinical development. We are also subject to various confidentiality obligations with respect to the clinical trials sponsored by third party sponsors, which could prevent us from disclosing current information about the progress or results from these trials until the applicable sponsor publicly discloses such information or permits us to do so. This may make it more difficult to evaluate our business and prospects at any given point in time and could also impair our ability to raise capital on our desired timelines.

We are dependent on 3D Medicines and Alphamab with respect to certain aspects of our development of envafolimab for the treatment of sarcoma in North America and on Eucure and Biocytogen with respect to certain aspects of our development of YH001 for the treatment of certain sarcoma subtypes in North America. The failure to maintain these collaboration and clinical trial agreements, the failure of 3D Medicines, Alphamab, Eucure or Biocytogen to perform their obligations under the agreements, or the actions of 3D Medicines, Alphamab, Eucure or Biocytogen or their other partners with respect to envafolimab and YH001 in other indications or outside North America could negatively impact our business.

Pursuant to the terms of our collaboration and clinical trial agreement with 3D Medicines and Alphamab, we were granted an exclusive license to develop and commercialize envafolimab for sarcoma in North America. Pursuant to the terms of our collaborative development and commercialization agreement with Eucure and Biocytogen, we were granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion. While we are generally responsible for clinical development, 3D Medicines and Alphamab are responsible for certain critical activities associated with envafolimab and Eucure and Biocytogen are responsible for certain critical activities associated with YH001, including, as applicable, the manufacture and supply of envafolimab and YH001, CMC activities and prosecution and enforcement of intellectual property rights. We have limited control over the amount and timing of resources that 3D Medicines, Alphamab, Eucure and Biocytogen will dedicate to their respective efforts, and their failure to perform their obligations would impair our ability to develop envafolimab for sarcoma in North America and YH001 for certain sarcoma subtypes in North America. In addition, we have very limited influence or control over 3D Medicines', Alphamab's, Eucure's or Biocytogen's (or their respective other partners') activities with respect to the development and commercialization of envafolimab and YH001 in non-licensed indications or indications outside of North America, even though these activities could have a significant impact on the development and commercialization of envafolimab for sarcoma in North America and YH001 for certain sarcoma subtypes in North America. For example, Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product, any of which could have a significant impact on the development and commercialization of YH001 for sarcoma in North America. Additionally, adverse events in clinical trials outside of the United States could cause the FDA to put clinical trials of envafolimab or YH001 in the United States on hold, and negative results of clinical trials of envafolimab in other indications may cast doubt as to the likelihood of positive results of clinical trials in UPS/MFS or other sarcoma indications.

We are subject to a number of other risks associated with these collaboration and clinical trial agreements, including:

- we and our corporate partners could disagree as to future development plans which could delay initiation of clinical trials or stop a future clinical trial;
- there may be disputes between us and our corporate partners, including disagreements regarding the terms of the collaboration and clinical trial agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives and/or costly litigation or arbitration that diverts our management's attention and resources;
- our corporate partners may not provide us with timely and accurate information regarding development progress and activities outside of sarcoma and North America, which could adversely impact our ability to report progress to our investors and may cause us to make ill-informed decisions with respect to our own development efforts;
- our corporate partners may not properly maintain or defend the intellectual property rights licensed to us in North America or may undertake activities that invite litigation that could jeopardize or invalidate the intellectual property rights licensed to us or expose us to potential litigation; and

- our corporate partners are responsible for conducting CMC activities for envafolimab and YH001 and may not conduct such activities at the quality level required to seek FDA approval.

If we have disagreements with our corporate partners, if they do not perform their obligations under the collaboration and clinical trial agreements or there are negative events with respect to envafolimab or YH001 outside of the licensed indications or North America, there could be material adverse consequences to our ability to successfully develop and commercialize envafolimab and YH001 in North America or to the value of envafolimab and YH001 to us.

We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our existing product candidates or to leverage our clinical development capabilities.*

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. In particular, we are actively seeking additional corporate partnerships in which we would share in the cost and risk of clinical development and commercialization of innovative product candidates of third parties. We face significant competition in seeking appropriate partners, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as having the requisite potential to demonstrate safety and efficacy and as being economically valuable in light of the terms that we are seeking and other available products for licensing by other companies. With respect to additional partnerships whereby we would develop third party product candidates, we will need to identify promising product candidates where the owner of the development and commercial rights could benefit from our clinical development capabilities. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any inability or delay in entering into new collaboration agreements related to our product candidates, in particular in foreign countries where we do not have and do not intend to establish significant capabilities, could delay the development and commercialization of our product candidates and reduce their market potential. If we are unable to enter into additional collaborations that leverage our clinical development capabilities, we may be forced to reduce these capabilities, which could lower the value of our company and make it less likely that third parties will seek to collaborate with us to develop their product candidates.

We rely on third parties to conduct preclinical studies and clinical trials of product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for product candidates.

We do not have our own capabilities to perform preclinical testing of product candidates, and therefore rely entirely on third party contractors and laboratories to conduct these studies for us. In addition, while we intend to continue designing, monitoring and managing our clinical trials of product candidates using our clinical operations and regulatory team, we still depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials at their sites under agreements with us. We will compete with many other companies for the resources of these third-party contractors, laboratories, investigators and collaborators, and the initiation and completion of our preclinical studies and clinical trials may be delayed if we encounter difficulties in engaging these third parties or need to change service providers during a preclinical study or clinical trial.

We control only certain aspects of the activities conducted for us by the third parties on which we currently rely and on which we will rely in the future for our preclinical studies and clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials and certain of our preclinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state health care laws, including, among others, fraud and abuse, false claims, privacy and security, and physician payment transparency laws. Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical development programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize product candidates. As a result, our financial results and the commercial prospects for our product candidates or those of our partners would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies which could do harm to our business and affect our ability to be profitable. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. Additionally, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations in a legal framework that is constantly evolving. The standards applied by the United States Patent and Trademark Office (USPTO), and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate.

For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the claims of our applications and patents. As of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear, what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Furthermore, due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all our product candidates or methods involving these product candidates in the parent patent application.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and biosimilar products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensors' operations.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.*

Specific to the development of YH001 in North America, we hold an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion. As it relates to the development of envafolimab for the treatment of sarcoma in North America, we hold an exclusive license from 3D Medicines and Alphamab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering envafolimab. We also hold a non-exclusive license for the conduct of clinical trials in the EU in support of the development of envafolimab for the treatment of sarcoma in North America.

As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

Third party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination and review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we and our partners are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates or methods of use of our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any third party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we or our partner obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we or our partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we or our partner could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our partner are unable to enter into licenses on acceptable terms.

Parties making claims against us or our partner may obtain injunctive or other equitable relief, which could effectively block our or our partner's ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the EU member states seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our products.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patent of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.*

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. YH001 and associated intellectual property have been licensed from Eucure and Biocytogen and envafolimab and associated intellectual property have been licensed from 3D Medicines and Alphamab. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment or diligence obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partners' ability to utilize the affected intellectual property in our drug development efforts, and our ability to enter into collaboration or marketing agreements for a product candidate, may be adversely affected.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate; and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Risks Related to Commercialization of Product Candidates

Even if we obtain regulatory approval of product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community.

Factors that will influence whether product candidates are accepted in the market include:

- the clinical indications for which product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering product candidates as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by governmental and commercial third party payors;
- the willingness of patients to pay out-of-pocket in the absence of coverage by governmental and commercial third party payors;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If, for any of these or other reasons, product candidates fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Off-label use of approved drugs could adversely impact peak sales of our product candidates if approved, including Keytruda's off-label use in UPS/MFS.

While no PD-(L)1 treatments are currently FDA approved in UPS/MFS or any other sarcoma subtype, Keytruda (pembrolizumab, marketed by Merck & Co.) has a compendia listing in UPS and is reimbursed for off-label use in UPS. The off-label use of Keytruda in UPS/MFS may adversely affect the peak net sales of envafolimab in UPS/MFS and other sarcoma subtypes, if envafolimab is approved by the FDA and commercialized in the United States. Similarly, while no CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma, if YH001 is approved, it may nevertheless compete with the currently marketed CTLA-4 inhibitor ipilimumab (Yervoy, marketed by Bristol Myers Squibb), which is approved by the FDA in multiple indications other than soft tissue sarcoma.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize product candidates.

We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing product candidates against competitors.

Under the terms of our license agreement with Case Western, we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to TRC102. Despite our exclusive license, Case Western retained the right to grant non-exclusive licenses to third parties in the same field of use as our exclusive license as a means to settle any intellectual property disputes Case Western may have in the future with such third parties. While Case Western has not made us aware of any present intent to exercise this right, there can be no guarantee that Case Western will not do so in the future or that it would not grant such a non-exclusive license to a competitor of ours seeking to develop and commercialize a product that is identical to TRC102 in the same field of use that we are pursuing. If this were to occur, and we did not have other intellectual property outside of the Case Western license agreement to prevent competitive products for the same indications, we may face competition much earlier than we currently anticipate and the value of TRC102 may decline substantially.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from "biosimilars" due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or "biosimilar," to or "interchangeable" with an FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. Future FDA standards or criteria for determining biosimilarity and interchangeability, and FDA discretion to determine the nature and extent of product characterization, non-clinical testing and clinical testing on a product-by-product basis, may further facilitate the approval of biosimilar products and their ability to compete with our product candidates or those of our partners. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Any such event or further changes in the law could decrease the period for which we have exclusivity and consequently negatively impact our business and competitive position. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Coverage and reimbursement may be limited or unavailable in certain market segments for product candidates, which could make it difficult for us to sell product candidates profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates and those of our partners represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from these product candidates.

Patients who are provided medical treatment for their conditions generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third party payors, such as commercial health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third party payor may depend upon a number of factors, including, but not limited to, the third party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Obtaining coverage and reimbursement approval of a product from a government or other third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data to each payor separately for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of product candidates. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We intend to seek approval to market product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for product candidates.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.*

Third party payors, whether domestic or foreign, or governmental or commercial, and governments are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in the United States. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative changes to the statute will remain in effect until 2032 unless additional Congressional action is taken. In January 2013, former U.S. President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been heightened governmental scrutiny over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain market acceptance in the medical community;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any product candidates are approved for commercialization, we expect that we or our partners will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- different payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements, including the significant sanctions and export controls imposed against Russia, Russian banks and certain Russian individuals by the United States, United Kingdom and EU, along with others;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we or our partners outside of the United States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates or those of our partners outside the United States will be limited and our results of operations may be harmed.

Risks Related to Our Business and Industry

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.*

We do not have internal new drug discovery capabilities or a technology platform with which to develop novel product candidates. Unless we develop or acquire these capabilities or a technology platform, our only means of expanding our product pipeline will be to acquire or in-license product candidates that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. In addition, part of our corporate strategy is to leverage our existing internal clinical development and regulatory capabilities by entering into collaborations where we conduct development activities related to third party product candidates in exchange for commercialization and payment rights, such as our collaborations with Eucure and Biocytogen with respect to YH001 and 3D Medicines and Alphamab with respect to envafolimab. Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. With respect to envafolimab, 3D Medicines and Alphamab retain certain rights to reacquire the rights for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications. While we and 3D Medicines and Alphamab must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights, we cannot guarantee that any compensation paid to us would adequately cover our investments in the program, the present value of the rights to us or our opportunity costs as a result of having advanced the program prior to reacquisition. Also, in the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we do not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities. However, we may not be able to agree with 3D Medicines and Alphamab on adequate compensation and cannot guarantee that any agreed-upon compensation would adequately cover our investments in commercializing envafolimab in North America or our lost opportunity costs in pursuing commercialization. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, we may not be able to execute on an important part of our business strategy and our long-term business and prospects will be limited.

We and our partners are subject to extensive federal, state, and foreign regulation, and our failure to comply with healthcare laws could harm our business.*

Although we do not currently have any products on the market, we and our partners are subject to healthcare regulation and enforcement by the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws that may affect our ability to operate include:

- the federal anti-kickback statute, which applies to our business activities, including our research, marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs;
- federal civil and criminal false claims laws, including the federal False Claims Act, and federal civil monetary penalty law that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other governmental healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, imposes certain regulatory and contractual requirements on covered entities, and their business associates and subcontractors that create, receive, maintain or transmit individually identifiable health information for or on their behalf, as well as their covered subcontractors, regarding the privacy, security and transmission of individually identifiable health information;
- federal “sunshine” requirements imposed by the ACA on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information regarding any payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members; and
- state or foreign law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened certain of these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

We are also subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the EU is governed by the General Data Protection Regulation, or the EU GDPR. The EU GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The EU GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The EU GDPR requirements apply not only to third party transactions, but also to transfers of information within our company, including employee information. The EU GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third party vendors process, including in clinical trials conducted in the United States and EU. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, exclusion from governmental health care programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates or those of our partners. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize product candidates; and
- decreased demand for product candidates, if approved for commercial sale.

We currently carry product liability insurance covering our clinical trials with limits we believe are customary for other companies in our field and stage of development. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had federal and California NOL carryforwards of $194.3 million and $144.5 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030 and 2033, respectively, if not utilized. The federal NOL generated after 2017 of $111.1 million will carryforward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. As of December 31, 2022, we also had federal research and development and Orphan Drug tax credit carryforwards of $13.7 million and California research and development tax credit carryforwards of $3.0 million. The federal research and development and Orphan Drug tax credit carryforwards will begin expiring in 2031 and 2036, respectively, if not utilized. The California research credit will carry forward indefinitely under current law. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

New or future changes to tax laws could materially adversely affect us.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), modified certain provisions of the Tax Act and the recently enacted IRA, includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA or any newly enacted federal tax legislation. The impact of such legislation and any future changes in tax laws on holders of our common stock is also uncertain and could be adverse.

If we fail to attract and keep senior management and key clinical operations and regulatory personnel, we may be unable to successfully develop product candidates and execute our business strategy.

We are highly dependent on members of our senior management, including Charles Theuer, M.D., Ph.D., our President and Chief Executive Officer. Our clinical development strategy and ability to directly manage or oversee our on-going and planned clinical trials are also dependent on the members of our clinical operations and regulatory team. The loss of the services of any of these persons could impede the development of product candidates and our ability to execute our business strategy. We may be particularly impacted by the unexpected loss of employees due to our small employee base and limited ability to quickly shift responsibilities to other employees in our organization. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining other qualified employees for our business, including scientific, quality assurance and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue, making recruitment and retention competitive. This competition has become exacerbated by the increase in employee resignations currently taking place throughout the United States as a result of the COVID-19 pandemic, which is commonly referred to as the "great resignation." We may also experience employee turnover as a result of the ongoing "great resignation." As a result, competition for skilled personnel is intense, particularly in the San Diego, California area, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our development and strategic objectives. In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing stockholders.

Unfavorable U.S. and global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse macroeconomic and geopolitical developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including the ongoing COVID-19 pandemic, material shortages and related supply chain challenges, recent and potential future bank failures, geopolitical developments such as the conflict between Ukraine and Russia, and higher inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, United Kingdom and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability and/or supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia-Ukraine conflict has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. Further, a weak or declining economy could strain our suppliers, manufacturers and collaborators, possibly resulting in additional supply disruption for our product candidates and delays to our clinical trials. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. If economic conditions in Europe and other key markets for our business and the business of our suppliers, manufacturers and collaborators remain uncertain or deteriorate further, including as a result of the COVID-19 pandemic or otherwise, we could experience adverse effects on our business, financial condition or results of operations.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment.*

Even though our common stock trades on the Nasdaq Capital Market, we cannot assure you that an active, liquid trading market for our shares will develop or persist. Our stockholders may not be able to sell their shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock has been, and is likely to continue to be, volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- any delay in submitting a BLA or an NDA for any product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that marketing application;
- failure to successfully develop and commercialize product candidates;
- changes in laws or regulations applicable to product candidates;

- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors;
- failure to maintain our collaboration and clinical trial agreements;
- failure of 3D Medicines or Alphamab to perform their obligations under our collaboration and clinical trial agreements, or the actions of 3D Medicines or Alphamab or their other partners with respect to envafolimab in other indications or outside North America;
- failure of Eucure and Biocytogen to perform their obligations under our collaborative development and commercialization agreement, or the actions of Eucure or Biocytogen or their other partners with respect to YH001 in other indications or outside North America, or within North America in combination with other Eucure product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the impact of macroeconomic and geopolitical events, such as general political, health and economic conditions, including recent and potential future bank failures, the COVID-19 pandemic, economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets on our business;
- sales of our common stock by us or our stockholders in the future, in particular any sales by significant stockholders or our affiliates; and
- trading volume of our common stock.

In addition, the stock market in general, and the Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations, and we have in the past experienced volatility that has been unrelated or disproportionate to our operating performance. From January 1, 2022 through May 5, 2023, the closing price of our common stock has ranged between $0.69 and $3.00 per share. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could have an adverse impact on the liquidity and market price of our common stock.*

Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria. If we are unable to meet all of the Nasdaq continued listing requirements and at least one of the Nasdaq continued listing standards in the future, including if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days (the Minimum Bid Price Requirement), or if we are unable to maintain at least $2.5 million in stockholders' equity or a market capitalization of at least $35 million, Nasdaq could determine to delist our common stock. For example, on December 30, 2022, we received a letter from the Nasdaq Stock Market LLC (Nasdaq) notifying us that for 30 consecutive business days prior to the date of such letter, the market value of our common stock was less than $35.0 million, which did not meet the requirement for continued listing on the Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(b)(2) (the Market Value Rule). On January 20, 2023, Nasdaq notified us that we had regained compliance with the Market Value Rule because the market value of our common stock was $35.0 million or greater for the ten consecutive business days from January 5, 2023 to January 19, 2023. Also, as of May 5, 2023, the closing price of our common stock was $0.72. If the price of our common stock closes below $1.00 for 30 consecutive business days, we would receive notice from Nasdaq that we are not in compliance with the Minimum Bid Price Requirement.

Although we have regained compliance with Nasdaq continued listing requirements, if we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock may become subject to delisting. If that were to happen, we may not be able to regain compliance. If we cannot regain compliance after any such notice and if our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.*

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know-how or information that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

General Risk Factors

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations, reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information (collectively, sensitive data) .

Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the California Consumer Privacy Act of 2018(CCPA), applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties for noncompliance (up to $7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, it the California Privacy Rights Act of 2020 (CPRA), expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law.

Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon which we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR) impose strict requirements for processing personal data.

For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Obligations related to data privacy and security are quickly changing becoming increasingly stringent, and creating regulatory uncertainty Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations. If we or the third parties upon which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or our operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to interruptions to our operations such as our clinical trials; regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including, but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Third party sites that take part in clinical trials we sponsor or third parties that are also sponsoring clinical trials involving our product candidates or those of our partners, such as NCI and Case Western, face similar threats and any security breach of their systems could adversely affect us. Security breaches could be particularly harmful to our business due to our reliance on internal clinical development functions and systems to conduct our clinical trials. For example, for clinical trials that we conduct, we rely on third party hosted software to manage the resulting clinical data. While the third party vendor is obligated to back up our clinical data on its servers, we do not independently back up our clinical data, and a loss of our clinical data by the third party vendor could result in delays in our development programs, cause us to breach our obligations to our third party collaborators, and significantly increase our costs to recover or reproduce the data.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon which we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our clinical development activities.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities , but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon which we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our unaudited condensed consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Other business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contractors, consultants and collaborators, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. To the extent our collaborators are unable to comply with their obligations under our agreements with them or they are otherwise unable to complete or are delayed in completing development activities due to business disruptions, our ability to advance development in the United States may become impaired. In addition, NCI may be affected by government shutdowns in the United States or withdrawn funding, which may lead to suspension or termination of ongoing NCI-sponsored clinical development of our product candidates. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability and the ability of our partners to obtain clinical supplies of product candidates could be disrupted if the operations of our third party manufacturers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

Our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate:

- FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state fraud and abuse laws and other healthcare laws;
- laws governing the conduct of business abroad; or
- laws that require the reporting of true and accurate financial information or data.

Additionally, these parties may fail to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with additional third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with partners, consultants, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management, including having to divert a disproportionate amount of its attention away from day-to-day operating activities to implement and manage future growth. Our future financial performance and our ability to commercialize product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, including through obligations to indemnify our third party manufacturers, or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts or those of our third party manufacturers, which could harm our business, prospects, financial condition or results of operations.

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

Recent Sales of Unregistered Securities

There were no sales of equity securities during the period covered by this report that were not registered under the Securities Act and were not previously reported in a Current Report on Form 8-K filed by us.

Purchases of Equity Securities by the Issue and Affiliated Purchasers

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Entry into a Material Definitive Agreement

The following disclosure is provided in this Part II, Item 5 in lieu of disclosure under Item 1.01 of Form 8-K.

On May 8, 2023, we entered into a purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement"), each dated as of May 8, 2023, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $26.0 million of the our common stock, par value 0.001 per share ("Common Stock"), subject to certain limitations and satisfaction of the conditions set forth in the Purchase Agreement, from time to time and at our sole discretion during the term of the Purchase Agreement.

Upon the terms and subject to the satisfaction of the conditions set forth in the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $26.0 million of our Common Stock. Such sales of Common Stock by us, if any, will be subject to certain limitations set forth in the Purchase Agreement, and may occur from time to time, at our sole discretion, over a period of up to 36-months commencing on the date that each of the conditions to Lincoln Park's purchase obligations set forth in the Purchase Agreement have initially been satisfied, including that a registration statement registering under the Securities Act the resale by Lincoln Park of shares of Common Stock that have been and may be issued by us to Lincoln Park under the Purchase Agreement, which we agreed to file with respect to a certain amount of shares of Common Stock with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement not later than 10 business days after the date of execution of the Purchase Agreement and the Registration Rights Agreement, is declared effective by the SEC and a final prospectus relating thereto is filed with the SEC (the date on which all of such conditions are satisfied, the "Commencement Date").

On the Commencement Date, we may, by written notice delivered by us to Lincoln Park, direct Lincoln Park to purchase shares of Common Stock (the "Initial Purchase"); provided, however, that the dollar amount of Lincoln Park's maximum purchase commitment under the Initial Purchase may not exceed $1.0 million. The purchase price per share for the Initial Purchase will be equal to the lesser of (i) the lowest sale price for Common Stock on The Nasdaq Capital Market on the business day immediately preceding the Commencement Date and (ii) the average of the 10 closing sale prices of the Common Stock on The Nasdaq Capital Market during the 10 consecutive business days prior to the Commencement Date.

From and after the first business day following the Commencement Date, we may from time to time, on any business day selected by us on which the closing sale price per share of Common Stock as reported on The Nasdaq Capital Market is not less than the "floor price" threshold set forth in the Purchase Agreement (each such business day, a "purchase date"), by written notice delivered by us to Lincoln Park, direct Lincoln Park to purchase up to 125,000 shares of Common Stock on such purchase date, at a purchase price per share that will be determined and fixed in accordance with the Purchase Agreement at the time we deliver such written notice to Lincoln Park (each, a "regular purchase"). The maximum number of shares we may sell to Lincoln Park in a regular purchase may be increased by certain amounts to up to 175,000 shares, with the applicable maximum share limit determined by whether the closing sale price per share of Common Stock as reported on The Nasdaq Capital Market on the applicable purchase date for such regular purchase equals or exceeds certain minimum price thresholds set forth in the Purchase Agreement, in each case, subject to adjustment for any recapitalization, non-cash dividend, forward or reverse stock split or other similar transactions as provided in the Purchase Agreement; provided, however, that the dollar amount of Lincoln Park's maximum purchase commitment in any single regular purchase may not exceed $1.0 million. The purchase price per share of Common Stock sold by us to Lincoln Park in each such regular purchase, if any, will be based on the market prices of the Common Stock over a certain period ending immediately prior to the time of sale calculated in accordance with the pricing terms for a regular purchase set forth in the Purchase Agreement.

In addition to regular purchases, provided that we have directed Lincoln Park to purchase the maximum amount of shares that we are then able to sell to Lincoln Park in a regular purchase, we may, in our sole discretion, also direct Lincoln Park to purchase additional shares of Common Stock in "accelerated purchases," and "additional accelerated purchases" as set forth in the Purchase Agreement. The purchase price per share of Common Stock sold in each such accelerated purchase and additional accelerated purchase, if any, will be based on the market prices of the Common Stock over a certain period during regular trading hours on the applicable purchase date for such accelerated purchase and such additional accelerated purchase, respectively, calculated in accordance with the pricing terms for an accelerated purchase and an additional accelerated purchase, as applicable, set forth in the Purchase Agreement. There are no upper limits on the price per share that Lincoln Park must pay for shares of Common Stock in any purchase under the Purchase Agreement.

We will control the timing and amount of any sales of Common Stock to Lincoln Park pursuant to the Purchase Agreement. Lincoln Park has no right to require us to sell any shares of Common Stock to Lincoln Park, but Lincoln Park is obligated to make purchases as we direct, subject to certain conditions set forth in the Purchase Agreement. Actual sales of shares of Common Stock to Lincoln Park will depend on a variety of factors to be determined by us from time to time, including, among others, general market conditions, the trading prices for our Common Stock at or prior to the time of sale and determinations by us as to the appropriate sources of funding for us and our operations.

In accordance with applicable Nasdaq listing rules, the aggregate number of shares of Common Stock that we may issue to Lincoln Park under the Purchase Agreement cannot exceed 4,809,486 shares (subject to adjustment for any recapitalization, non-cash dividend, forward or reverse stock split or other similar transactions), which number of shares equals 19.99% of the shares of Common Stock issued and outstanding immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) we first obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap in accordance with applicable Nasdaq listing rules, or (ii) at the time we have issued shares of Common Stock equal to the Exchange Cap and at all times thereafter, the average price per share of Common Stock for all shares of Common Stock sold by us to Lincoln Park under the Purchase Agreement equals or exceeds $0.8225 per share (representing the lower of the official closing price of the Common Stock on Nasdaq on the trading day immediately preceding the date of the Purchase Agreement and the average official closing price of the Common Stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the Purchase Agreement, as adjusted pursuant to applicable Nasdaq rules), such that the Exchange Cap limitation would no longer apply to issuances and sales of Common Stock by us to Lincoln Park under the Purchase Agreement under applicable Nasdaq listing rules.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of Common Stock if those shares, when aggregated with all other shares of Common Stock then beneficially owned by Lincoln Park (as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder), would result in Lincoln Park beneficially owning more than 9.99% of the issued and outstanding shares of Common Stock.

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, except we are prohibited (with certain specified exceptions set forth in the Purchase Agreement), during the term of the Purchase Agreement, from effecting or entering into an agreement to effect an "equity line of credit" or other substantially similar equity line of credit offering in which we may offer, issue or sell, and the purchaser is irrevocably bound to purchase, Common Stock or securities convertible or exercisable into Common Stock at a future determined price. Lincoln Park has agreed not to engage in or effect, directly or indirectly, for its own principal account or for the principal account of any of its affiliates, any short sales of the Common Stock or hedging transaction that establishes a net short position in the Common Stock during the term of the Purchase Agreement.

As consideration for Lincoln Park's commitment to purchase shares of Common Stock at our direction, from time to time during the term of the Purchase Agreement, upon the terms of and subject to satisfaction of the conditions set forth in the Purchase Agreement, we issued 599,216 shares of Common Stock to Lincoln Park as a commitment fee (such shares, the "Commitment Shares") on May 8, 2023.

The Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties, conditions and indemnification obligations of the parties. We have the right to terminate the Purchase Agreement at any time with one business day's prior written notice to Lincoln Park, at no cost or penalty. During any "Event of Default" under the Purchase Agreement, Lincoln Park does not have the right to terminate the Purchase Agreement; however, we may not deliver to Lincoln Park any purchase notice for a regular purchase, an accelerated purchase or an additional accelerated purchase of Common Stock, until such Event of Default is cured.

The foregoing descriptions of the Purchase Agreement and the Registration Rights Agreement are qualified in their entirety by reference to the full text of such agreements, copies of which are attached to this Quarterly Report on Form 10-Q as Exhibits 10.5 and 4.14, respectively, and each of which is incorporated into this Part II, Item 5 in its entirety by reference. The representations, warranties and covenants contained in such agreements were made only for purposes of such agreements and as of specific dates, were solely for the benefit of the parties to such agreements and may be subject to limitations agreed upon by the contracting parties.

This Part II, Item 5 shall not constitute an offer to sell or a solicitation of an offer to buy any shares of common stock in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Unregistered Sales of Equity Securities

The following disclosure is provided in this Part II, Item 5 in lieu of disclosure under Item 3.02 of Form 8-K.

To the extent required by Item 3.02 of Form 8-K, the information contained under the heading “Entry into a Material Definitive Agreement” in this Part II, Item 5 is incorporated herein by reference.

In the Purchase Agreement, Lincoln Park represented to us, among other things, that it is an “accredited investor” (as such term is defined in Rule 501(a)(3) of Regulation D under the Securities Act). The securities referred to in this current report on Form 8-K are being issued and sold by us to Lincoln Park under the Purchase Agreement in reliance upon the exemptions from the registration requirements of the Securities Act afforded by Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D thereunder.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TRACON Pharmaceuticals, Inc.
3.3(8)	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended, of TRACON Pharmaceuticals, Inc.
3.4(1)	Amended and Restated Bylaws.
4.1(3)	Form of Common Stock Certificate of the Registrant.
4.2(4)	Form of Pre-Funded Warrant dated March 27, 2018 (attached as Exhibit B-1 to the Securities Purchase Agreement).
4.3(4)	Form of Common Warrant dated March 27, 2018 (attached as Exhibit B-2 to the Securities Purchase Agreement).
4.4(5)	Form of Pre-Funded Warrant dated June 21, 2022.
4.5(5)	Form of Amended and Restated Pre-Funded Warrant 2 dated June 21, 2022.
4.6(5)	Form of Amended and Restated Pre-Funded Warrant 3 dated June 21, 2022.
4.7(3)	Warrant to Purchase Stock issued to Silicon Valley Bank on November 14, 2013.
4.8(3)	Warrant to Purchase Stock issued to Silicon Valley Bank on June 4, 2014.
4.9(3)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 13, 2015.
4.10(9)	Warrant to Purchase Stock issued to Silicon Valley Bank on January 25, 2017.
4.11(10)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 3, 2018.
4.12(6)	Form of Warrant to Purchase Common Stock dated September 2, 2022.
4.13(7)	Form of Pre-Funded Warrant to Purchase Common Stock dated March 10, 2023 (attached as Exhibit B to Securities Purchase Agreement dated March 9, 2023.
4.14	Registration Rights Agreement, dated May 8, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC.
10.1	Second Amendment to Loan and Security Agreement, effective as of March 31, 2023, by and between the Registrant and Runway Growth Finance Corp.
10.2	Third Amendment to Loan and Security Agreement, effective as of April 15, 2023, by and between the Registrant and Runway Growth Finance Corp.
10.3+	Summary of Management Bonus Arrangement.
10.4(7)	Securities Purchase Agreement, dated March 9, 2023, by and between the Registrant and the purchaser listed on Exhibit A thereto.
10.5	Securities Purchase Agreement, dated May 8, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.

Exhibit Number	Description of Document
101.INS	Inline XBRL Instance 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	The cover page for the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101

+ Indicates management contract or compensatory plan.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 4, 2015.

(2) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on December 9, 2020.

(3) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-201280), as amended.

(4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 23, 2018.

(5) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on June 21, 2022.

(6) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on September 6, 2022.

(7) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on March 9, 2023.

(8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on April 20, 2023.

(9) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on January 31, 2017.

(10) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 10, 2018.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TRACON Pharmaceuticals, Inc.

Date: May 10, 2023

/s/ Charles P. Theuer, M.D., Ph.D.

Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2023

/s/ Scott B. Brown, CPA

Scott B. Brown, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 4.14

REGISTRATION RIGHTS AGREEMENT

This **REGISTRATION RIGHTS AGREEMENT** (this "Agreement"), dated as of May 8, 2023, by and between **TRACON PHARMACEUTICALS, INC.,** a Delaware corporation (the "Company"), and **LINCOLN PARK CAPITAL FUND, LLC,** an Illinois limited liability company (together with it permitted assigns, the "Buyer"). Capitalized terms used herein and not otherwise defined herein shall have the respective meanings set forth in the Purchase Agreement by and between the parties hereto, dated as of the date hereof (as amended, restated, supplemented or otherwise modified from time to time, the "Purchase Agreement").

WHEREAS:

A. Upon the terms and subject to the conditions of the Purchase Agreement, (i) the Company has agreed to issue to the Investor, and the Investor has agreed to purchase, up to Twenty-Six Million Dollars ($26,000,000) of the Company's common stock, par value $0.001 per share (the "Common Stock"), pursuant to the Purchase Agreement (such shares, the "Purchase Shares"), and (ii) the Company has agreed to issue to the Investor such number of shares of Common Stock as consideration for its commitment to purchase shares of Common Stock under the Purchase Agreement at such times and otherwise in accordance with the terms set forth in Section 5(e) of the Purchase Agreement (collectively, the "Commitment Shares"); and

B. To induce the Investor to enter into the Purchase Agreement, the Company has agreed to provide certain registration rights under the Securities Act of 1933, as amended, and the rules and regulations thereunder, or any similar successor statute (collectively, the "Securities Act"), and applicable state securities laws.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Buyer hereby agree as follows:

1. DEFINITIONS.

As used in this Agreement, the following terms shall have the following meanings:

a. "Investor" means the Buyer, any transferee or assignee thereof to whom a Buyer assigns its rights under this Agreement in accordance with Section 9 and who agrees to become bound by the provisions of this Agreement, and any transferee or assignee thereof to whom a transferee or assignee assigns its rights under this Agreement in accordance with Section 9 and who agrees to become bound by the provisions of this Agreement.

b. "Person" means any individual or entity including but not limited to any corporation, a limited liability company, an association, a partnership, an organization, a business, an individual, a governmental or political subdivision thereof or a governmental agency.

c. "Register," "registered," and "registration" refer to a registration effected by preparing and filing one or more registration statements of the Company in compliance with the Securities Act and pursuant to Rule 415 under the Securities Act or any successor rule providing for offering securities on a continuous basis ("Rule 415"), and the declaration or ordering of effectiveness of such registration statement(s) by the United States Securities and Exchange Commission (the "SEC").

d. "Registrable Securities" means all of the Commitment Shares and all of the Purchase Shares, that may, from time to time, be issued or become issuable to the Investor under the Purchase Agreement (without regard to any limitation or restriction on purchases), and any and all shares of capital stock issued or issuable with respect to the Purchase Shares, the Commitment Shares or the Purchase Agreement as a result of any stock split, stock dividend, recapitalization, exchange or similar event or otherwise, without regard to any limitation on purchases under the Purchase Agreement.

e. "Registration Statement" means one or more registration statements of the Company covering only the resale of the Registrable Securities.

2. REGISTRATION.

a. Mandatory Registration. The Company shall, within ten (10) Business Days after the date hereof, file with the SEC an initial Registration Statement covering the number of Registrable Securities that include all of the Commitment Shares and such number of additional Registrable Securities (but not to exceed an aggregate of 5,000,000 shares of Common Stock) as shall be permitted to be included thereon in accordance with applicable SEC rules, regulations and interpretations so as to permit the resale of such Registrable Securities by the Investor under Rule 415 under the Securities Act at then prevailing market prices (and not fixed prices), as mutually determined by both the Company and the Investor in consultation with their respective legal counsel. The initial Registration Statement shall register only the Registrable Securities in the amount determined as set forth above. The Investor and its counsel shall have a reasonable opportunity to review and comment upon such Registration Statement and any amendment or supplement to such Registration Statement and any related prospectus prior to its filing with the SEC, and the Company shall give due consideration to all such comments. The Investor shall furnish all information reasonably requested by the Company for inclusion therein. The Company shall use commercially reasonable efforts to have the Registration Statement and any amendment declared effective by the SEC at the earliest possible date. The Company shall use commercially reasonable efforts to keep the Registration Statement effective pursuant to Rule 415 promulgated under the Securities Act and available for the resale by the Investor of all of the Registrable Securities covered thereby at all times until the earlier of (i) the date on which the Investor shall have resold all the Registrable Securities covered thereby and no Available Amount remains under the Purchase Agreement and (ii) one year after the termination of the Purchase Agreement (the "Registration Period"). The Registration Statement (including any amendments or supplements thereto and prospectuses contained therein) shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading.

b. Rule 424 Prospectus. The Company shall, as required by applicable securities regulations, from time to time file with the SEC, pursuant to Rule 424 promulgated under the Securities Act, the prospectus and prospectus supplements, if any, to be used in connection with sales of the Registrable Securities under the Registration Statement. The Investor and its counsel shall have a reasonable opportunity to review and comment upon such prospectus prior to its filing with the SEC, and the Company shall give due consideration to all such comments. The Investor shall use its reasonable best efforts to comment upon such prospectus within one (1) Business Day from the date the Investor receives the final pre-filing version of such prospectus.

c. Sufficient Number of Shares Registered. In the event the number of shares available under the Registration Statement is insufficient to cover all of the Registrable Securities reserved for issuance by the Company under the Purchase Agreement, the Company shall amend the Registration Statement or file a new Registration Statement (a "New Registration Statement"), so as to cover all of such Registrable Securities (subject to the limitations set forth in Section 2(a)) as soon as reasonably practicable, but in any event not later than ten (10) Business Days after the necessity therefor arises, subject to any limits that may be imposed by the SEC pursuant to Rule 415 under the Securities Act. The Company shall use its commercially reasonable efforts to cause such amendment and/or New Registration Statement to become effective as soon as practicable following the filing thereof.

d. Offering. If the staff of the SEC (the "Staff") or the SEC seeks to characterize any offering pursuant to a Registration Statement filed pursuant to this Agreement as constituting an offering of securities that does not permit such Registration Statement to become effective and be used for resales by the Investor under Rule 415 at then-prevailing market prices (and not fixed prices), or if after the filing of the initial Registration Statement with the SEC pursuant to Section 2(a), the Company is otherwise required by the Staff or the SEC to reduce the number of Registrable Securities included in such initial Registration Statement, then the Company shall reduce the number of Registrable Securities to be included in such initial Registration Statement (after consulting with the Investor and its legal counsel as to the specific Registrable Securities to be removed therefrom) until such time as the Staff and the SEC shall so permit such Registration Statement to become effective and be used as aforesaid. In the event of any reduction in Registrable Securities pursuant to this paragraph, the Company shall file one or more New Registration Statements in accordance with Section 2(c) until such time as all Registrable Securities have been included in Registration Statements that have been declared effective and the prospectus contained therein is available for use by the Investor. Notwithstanding any provision herein or in the Purchase Agreement to the contrary, the Company's obligations to register Registrable Securities (and any related conditions to the Investor's obligations) shall be qualified as necessary to comport with any requirement of the SEC or the Staff as addressed in this Section 2(d).

3. RELATED OBLIGATIONS.

With respect to the Registration Statement and whenever any Registrable Securities are to be registered pursuant to Section 2 including on any New Registration Statement, the Company shall use its reasonable best efforts to effect the registration of the Registrable Securities in accordance with the intended method of disposition thereof and, pursuant thereto, the Company shall have the following obligations:

a. The Company shall prepare and file with the SEC such amendments (including post-effective amendments) and supplements to any Registration Statement and the prospectus used in connection with such Registration Statement, which prospectus is to be filed pursuant to Rule 424 promulgated under the Securities Act, as may be necessary to keep the Registration Statement or any New Registration Statement effective at all times during the Registration Period, and, during such period, comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities of the Company covered by the Registration Statement or any New Registration Statement until such time as all of such Registrable Securities shall have been disposed of in accordance with the intended methods of disposition by the seller or sellers thereof as set forth in such Registration Statement.

b. The Company shall permit the Investor to review and comment upon the Registration Statement or any New Registration Statement and all amendments and supplements thereto at least two (2) Business Days prior to their filing with the SEC, and not file any such document in a form to which Investor reasonably objects. The Investor shall use its reasonable best efforts to comment upon the Registration Statement or any New Registration Statement and any amendments or supplements thereto within two (2) Business Days from the date the Investor receives the final version thereof. The Company shall furnish to the Investor, without charge any correspondence from the SEC or the staff of the SEC to the Company or its representatives relating to the Registration Statement or any New Registration Statement.

c. Upon request of the Investor, the Company shall furnish to the Investor, (i) promptly after the same is prepared and filed with the SEC, at least one copy of such Registration Statement and any amendment(s) thereto, including financial statements and schedules, all documents incorporated therein by reference and all exhibits, (ii) upon the effectiveness of any Registration Statement, a copy of the prospectus included in such Registration Statement and all amendments and supplements thereto (or such other number of copies as the Investor may reasonably request) and (iii) such other documents, including copies of any preliminary or final prospectus, as the Investor may reasonably request from time to time in order to facilitate the disposition of the Registrable Securities owned by the Investor. For the avoidance of doubt, any filing available to the Investor via the SEC's live EDGAR system shall be deemed "furnished to the Investor" hereunder.

d. The Company shall use reasonable best efforts to (i) register and qualify the Registrable Securities covered by a Registration Statement under such other securities or "blue sky" laws of such jurisdictions in the United States as the Investor reasonably requests, (ii) prepare and file in those jurisdictions, such amendments (including post-effective amendments) and supplements to such registrations and qualifications as may be necessary to maintain the effectiveness thereof during the Registration Period, (iii) take such other actions as may be reasonably necessary to maintain such registrations and qualifications in effect at all times during the Registration Period, and (iv) take all other actions reasonably necessary or advisable to qualify the Registrable Securities for sale in such jurisdictions; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to (x) qualify to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 3(d), (y) subject itself to general taxation in any such jurisdiction, or (z) file a general consent to service of process in any such jurisdiction. The Company shall promptly notify the Investor who holds Registrable Securities of the receipt by the Company of any notification with respect to the suspension of the registration or qualification of any of the Registrable Securities for sale under the securities or "blue sky" laws of any jurisdiction in the United States or its receipt of actual notice of the initiation or threatening of any proceeding for such purpose.

e. As promptly as practicable after becoming aware of such event or facts, the Company shall notify the Investor in writing of the happening of any event or existence of such facts as a result of which the prospectus included in any Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and promptly prepare a supplement or amendment to such Registration Statement to correct such untrue statement or omission, and deliver a copy of such supplement or amendment to the Investor (or such other number of copies as the Investor may reasonably request). The Company shall also promptly notify the Investor in writing (i) when a prospectus or any prospectus supplement or post-effective amendment has been filed, and when a Registration Statement or any post-effective amendment has become effective (notification of such effectiveness shall be delivered to the Investor by email on the same day of such effectiveness and by overnight mail), (ii) of any request by the SEC for amendments or supplements to any Registration Statement or related prospectus or related information, and (iii) of the Company's reasonable determination that a post-effective amendment to a Registration Statement would be appropriate.

f. The Company shall use its reasonable best efforts to prevent the issuance of any stop order or other suspension of effectiveness of any Registration Statement, or the suspension of the qualification of any Registrable Securities for sale in any jurisdiction and, if such an order or suspension is issued, to obtain the withdrawal of such order or suspension at the earliest possible moment and to notify the Investor of the issuance of such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

g. The Company shall (i) cause all the Registrable Securities to be listed on each securities exchange on which securities of the same class or series issued by the Company are then listed, if any, if the listing of such Registrable Securities is then permitted under the rules of such exchange, or (ii) secure designation and quotation of all the Registrable Securities on the Principal Market. The Company shall pay all fees and expenses in connection with satisfying its obligation under this Section.

h. The Company shall cooperate with the Investor to facilitate the timely issuance of the Registrable Securities to be offered pursuant to any Registration Statement, it being agreed that such Registrable Securities shall be issued as DWAC Shares and in such denominations or amounts as the Investor may reasonably request and registered in such names as the Investor may request.

i. The Company shall at all times provide a transfer agent and registrar with respect to its Common Stock.

j. If reasonably requested by the Investor, the Company shall (i) as soon as reasonably practicable after receipt of written notice from the Investor, incorporate in a prospectus supplement or post-effective amendment such information as the Investor reasonably requests should be included therein relating to the sale and distribution of Registrable Securities, including, without limitation, information with respect to the number of Registrable Securities being sold, the purchase price being paid therefor and any other terms of the offering of the Registrable Securities; (ii) make all required filings of such prospectus supplement or post-effective amendment as soon as practicable upon notification of the matters to be incorporated in such prospectus supplement or post-effective amendment; and (iii) supplement or make amendments to any Registration Statement or New Registration Statement.

k. The Company shall use its reasonable best efforts to cause the Registrable Securities covered by any Registration Statement to be registered with or approved by such other governmental agencies or authorities in the United States as may be necessary to consummate the disposition of such Registrable Securities.

l. Within one (1) Business Day after any Registration Statement which includes the Registrable Securities is declared effective by the SEC, the Company shall deliver, and shall cause legal counsel for the Company to deliver, to the transfer agent for such Registrable Securities (with copies to the Investor) confirmation that such Registration Statement has been declared effective by the SEC substantially in the form attached hereto as Exhibit A. Thereafter, if requested by the Buyer at any time, the Company shall require its counsel to deliver to the Buyer a written confirmation whether or not the effectiveness of such Registration Statement has lapsed at any time for any reason (including, without limitation, the issuance of a stop order) and whether or not the Registration Statement is current and available to the Buyer for sale of all of the Registrable Securities.

m. The Company shall take all other reasonable actions necessary to expedite and facilitate disposition by the Investor of the Registrable Securities pursuant to any Registration Statement.

4. OBLIGATIONS OF THE INVESTOR.

a. The Company shall notify the Investor in writing of the information the Company reasonably requires from the Investor in connection with any Registration Statement hereunder. The Investor shall promptly furnish to the Company such information regarding itself, the Registrable Securities held by it and the intended method of disposition of the Registrable Securities held by it as shall be reasonably required to effect the registration of such Registrable Securities and shall execute such documents in connection with such registration as the Company may reasonably request.

b. The Investor agrees to cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of any Registration Statement hereunder, and any amendments or supplements thereof.

c. The Investor agrees that, upon receipt of any notice from the Company of the happening of any event or existence of facts of the kind described in Section 3(f) or the first sentence of Section 3(e), the Investor will immediately discontinue disposition of Registrable Securities pursuant to any Registration Statement(s) covering such Registrable Securities until the Investor's receipt of the notice regarding the resolution or withdrawal of the stop order or suspension contemplated by Section 3(f) or the copies of the supplemented or amended prospectus contemplated by the first sentence of 3(e). Notwithstanding anything to the contrary, the Company shall cause its transfer agent to promptly deliver shares of Common Stock without any restrictive legend in accordance with the terms of the Purchase Agreement in connection with any sale of Registrable Securities with respect to which an Investor has entered into a contract for sale prior to the Investor's receipt of a notice from the Company of the happening of any event of the kind described in Section 3(f) or the first sentence of Section 3(e) and for which the Investor has not yet settled.

5. EXPENSES OF REGISTRATION.

All reasonable expenses of the Company, other than sales or brokerage commissions, incurred in connection with registrations, filings or qualifications pursuant to Sections 2 and 3, including, without limitation, all registration, listing and qualifications fees, printers and accounting fees, and fees and disbursements of counsel for the Company, shall be paid by the Company.

6. INDEMNIFICATION.

a. To the fullest extent permitted by law, the Company will, and hereby does, indemnify, hold harmless and defend the Investor, the members, the directors, officers, partners, employees, agents, representatives of the Investor and each Person, if any, who controls the Investor within the meaning of the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act") (each, an "Indemnified Person"), against any losses, claims, damages, liabilities, judgments, fines, penalties, charges, costs, reasonable attorneys' fees, amounts paid in settlement (with the consent of the Company, such consent not to be unreasonably withheld) or reasonable expenses, joint or several, (collectively, "Claims") incurred in investigating, preparing or defending any action, claim, suit, inquiry, proceeding, investigation or appeal taken from the foregoing by or before any court or governmental, administrative or other regulatory agency, body or the SEC, whether pending or threatened, whether or not an indemnified party is or may be a party thereto ("Indemnified Damages"), to which any of them may become subject insofar as such Claims (or actions or proceedings, whether commenced or threatened, in respect thereof) arise out of or are based upon: (i) any untrue statement or alleged untrue statement of a material fact in the Registration Statement, any New Registration Statement or any post-effective amendment thereto or in any filing made in connection with the qualification of the offering under the securities or other "blue sky" laws of any jurisdiction in which Registrable Securities are offered ("Blue Sky Filing"), or the omission or alleged

omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) any untrue statement or alleged untrue statement of a material fact contained in the final prospectus (as amended or supplemented, if the Company files any amendment thereof or supplement thereto with the SEC) or the omission or alleged omission to state therein any material fact necessary to make the statements made therein, in light of the circumstances under which the statements therein were made, not misleading, (iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any other law, including, without limitation, any state securities law, or any rule or regulation thereunder relating to the offer or sale of the Registrable Securities pursuant to the Registration Statement or any New Registration Statement or (iv) any material violation by the Company of this Agreement (the matters in the foregoing clauses (i) through (iv) being, collectively, "Violations"). The Company shall reimburse each Indemnified Person promptly as such expenses are incurred and are due and payable, for any reasonable legal fees or other reasonable expenses incurred by them in connection with investigating or defending any such Claim. Notwithstanding anything to the contrary contained herein, the indemnification agreement contained in this Section 6(a): (i) shall not apply to a Claim by an Indemnified Person arising out of or based upon a Violation which occurs in reliance upon and in conformity with information about the Investor furnished in writing to the Company by such Indemnified Person expressly for use in connection with the preparation of the Registration Statement, any New Registration Statement or any such amendment thereof or supplement thereto, if such prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e); (ii) with respect to any superseded prospectus, shall not inure to the benefit of any such person from whom the person asserting any such Claim purchased the Registrable Securities that are the subject thereof (or to the benefit of any person controlling such person) if the untrue statement or omission of material fact contained in the superseded prospectus was corrected in the revised prospectus, as then amended or supplemented, if such revised prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e), and the Indemnified Person was promptly advised in writing not to use the incorrect prospectus prior to the use giving rise to a violation and such Indemnified Person, notwithstanding such advice, used it; (iii) shall not be available to the extent such Claim is based on a failure of the Investor to deliver or to cause to be delivered the prospectus made available by the Company, if such prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e); and (iv) shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Company, which consent shall not be unreasonably withheld. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of the Indemnified Person and shall survive the transfer of the Registrable Securities by the Investor pursuant to Section 9.

b. In connection with the Registration Statement or any New Registration Statement or prospectus, the Investor agrees to indemnify, hold harmless and defend, to the same extent and in the same manner as is set forth in Section 6(a), the Company, each of its directors, each of its officers who signs the Registration Statement or any New Registration Statement, and each Person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act (collectively and together with an Indemnified Person, an "Indemnified Party"), against any Claim or Indemnified Damages to which any of them may become subject, under the Securities Act, the Exchange Act or otherwise, insofar as such Claim or Indemnified Damages arise out of or are based upon any Violation, in each case to the extent, and only to the extent, that such Violation occurs in reliance upon and in conformity with written information about the Investor set forth on Exhibit B attached hereto or updated from time to time in writing by the Investor and furnished to the Company by the Investor expressly for use in connection with such Registration Statement; and, subject to Section 6(d), the Investor will reimburse any legal or other expenses reasonably incurred by any Indemnified Party in connection with investigating or defending any such Claim; provided, however, that the indemnity agreement contained in this Section 6(b) and the agreement with respect to contribution contained in Section 7 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Investor, which consent shall not be unreasonably withheld; provided, further, however, that the Investor shall be liable under this Section 6(b)

for only that amount of a Claim or Indemnified Damages as does not exceed the net proceeds to the Investor as a result of the sale of Registrable Securities pursuant to such Registration Statement. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such Indemnified Party and shall survive the transfer of the Registrable Securities by the Investor pursuant to Section 9.

c. Promptly after receipt by an Indemnified Person or Indemnified Party under this Section 6 of notice of the commencement of any action or proceeding (including any governmental action or proceeding) involving a Claim, such Indemnified Person or Indemnified Party shall, if a Claim in respect thereof is to be made against any indemnifying party under this Section 6, deliver to the indemnifying party a written notice of the commencement thereof, and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume control of the defense thereof with counsel mutually satisfactory to the indemnifying party and the Indemnified Person or the Indemnified Party, as the case may be; provided, however, that an Indemnified Person or Indemnified Party shall have the right to retain its own counsel with the fees and expenses to be paid by the indemnifying party, if, in the reasonable opinion of counsel retained by the indemnifying party, the representation by such counsel of the Indemnified Person or Indemnified Party and the indemnifying party would be inappropriate due to actual or potential differing interests between such Indemnified Person or Indemnified Party and any other party represented by such counsel in such proceeding. The Indemnified Party or Indemnified Person shall cooperate fully with the indemnifying party in connection with any negotiation or defense of any such action or claim by the indemnifying party and shall furnish to the indemnifying party all information reasonably available to the Indemnified Party or Indemnified Person which relates to such action or claim. The indemnifying party shall keep the Indemnified Party or Indemnified Person fully apprised at all times as to the status of the defense or any settlement negotiations with respect thereto. No indemnifying party shall be liable for any settlement of any action, claim or proceeding effected without its written consent, provided, however, that the indemnifying party shall not unreasonably withhold, delay or condition its consent. No indemnifying party shall, without the consent of the Indemnified Party or Indemnified Person, consent to entry of any judgment or enter into any settlement or other compromise which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party or Indemnified Person of a release from all liability in respect to such claim or litigation. Following indemnification as provided for hereunder, the indemnifying party shall be subrogated to all rights of the Indemnified Party or Indemnified Person with respect to all third parties, firms or corporations relating to the matter for which indemnification has been made. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action shall not relieve such indemnifying party of any liability to the Indemnified Person or Indemnified Party under this Section 6, except to the extent that the indemnifying party is prejudiced in its ability to defend such action.

d. The indemnification required by this Section 6 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or Indemnified Damages are incurred. Any Person receiving a payment pursuant to this Section 6 that is later determined not to be entitled to such payment shall return such payment to the Person making it.

e. The indemnity agreements contained herein shall be in addition to (i) any cause of action or similar right of the Indemnified Party or Indemnified Person against the indemnifying party or others, and (ii) any liabilities the indemnifying party may be subject to pursuant to applicable law.

7. CONTRIBUTION.

To the extent any indemnification by an indemnifying party is prohibited or limited by law, the indemnifying party agrees to make the maximum contribution with respect to any amounts for which it would otherwise be liable under Section 6 to the fullest extent permitted by law; provided, however, that: (i) no seller of Registrable Securities guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any seller of Registrable Securities who was not guilty of fraudulent misrepresentation; and (ii) contribution by any seller of Registrable Securities shall be limited in amount to the net amount of proceeds received by such seller from the sale of such Registrable Securities.

8. REPORTS AND DISCLOSURE UNDER THE SECURITIES ACT.

With a view to making available to the Investor the benefits of Rule 144 promulgated under the Securities Act or any other similar rule or regulation of the SEC that may at any time permit the Investor to sell securities of the Company to the public without registration ("Rule 144"), the Company agrees, at the Company's sole expense, so long as the Investor owns Registrable Securities, to use reasonable best efforts to:

a. make and keep public information available, as those terms are understood and defined in Rule 144;

b. file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act so long as the Company remains subject to such requirements and the filing of such reports and other documents is required for the applicable provisions of Rule 144;

c. furnish to the Investor so long as the Investor owns Registrable Securities, promptly upon reasonable written request, (i) a written statement by the Company that it has complied with the reporting and or disclosure provisions of Rule 144, the Securities Act and the Exchange Act, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested to permit the Investor to sell such securities pursuant to Rule 144 without registration; and

d. take such additional action as is reasonably requested by the Investor to enable the Investor to sell the Registrable Securities pursuant to Rule 144, including, without limitation, delivering all such legal opinions, consents, certificates, resolutions and instructions to the Company's Transfer Agent as may be reasonably requested in writing from time to time by the Investor and otherwise fully cooperate with Investor and Investor's broker to effect such sale of securities pursuant to Rule 144.

The Company agrees that damages may be an inadequate remedy for any breach of the terms and provisions of this Section 8 and that Investor shall, whether or not it is pursuing any remedies at law, be entitled to seek equitable relief in the form of a preliminary or permanent injunction, without having to post any bond or other security, upon any breach or threatened breach of any such terms or provisions.

9. ASSIGNMENT OF REGISTRATION RIGHTS.

The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Investor; provided, however, that any transaction, whether by merger, reorganization, restructuring, consolidation, financing or otherwise, whereby the Company remains the surviving entity immediately after such transaction shall not be deemed an assignment. The Investor may not assign its rights under this Agreement without the prior written consent of the Company, other than to an affiliate of the Investor controlled by Jonathan Cope or Josh Scheinfeld, in which case the assignee must agree in writing to be bound by the terms and conditions of this Agreement.

10. AMENDMENT OF REGISTRATION RIGHTS.

No provision of this Agreement may be amended or waived by the parties from and after the date that is one (1) Business Day immediately preceding the initial filing of the Registration Statement with the SEC. Subject to the immediately preceding sentence, no provision of this Agreement may be (i) amended other than by a written instrument signed by both parties hereto or (ii) waived other than in a written instrument signed by the party against whom enforcement of such waiver is sought. Failure of any party to exercise any right or remedy under this Agreement or otherwise, or delay by a party in exercising such right or remedy, shall not operate as a waiver thereof.

11. MISCELLANEOUS.

a. A Person is deemed to be a holder of Registrable Securities whenever such Person owns or is deemed to own of record such Registrable Securities. If the Company receives conflicting instructions, notices or elections from two or more Persons with respect to the same Registrable Securities, the Company shall act upon the basis of instructions, notice or election received from the registered owner of such Registrable Securities.

b. Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt, when delivered personally; (ii) upon receipt, when sent by email (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); or (iii) one (1) Business Day after deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and email addresses for such communications shall be:

If to the Company:
TRACON Pharmaceuticals, Inc.
4350 La Jolla Village Drive, Suite 800
San Diego, California 92122
Telephone:
E-mail:
Attention: Scott B. Brown, CFO

With a copy to (which shall not constitute notice or service of process):
Cooley LLP
10265 Science Center Drive
San Diego, California 92121
Telephone: (858) 550-6045
E-mail: mbrowne@cooley.com
Attention: Matthew Browne, Esq.

If to the Investor:

Lincoln Park Capital Fund, LLC
440 North Wells, Suite 410
Chicago, IL 60654
Telephone:
E-mail:
Attention: Josh Scheinfeld/Jonathan Cope

With a copy to (which shall not constitute notice or service of process):

Dorsey & Whitney LLP
51 West 52nd Street
New York, NY 10019
Telephone: (212) 415-9214
E-mail: marsico.anthony@dorsey.com
Attention: Anthony J. Marsico, Esq.

or at such other address and/or email address and/or to the attention of such other Person as the recipient party has specified by written notice given to each other party three (3) Business Days prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent, waiver or other communication, (B) mechanically or electronically generated by the sender's email account containing the time, date, and recipient email address and an image of the first page of such transmission or (C) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of personal service, receipt by email or receipt from a nationally recognized overnight delivery service in accordance with clause (i), (ii) or (iii) above, respectively.

c. The corporate laws of the State of Delaware shall govern all issues concerning the relative rights of the Company and its stockholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the State of Illinois, County of Cook, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

d. This Agreement and the Purchase Agreement constitute the entire agreement among the parties hereto with respect to the subject matter hereof and thereof. There are no restrictions, promises, warranties or undertakings among the parties hereto, other than those set forth or referred to herein and therein. This Agreement and the Purchase Agreement supersede all prior agreements and understandings among the parties hereto with respect to the subject matter hereof and thereof.

e. Subject to the requirements of Section 9, this Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties hereto, and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

f. The headings in this Agreement are for convenience of reference only and shall not limit or otherwise affect the meaning hereof.

g. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile signature or signature delivered by e-mail in a ".pdf" format data file, including any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com, www.echosign.adobe.com, etc., shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original signature.

h. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

i. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent and no rules of strict construction will be applied against any party.

*** * * * * ***

IN WITNESS WHEREOF, the parties have caused this Registration Rights Agreement to be duly executed as of day and year first above written.

THE COMPANY:

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles P. Theuer, M.D., Ph.D.
Name: Charles P. Theuer, M.D., Ph.D.
Title: Chief Executive Officer

BUYER:

LINCOLN PARK CAPITAL FUND, LLC
BY: LINCOLN PARK CAPITAL, LLC
BY: ROCKLEDGE CAPITAL CORPORATION

By: /s/ Josh Scheinfeld
Name: Josh Scheinfeld
Title: President

EXHIBIT A

TO REGISTRATION RIGHTS AGREEMENT

FORM OF NOTICE OF EFFECTIVENESS
OF REGISTRATION STATEMENT

EXHIBIT B

TO REGISTRATION RIGHTS AGREEMENT

Information About The Investor Furnished To The Company By The Investor Expressly For Use In Connection With The Registration Statement

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

This Second Amendment to Loan and Security Agreement (this "**Amendment**") is entered into as of April 5, 2023, by and among **TRACON PHARMACEUTICALS, INC.**, a Delaware corporation ("**Borrower Representative**"), and each other Person party to the Loan Agreement (as defined below) as a borrower from time to time (individually and collectively, jointly and severally, "**Borrower**"), the lenders from time to time party to the Loan Agreement (collectively, "**Lenders**", and each, a "**Lender**"), and **RUNWAY GROWTH FINANCE CORP.**, as administrative agent and collateral agent for Lenders (in such capacity, "**Agent**").

RECITALS

Borrower, Agent and the Lenders are parties to that certain Loan and Security Agreement dated as of September 2, 2022 (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of December 22, 2022, the "**Loan Agreement**"). The parties desire to amend the Loan Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree that the Loan Agreement shall be modified as set forth below, with effect from March 31, 2023:

1. Section 2.2(a)(i) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(i) Subject to the terms and conditions of this Agreement, on the Closing Date the Lenders, severally and not jointly, made term loans, in a single disbursement, to Borrower in an aggregate amount of Ten Million Dollars ($10,000,000) according to each Lender's Term A Loan Commitment as set forth on Schedule 1 hereto (such term loans are hereinafter referred to singly as a "**Term A Loan**", and collectively as the "**Term A Loans**"). After the Repayment Event, subject to Borrower's achievement of the New Equity Milestone and other terms and conditions of this Agreement, Lenders, in their sole and absolute discretion, severally and not jointly, may allow or deny Borrower's request to re-borrow the Term A Loans during the New Term A Draw Period in a single disbursement, in an aggregate amount of Ten Million Dollars ($10,000,000) according to each Lender's Term A Loan Commitment as set forth on Schedule 1 hereto. Other than as permitted explicitly in the foregoing sentence, once repaid no Term A Loan may be re-borrowed."

2. The following defined terms in Exhibit A to the Loan Agreement hereby are added or amended and restated, as appropriate, as follows:

"**Maturity Date**" means April 15, 2023; provided however, if the Term A Loans are re-borrowed in accordance with Section 2.2(a)(i), on the Funding Date of such re-borrowed Term A Loans the Maturity Date shall automatically be extended to September 1, 2026.

"**New Term A Draw Period**" is the period commencing on the date of the occurrence of the New Equity Milestone and ending on the earlier of (i) April 15, 2023 and (ii) the occurrence and continuance of an Event of Default; provided, however, that the New Term A Draw Period shall not commence if on the date of the occurrence of the New Equity Milestone an Event of Default has occurred and is continuing.

3. No course of dealing on the part of Agent or the Lenders or their officers, nor any failure or delay in the exercise of any right by Agent or any Lender, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Agent's or any Lender's failure at any time to require strict performance by Borrower of any provision shall not affect any right of Agent or any Lender thereafter to demand strict compliance and performance. Any suspension or waiver of a right must be in writing signed by an officer of Agent.

4. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Loan Agreement. The Loan Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Agent or any Lender under the Loan Agreement, as in effect prior to the date hereof.

5. To induce Agent and Lenders to enter into this Amendment, Borrower hereby makes the following representations and warranties to Agent and Lenders:

a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents (other than Section 5.6 of the Loan Agreement) are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date), and (b) no Event of Default has occurred and is continuing;

b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Borrower to the Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any material Requirement of Law binding on or affecting Borrower, (ii) any material agreement binding on Borrower, (iii) any applicable order, judgment or decree of any Governmental Authority binding on Borrower, or (iv) the organizational documents of Borrower;

e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any Governmental Authority, binding on Borrower, except as already has been obtained or made; and

f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

6. As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance satisfactory to Agent, the following:

(a) this Amendment, duly executed by Borrower;

(b) all reasonable Lender Expenses incurred through the date of this Amendment, which may be debited from any of Borrower's accounts; and

(c) such other documents, and completion of such other matters, as Agent may reasonably deem necessary or appropriate.

7. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

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IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the date above written.

BORROWER:

TRACON PHARMACEUTICALS, INC.

By: /s/ Scott Brown
Name: Scott Brown
Title: Chief Financial Officer

AGENT AND LENDER

RUNWAY GROWTH FINANCE CORP.

By: /s/ Thomas Raterman
Name: Thomas Raterman
Title: Chief Financial Officer

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

This Third Amendment to Loan and Security Agreement (this "**Amendment**") is entered into as of April 20, 2023, by and among **TRACON PHARMACEUTICALS, INC.**, a Delaware corporation ("**Borrower Representative**"), and each other Person party to the Loan Agreement (as defined below) as a borrower from time to time (individually and collectively, jointly and severally, "**Borrower**"), the lenders from time to time party to the Loan Agreement (collectively, "**Lenders**", and each, a "**Lender**"), and **RUNWAY GROWTH FINANCE CORP.**, as administrative agent and collateral agent for Lenders (in such capacity, "**Agent**").

RECITALS

Borrower, Agent and the Lenders are parties to that certain Loan and Security Agreement dated as of September 2, 2022 (as amended, restated, supplemented or otherwise modified from time to time, including by that certain First Amendment to Loan and Security Agreement dated as of December 22, 2022, and that certain Second Amendment to Loan and Security Agreement dated as of April 5, 2023, the "**Loan Agreement**"). The parties desire to amend the Loan Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree that the Loan Agreement shall be modified as set forth below, with effect from April 15, 2023:

1. The following defined terms in Exhibit A to the Loan Agreement hereby are added or amended and restated, as appropriate, as follows:

"**Maturity Date**" means April 28, 2023; provided however, if the Term A Loans are re-borrowed in accordance with Section 2.2(a)(i), on the Funding Date of such re-borrowed Term A Loans the Maturity Date shall automatically be extended to September 1, 2026.

"**New Term A Draw Period**" is the period commencing on the date of the occurrence of the New Equity Milestone and ending on the earlier of (i) April 28, 2023 and (ii) the occurrence and continuance of an Event of Default; provided, however, that the New Term A Draw Period shall not commence if on the date of the occurrence of the New Equity Milestone an Event of Default has occurred and is continuing.

2. No course of dealing on the part of Agent or the Lenders or their officers, nor any failure or delay in the exercise of any right by Agent or any Lender, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Agent's or any Lender's failure at any time to require strict performance by Borrower of any provision shall not affect any right of Agent or any Lender thereafter to demand strict compliance and performance. Any suspension or waiver of a right must be in writing signed by an officer of Agent.

3. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Loan Agreement. The Loan Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Agent or any Lender under the Loan Agreement, as in effect prior to the date hereof.

4. To induce Agent and Lenders to enter into this Amendment, Borrower hereby makes the following representations and warranties to Agent and Lenders:

a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents (other than Section 5.6 of the Loan Agreement) are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct

in all material respects as of such date), and (b) no Event of Default has occurred and is continuing;

b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Borrower to the Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any material Requirement of Law binding on or affecting Borrower, (ii) any material agreement binding on Borrower, (iii) any applicable order, judgment or decree of any Governmental Authority binding on Borrower, or (iv) the organizational documents of Borrower;

e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any Governmental Authority, binding on Borrower, except as already has been obtained or made; and

f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance satisfactory to Agent, the following:

(a) this Amendment, duly executed by Borrower;

(b) all reasonable Lender Expenses incurred through the date of this Amendment, which may be debited from any of Borrower's accounts; and

(c) such other documents, and completion of such other matters, as Agent may reasonably deem necessary or appropriate.

6. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

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IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the date above written.

BORROWER:

TRACON PHARMACEUTICALS, INC.

By: /s/ Scott Brown
Name: Scott Brown
Title: Chief Financial Officer

AGENT AND LENDER

RUNWAY GROWTH FINANCE CORP.

By: /s/ Thomas Raterman
Name: Thomas Raterman
Title: Chief Financial Officer

Exhibit 10.3

TRACON PHARMACEUTICALS, INC.
SUMMARY OF MANAGEMENT BONUS ARRANGEMENT

In January 2023, the Compensation Committee of the Board of Directors of TRACON Pharmaceuticals, Inc. (the "***Company***") approved a one-time discretionary bonus related to the results of the Company's arbitration with I-Mab Biopharma (the "***Arbitration Bonus***"). The terms of the Arbitration Bonus establish a cash bonus pool equal to 1% of any award in the Company's favor resulting from the arbitration to the extent the award is at least $30.0 million and no more than $50.0 million. Below are a series of examples showing the size of the cash bonus pool based on various award amounts in favor of the Company:

Award Amount in Favor of the Company	**Cash Bonus Pool Amount**
< $30.0 million	$0
$30.0 million	$300,000
$40.0 million	$400,000
$50.0 million	$500,000
> $50.0 million	$500,000

Payment of the Arbitration Bonus is conditioned on, among other things, (a) receipt by the Company of at least $10.0 million from equity sales or otherwise by June 30, 2023, including from the arbitration award, if any, and (b) employment in good standing of the recipient at the time the Arbitration Bonus is paid.

Of the Company's named executive officers disclosed in the Company's definitive proxy statement filed with the U.S. Securities and Exchange Commission on March 8, 2023, only Charles P. Theuer, M.D., Ph.D. and Scott B. Brown, CPA, M.S. will be among the employees to participate in the Arbitration Bonus. Dr. Theuer and Mr. Brown are entitled to 25% and 17% of the Arbitration Bonus's cash bonus pool, respectively.

Exhibit 10.5

PURCHASE AGREEMENT

PURCHASE AGREEMENT (the "Agreement"), dated as of May 8, 2023, by and between **TRACON PHARMACEUTICALS, INC.**, a Delaware corporation (the "Company"), and **LINCOLN PARK CAPITAL FUND, LLC**, an Illinois limited liability company (the "Investor").

WHEREAS:

Subject to the terms and conditions set forth in this Agreement, the Company wishes to issue and sell to the Investor, and the Investor wishes to buy from the Company, up to Twenty-Six Million Dollars ($26,000,000) of the Company's common stock, $0.001 par value per share (the "Common Stock"). The shares of Common Stock to be purchased hereunder are referred to herein as the "Purchase Shares."

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Investor hereby agree as follows:

1. CERTAIN DEFINITIONS.

For purposes of this Agreement, the following terms shall have the following meanings:

(a) "Accelerated Purchase Date" means, with respect to any Accelerated Purchase made pursuant to Section 2(c) hereof, the Business Day immediately following the applicable Purchase Date with respect to the corresponding Regular Purchase referred to in clause (i) of the second sentence of Section 2(c) hereof.

(b) "Accelerated Purchase Minimum Price Threshold" means, with respect to any Accelerated Purchase made pursuant to Section 2(c) hereof, the greater of (i) seventy-five percent (75%) of the Closing Sale Price of the Common Stock on the applicable Purchase Date with respect to the corresponding Regular Purchase referred to in clause (i) of the second sentence of Section 2(c) hereof and (ii) the minimum per share price threshold set forth in the applicable Accelerated Purchase Notice.

(c) "Accelerated Purchase Notice" means, with respect to an Accelerated Purchase made pursuant to Section 2(c) hereof, an irrevocable written notice from the Company to the Investor directing the Investor to purchase the number of Purchase Shares specified by the Company therein as the Accelerated Purchase Share Amount to be purchased by the Investor (such specified Accelerated Purchase Share Amount subject to adjustment in accordance with Section 2(c) hereof as necessary to give effect to the Purchase Share amount limitations applicable to such Accelerated Purchase Share Amount as set forth in this Agreement) at the applicable Accelerated Purchase Price on the applicable Accelerated Purchase Date for such Accelerated Purchase.

(d) "Accelerated Purchase Price" means, with respect to an Accelerated Purchase made pursuant to Section 2(c) hereof, ninety-seven percent (97%) of the lower of (i) the VWAP for the period beginning at 9:30:01 a.m., Eastern time, on the applicable Accelerated Purchase Date, or such other time publicly announced by the Principal Market as the official open (or commencement) of trading on the Principal Market on such applicable Accelerated Purchase Date (the "Accelerated Purchase Commencement Time"), and ending at the earliest of (A) 4:00:00 p.m., Eastern time, on such applicable Accelerated Purchase Date, or such other time publicly announced by the Principal Market as the official close of trading on the Principal Market on such applicable Accelerated Purchase Date, (B) such time, from and after the Accelerated Purchase Commencement Time for such Accelerated Purchase, that the total number (or volume) of shares of Common Stock traded on the Principal Market has exceeded the applicable Accelerated Purchase Share Volume Maximum, and (C) such time, from and after the Accelerated Purchase Commencement Time for such Accelerated Purchase, that the Sale Price has fallen below the applicable Accelerated Purchase Minimum Price Threshold (such earliest of (i)(A), (i)(B) and (i)(C) above, the "Accelerated Purchase Termination Time"), and (ii) the Closing Sale Price of the Common Stock on such applicable Accelerated Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(e) "Accelerated Purchase Share Amount" means, with respect to an Accelerated Purchase made pursuant to Section 2(c) hereof, the number of Purchase Shares directed by the Company to be purchased by the Investor in an Accelerated Purchase Notice, which number of Purchase Shares shall not exceed the lesser of (i) 300% of the number of Purchase Shares directed by the Company to be purchased by the Investor pursuant to the corresponding Regular Purchase Notice for the corresponding Regular Purchase referred to in clause (i) of the second sentence of Section 2(c) hereof (subject to the Purchase Share limitations contained in Section 2(b) hereof) and (ii) an amount equal to (A) the Accelerated Purchase Share Percentage multiplied by (B) the total number (or volume) of shares of Common Stock traded on the Principal Market during the period on the applicable Accelerated Purchase Date beginning at the Accelerated Purchase Commencement Time for such Accelerated Purchase and ending at the Accelerated Purchase Termination Time for such Accelerated Purchase.

(f) "Accelerated Purchase Share Percentage" means, with respect to an Accelerated Purchase made pursuant to Section 2(c) hereof, thirty percent (30%).

(g) "Accelerated Purchase Share Volume Maximum" means, with respect to an Accelerated Purchase made pursuant to Section 2(c) hereof, a number of shares of Common Stock equal to (i) the number of Purchase Shares specified by the Company in the applicable Accelerated Purchase Notice as the Accelerated Purchase Share Amount to be purchased by the Investor in such Accelerated Purchase, divided by (ii) the Accelerated Purchase Share Percentage (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(h) "Additional Accelerated Purchase Date" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, the Business Day (i) that is the Accelerated Purchase Date with respect to the corresponding Accelerated Purchase referred to in clause (i) of the proviso in the second sentence of Section 2(d) hereof and (ii) on which the Investor receives, prior to 1:00 p.m., Eastern time, on such Business Day, a valid Additional Accelerated Purchase Notice for such Additional Accelerated Purchase in accordance with this Agreement.

(i) "Additional Accelerated Purchase Minimum Price Threshold" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, the greater of (i) seventy-five percent (75%) of the Closing Sale Price of the Common Stock on the Business Day immediately preceding the applicable Additional Accelerated Purchase Date with respect to such Additional Accelerated Purchase and (ii) the minimum per share price threshold set forth in the applicable Additional Accelerated Purchase Notice.

(j) "Additional Accelerated Purchase Notice" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, an irrevocable written notice from the Company to the Investor directing the Investor to purchase the number of Purchase Shares specified by the Company therein as the Additional Accelerated Purchase Share Amount to be purchased by the Investor (such specified Additional Accelerated Purchase Share Amount subject to adjustment in accordance with Section 2(d) hereof as necessary to give effect to the Purchase Share amount limitations applicable to such Additional Accelerated Purchase Share Amount as set forth in this Agreement) at the applicable Additional Accelerated Purchase Price on the applicable Additional Accelerated Purchase Date for such Additional Accelerated Purchase.

(k) "Additional Accelerated Purchase Price" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, ninety-seven percent (97%) of the lower of (i) the VWAP for the period on the applicable Additional Accelerated Purchase Date, beginning at the latest of (A) the applicable Accelerated Purchase Termination Time with respect to the corresponding Accelerated Purchase referred to in clause (i) of the proviso in the second sentence of Section 2(d) hereof on such Additional Accelerated Purchase Date, (B) the applicable Additional Accelerated Purchase Termination Time with respect to the most recently completed prior Additional Accelerated Purchase on such Additional Accelerated Purchase Date, as applicable, and (C) the time at which all Purchase Shares subject to all prior Accelerated Purchases and Additional Accelerated Purchases (as applicable), including, without limitation, those that have been effected on the same Business Day as the applicable Additional Accelerated Purchase Date with respect to which the applicable Additional Accelerated Purchase relates, have theretofore been received by the Investor as DWAC Shares in accordance with this Agreement (such latest of (i)(A), (i)(B) and (i)(C) above, the "Additional Accelerated Purchase Commencement Time"), and ending at the earliest of (X) 4:00 p.m., Eastern time, on such Additional Accelerated Purchase Date, or such other time publicly announced by the Principal Market as the official close of trading on the Principal Market on such Additional Accelerated Purchase Date, (Y) such time, from and after the Additional Accelerated Purchase Commencement Time for such Additional Accelerated Purchase, that total number (or volume) of shares of Common Stock traded on the Principal Market has exceeded the applicable Additional Accelerated Purchase Share Volume Maximum, and (Z) such time, from and after the Additional Accelerated Purchase Commencement Time for such Additional Accelerated Purchase, that the Sale Price has fallen below the applicable Additional Accelerated Purchase Minimum Price Threshold (such earliest of (i)(X), (i)(Y) and (i)(Z) above, the "Additional Accelerated Purchase Termination Time"), and (ii) the Closing Sale Price of the Common Stock on such Additional Accelerated Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(l) "Additional Accelerated Purchase Share Amount" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, the number of Purchase Shares directed by the Company to be purchased by the Investor on an Additional Accelerated Purchase Notice, which number of Purchase Shares shall not exceed the lesser of (i) 300% of the number of Purchase Shares directed by the Company to be purchased by the Investor pursuant to the corresponding Regular Purchase Notice for the corresponding Regular Purchase referred to in clause (i) of the proviso in the second sentence of Section 2(d) hereof (subject to the Purchase Share limitations contained in Section 2(b) hereof) and (ii) an amount equal to (A) the Additional Accelerated Purchase Share Percentage multiplied by (B) the total number (or volume) of shares of Common Stock traded on the Principal Market during the period on the applicable Additional Accelerated Purchase Date beginning at the Additional Accelerated Purchase Commencement Time for such Additional Accelerated Purchase and ending at the Additional Accelerated Purchase Termination Time for such Additional Accelerated Purchase.

(m) "Additional Accelerated Purchase Share Percentage" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, thirty percent (30%).

(n) "Additional Accelerated Purchase Share Volume Maximum" means, with respect to an Additional Accelerated Purchase made pursuant to Section 2(d) hereof, a number of shares of Common Stock equal to (i) the number of Purchase Shares specified by the Company in the applicable Additional Accelerated Purchase Notice as the Additional Accelerated Purchase Share Amount to be purchased by the Investor in such Additional Accelerated Purchase, divided by (ii) the Additional Accelerated Purchase Share Percentage (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(o) "Alternate Adjusted Regular Purchase Share Limit" means, with respect to a Regular Purchase made pursuant to Section 2(b) hereof, the maximum number of Purchase Shares which, taking into account the applicable per share Purchase Price therefor calculated in accordance with this Agreement, would enable the Company to deliver to the Investor, on the applicable Purchase Date for such Regular Purchase, a Regular Purchase Notice for a Purchase Amount equal to, or as closely approximating without exceeding, Two Hundred Thousand Dollars ($200,000).

(p) "Available Amount" means, initially, Twenty-Six Million Dollars ($26,000,000) in the aggregate, which amount shall be reduced by the Purchase Amount each time the Investor purchases Purchase Shares pursuant to Section 2 hereof.

(q) "Average Price" means a price per Purchase Share (rounded to the nearest tenth of a cent) equal to the quotient obtained by dividing (i) the aggregate gross purchase price paid by the Investor for all Purchase Shares purchased pursuant to this Agreement, by (ii) the aggregate number of Purchase Shares issued pursuant to this Agreement.

(r) "Bankruptcy Law" means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors.

(s) "Base Price" means a price per Purchase Share equal to the sum of (i) the Signing Market Price and (ii) $0.1025 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction that occurs on or after the date of this Agreement).

(t) "Business Day" means any day on which the Principal Market is open for trading, including any day on which the Principal Market is open for trading for a period of time less than the customary time.

(u) "Closing Sale Price" means, for any security as of any date, the last closing sale price for such security on the Principal Market as reported by the Principal Market.

(v) "Confidential Information" means any information disclosed by either party to the other party, either directly or indirectly, in writing, orally or by inspection of tangible objects (including, without limitation, documents, prototypes, samples, plant and equipment), which is designated as "Confidential," "Proprietary" or some similar designation. Information communicated orally shall be considered Confidential Information if such information is confirmed in writing as being Confidential Information within ten (10) Business Days after the initial disclosure. Confidential Information may also include information disclosed to a disclosing party by third parties. Confidential Information shall not, however, include any information which (i) was publicly known and made generally available in the public domain prior to the time of disclosure by the disclosing party; (ii) becomes publicly known and made generally available after disclosure by the disclosing party to the receiving party through no action or inaction of the receiving party; (iii) is already in the possession of the receiving party without confidential restriction at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately prior to the time of disclosure; (iv) is obtained by the receiving party from a third party without a breach of such third party's obligations of confidentiality; (v) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as shown by documents and other competent evidence in the receiving party's possession; or (vi) is required by law to be disclosed by the receiving party, provided that the receiving party gives the disclosing party prompt written notice of such requirement prior to such disclosure and assistance in obtaining an order protecting the information from public disclosure.

(w) "Custodian" means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

(x) "DTC" means The Depository Trust Company, or any successor performing substantially the same function for the Company.

(y) "DWAC Shares" means shares of Common Stock that are (i) issued in electronic form, (ii) freely tradable and transferable and without restriction on resale and (iii) timely credited by the Company to the Investor's or its designee's specified Deposit/Withdrawal at Custodian (DWAC) account with DTC under its Fast Automated Securities Transfer (FAST) Program, or any similar program hereafter adopted by DTC performing substantially the same function.

(z) "Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(aa) "Floor Price" means, with respect to a Regular Purchase made pursuant to Section 2(b) hereof, $0.10, which shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, share split, reverse share split or other similar transaction and, effective upon the consummation of any such reorganization, recapitalization, non-cash dividend, share split, reverse share split or other similar transaction, the Floor Price shall mean the lower of (i) the adjusted price and (ii) $0.10.

(bb) "Fully Adjusted Regular Purchase Share Limit" means, with respect to any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction from and after the date of this Agreement, the Regular Purchase Share Limit (as defined in Section 2(b) hereof) in effect on the applicable date of determination, after giving effect to the full proportionate adjustment thereto made pursuant to Section 2(b) hereof for or in respect of such reorganization, recapitalization, non-cash dividend, stock split or other similar transaction.

(cc) "Initial Purchase Notice" means, with respect to the Initial Purchase pursuant to Section 2(a) hereof, an irrevocable written notice delivered by the Company to the Investor promptly following the Commencement on the Commencement Date, so that it is received by the Investor not later than 4:15 p.m., Eastern time, on the Commencement Date (confirmation of which shall be provided by the Investor to the Company promptly upon such receipt), directing the Investor to buy the Initial Purchase Shares at the Initial Purchase Price, calculated in accordance with this Agreement and specified by the Company therein, on the Commencement Date.

(dd) "Initial Purchase Price" means, with respect to the Initial Purchase made pursuant to Section 2(a) hereof, the lower of: (i) the Closing Sale Price for the Common Stock on the Business Day immediately preceding the Commencement Date and (ii) the arithmetic average of the ten (10) Closing Sale Prices for the Common Stock during the ten (10) consecutive Business Day-period ending on the Business Day immediately preceding the Commencement Date (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of this Agreement).

(ee) "Initial Purchase Shares" means, with respect to the Initial Purchase made pursuant to Section 2(a) hereof, the number of Purchase Shares (rounded to the nearest whole share) directed by the Company to be purchased by the Investor in the Initial Purchase Notice, which number of Purchase Shares shall be equal to the quotient obtained by dividing (i) $1,000,000 by (ii) the Initial Purchase Price (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of this Agreement).

(ff) "Material Adverse Effect" means any material adverse effect on (i) the enforceability of any Transaction Document, (ii) the results of operations, assets, business or financial condition of the Company and its Subsidiaries, taken as a whole, other than any material adverse effect that resulted exclusively from (A) any change in the United States or foreign economies or securities or financial markets in general that does not have a disproportionate effect on the Company and its Subsidiaries, taken as a whole, (B) any change that generally affects the industry in which the Company and its Subsidiaries operate that does not have a disproportionate effect on the Company and its Subsidiaries, taken as a whole, (C) any change arising in connection with earthquakes, hostilities, acts of war, sabotage or terrorism or military actions or any escalation or material worsening of any such hostilities, acts of war, sabotage or terrorism or military actions existing as of the date hereof, (D) any action taken by the Investor, its affiliates or its or their successors and assigns with respect to the transactions contemplated by this Agreement, (E) the effect of any change in applicable laws or accounting rules that does not have a disproportionate effect on the Company and its Subsidiaries, taken as a whole, or (F) any change resulting from compliance with terms of this Agreement or the consummation of the transactions contemplated by this Agreement, or (iii) the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document to be performed as of the date of determination.

(gg) "Maturity Date" means the first day of the month immediately following the thirty-six (36) month anniversary of the Commencement Date.

(hh) "PEA Period" means the period commencing at 9:30 a.m., Eastern time, on the fifth (5^{th}) Business Day immediately prior to the filing of any post-effective amendment to the Registration Statement (as defined herein) or New Registration Statement (as such term is defined in the Registration Rights Agreement), and ending at 9:30 a.m., Eastern time, on the Business Day immediately following, the effective date of any post-effective amendment to the Registration Statement (as defined herein) or New Registration Statement (as such term is defined in the Registration Rights Agreement).

(ii) "Person" means an individual or entity including but not limited to any limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

(jj) "Principal Market" means The Nasdaq Capital Market (or any nationally recognized successor thereto); provided, however, that in the event the Common Stock is ever listed or traded on The Nasdaq Global Market, The Nasdaq Global Select Market, the New York Stock Exchange, the NYSE American, the NYSE Arca, or the OTCQB or the OTCQX operated by OTC Markets Group, Inc. (or any nationally recognized successor to any of the foregoing), then the "Principal Market" shall mean such other market or exchange on which the Common Stock is then listed or traded.

(kk) "Purchase Amount" means, with respect to the Initial Purchase, any Regular Purchase, any Accelerated Purchase or any Additional Accelerated Purchase made hereunder, as applicable, the portion of the Available Amount to be purchased by the Investor pursuant to Section 2 hereof.

(ll) "Purchase Date" means, with respect to a Regular Purchase made pursuant to Section 2(b) hereof, the Business Day on which the Investor receives, after 4:00 p.m., Eastern time, but prior to 6:00 p.m., Eastern time, on such Business Day, a valid Regular Purchase Notice for such Regular Purchase in accordance with this Agreement.

(mm) "Purchase Price" means, with respect to any Regular Purchase made pursuant to Section 2(b) hereof, the lower of: (i) the lowest Sale Price on the applicable Purchase Date for such Regular Purchase and (ii) the arithmetic average of the three (3) lowest Closing Sale Prices for the Common Stock during the ten (10) consecutive Business Days ending on the Business Day immediately preceding such Purchase Date for such Regular Purchase (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of this Agreement).

(nn) "Regular Purchase Notice" means, with respect to any Regular Purchase pursuant to Section 2(b) hereof, an irrevocable written notice from the Company to the Investor directing the Investor to buy such applicable amount of Purchase Shares at the applicable Purchase Price as specified by the Company therein on the applicable Purchase Date for such Regular Purchase.

(oo) "Sale Price" means any trade price for the shares of Common Stock on the Principal Market as reported by the Principal Market.

(pp) "SEC" means the U.S. Securities and Exchange Commission.

(qq) "Securities" means, collectively, the Purchase Shares and the Commitment Shares.

(rr) "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

(ss) "Signing Market Price" means $0.72, representing the official closing price of the Common Stock on The Nasdaq Capital Market (as reflected on Nasdaq.com) on the trading day immediately preceding the date of this Agreement.

(tt) "Subsidiary" means any Person the Company wholly-owns or controls, or in which the Company, directly or indirectly, owns a majority of the voting stock or similar voting interest, in each case that would be disclosable pursuant to Item 601(b)(21) of Regulation S-K promulgated under the Securities Act.

(uu) "Transaction Documents" means, collectively, this Agreement and the schedules and exhibits hereto, the Registration Rights Agreement and the schedules and exhibits thereto, and each of the other agreements, documents, certificates and instruments entered into or furnished by the parties hereto in connection with the transactions contemplated hereby and thereby.

(vv) "Transfer Agent" means American Stock Transfer & Trust Company, LLC, or such other Person who is then serving as the transfer agent for the Company in respect of the Common Stock.

(ww) "VWAP" means in respect of an Accelerated Purchase Date and an Additional Accelerated Purchase Date, as applicable, the volume weighted average price of the Common Stock on the Principal Market, as reported on the Principal Market or by another reputable source such as Bloomberg, L.P.

2. PURCHASE OF COMMON STOCK.

Subject to the terms and conditions set forth in this Agreement, the Company has the right to sell to the Investor, and the Investor has the obligation to purchase from the Company, Purchase Shares as follows:

(a) Initial Purchase. Upon the satisfaction of all of the conditions set forth in Sections 7 and 8 hereof (the "Commencement" and the date of satisfaction of such conditions the "Commencement Date"), the Company shall have the right, but not the obligation, to direct the Investor, by the Company's delivery of the Initial Purchase Notice to the Investor promptly following the Commencement on the Commencement Date, so that it is received by the Investor not later than 4:15 p.m., Eastern time, on the Commencement Date (confirmation of which shall be provided by the Investor to the Company promptly upon such receipt), and the Investor thereupon shall have the obligation to subscribe for and purchase the Initial Purchase Shares at the Initial Purchase Price on the Commencement Date (the "Initial Purchase") with the settlement of such Initial Purchase to occur in accordance with the procedures set forth in this Agreement provided, however, that the Investor's maximum committed obligation under the Initial Purchase shall not exceed One Million Dollars ($1,000,000). If the Company delivers the Initial Purchase Notice directing the Investor to purchase in the Initial Purchase an amount of Initial Purchase Shares in excess of the limitations contained in the definition of Initial Purchase Shares and in this Section 2(a), such Initial Purchase Notice shall be void *ab initio* to the extent of the amount by which the number of Initial Purchase Shares set forth in such Initial Purchase Notice exceeds the number of Initial Purchase Shares which the Company is permitted to include in such Initial Purchase Notice in accordance herewith, and the Investor shall have no obligation to purchase such excess Purchase Shares in respect of such Initial Purchase Notice; provided that the Investor shall remain obligated to purchase the number of Initial Purchase Shares which the Company is permitted to include in such Initial Purchase Notice.

(b) Commencement of Regular Purchases. Subject to the terms and conditions of this Agreement, from and after the first (1^{st}) Business Day next following the Commencement Date, the Company shall have the right, but not the obligation, to direct the Investor, by its delivery to the Investor of a Regular Purchase Notice from time to time, to purchase up to One Hundred Twenty-Five Thousand (125,000) Purchase Shares, subject to adjustment as set forth below in this Section 2(b) (such maximum number of Purchase Shares, as may be adjusted from time to time, the "Regular Purchase Share Limit"), at the Purchase Price on the Purchase Date (each such purchase a "Regular Purchase"); provided, however, that (i) the Regular Purchase Share Limit shall be increased to One Hundred Fifty Thousand (150,000) Purchase Shares, if the Closing Sale Price of the Common Stock on the applicable Purchase Date is not below $2.00, and (ii) the Regular Purchase Share Limit shall be increased to One Hundred Seventy-Five Thousand (175,000) Purchase Shares, if the Closing Sale Price of the Common Stock on the applicable Purchase Date is not below $4.00 (all of which share and dollar amounts shall be appropriately proportionately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction; provided that if,

after giving effect to the full proportionate adjustment to the Regular Purchase Share Limit therefor, the Fully Adjusted Regular Purchase Share Limit then in effect would preclude the Company from delivering to the Investor a Regular Purchase Notice hereunder for a Purchase Amount (calculated by multiplying (X) the number of Purchase Shares equal to the Fully Adjusted Regular Purchase Share Limit, by (Y) the Purchase Price per Purchase Share covered by such Regular Purchase Notice on the applicable Purchase Date therefor) equal to or greater than Two Hundred Thousand Dollars ($200,000), the Regular Purchase Share Limit for such Regular Purchase Notice shall not be fully adjusted to equal the applicable Fully Adjusted Regular Purchase Share Limit, but rather the Regular Purchase Share Limit for such Regular Purchase Notice shall be adjusted to equal the applicable Alternate Adjusted Regular Purchase Share Limit as of the applicable Purchase Date for such Regular Purchase Notice); and provided, further, however, that the Investor's committed obligation under any single Regular Purchase, other than any Regular Purchase with respect to which an Alternate Adjusted Regular Purchase Share Limit shall apply, shall not exceed One Million Dollars ($1,000,000). If the Company delivers any Regular Purchase Notice for a Purchase Amount in excess of the limitations contained in the immediately preceding sentence, such Regular Purchase Notice shall be void *ab initio* to the extent of the amount by which the number of Purchase Shares set forth in such Regular Purchase Notice exceeds the number of Purchase Shares which the Company is permitted to include in such Regular Purchase Notice in accordance herewith, and the Investor shall have no obligation to purchase such excess Purchase Shares in respect of such Regular Purchase Notice; provided, however, that the Investor shall remain obligated to purchase the number of Purchase Shares which the Company is permitted to include in such Regular Purchase Notice. The Company may deliver a Regular Purchase Notice to the Investor as often as every Business Day, so long as (i) the Closing Sale Price of the Common Stock on such Business Day is not less than the Floor Price and (ii) all Purchase Shares subject to all prior Regular Purchases have theretofore been received by the Investor as DWAC Shares in accordance with this Agreement. Notwithstanding the foregoing, the Company shall not deliver any Regular Purchase Notices to the Investor during the PEA Period.

(c) Accelerated Purchases. Subject to the terms and conditions of this Agreement, from and after the first (1st) Business Day next following the Commencement Date, in addition to purchases of Purchase Shares as described in Section 2(b) above, the Company shall also have the right, but not the obligation, to direct the Investor, by its delivery to the Investor of an Accelerated Purchase Notice from time to time in accordance with this Agreement, to purchase the applicable Accelerated Purchase Share Amount at the Accelerated Purchase Price on the Accelerated Purchase Date therefor in accordance with this Agreement (each such purchase, an "Accelerated Purchase"). The Company may deliver an Accelerated Purchase Notice to the Investor only (i) on a Purchase Date on which the Company also properly submitted a Regular Purchase Notice providing for a Regular Purchase of a number of Purchase Shares not less than the Regular Purchase Share Limit then in effect on such Purchase Date in accordance with this Agreement (including, without limitation, giving effect to any automatic increase to the Regular Purchase Share Limit as a result of the Closing Sale Price of the Common Stock exceeding certain thresholds set forth in Section 2(b) above on such Purchase Date and any other adjustments to the Regular Purchase Share Limit, in each case pursuant to Section 2(b) above) and (ii) if all Purchase Shares subject to all Regular Purchases, Accelerated Purchases and Additional Accelerated Purchases prior to the Purchase Date referred to in clause (i) hereof (as applicable) have theretofore been received by the Investor as DWAC Shares in accordance with this Agreement. If the Company delivers any Accelerated Purchase Notice directing the Investor to purchase an amount of Purchase Shares that exceeds the Accelerated Purchase Share Amount that the Company is then permitted to include in such Accelerated Purchase Notice, such Accelerated Purchase Notice shall be void *ab initio* to the extent of the amount by which the number of Purchase Shares set forth in such Accelerated Purchase Notice exceeds the Accelerated Purchase Share Amount that the Company is then permitted to include in such Accelerated Purchase Notice (which shall be confirmed in an Accelerated Purchase Confirmation), and the Investor shall have no obligation to purchase such excess Purchase Shares in respect of such Accelerated Purchase Notice; provided, however, that the Investor shall remain obligated to purchase the Accelerated Purchase Share Amount which the Company is permitted to include in such

Accelerated Purchase Notice. Within one (1) Business Day after completion of each Accelerated Purchase Date for an Accelerated Purchase, the Investor will provide to the Company a written confirmation of such Accelerated Purchase setting forth the applicable Accelerated Purchase Share Amount and Accelerated Purchase Price for such Accelerated Purchase (each, an "Accelerated Purchase Confirmation"). Notwithstanding the foregoing, the Company shall not deliver any Accelerated Purchase Notices to the Investor during the PEA Period.

(d) Additional Accelerated Purchases. Subject to the terms and conditions of this Agreement, from and after the first (1st) Business Day next following the Commencement Date, in addition to purchases of Purchase Shares as described in Section 2(b) and Section 2(c) above, the Company shall also have the right, but not the obligation, to direct the Investor, by its timely delivery to the Investor of an Additional Accelerated Purchase Notice on an Additional Accelerated Purchase Date in accordance with this Agreement, to purchase the applicable Additional Accelerated Purchase Share Amount at the applicable Additional Accelerated Purchase Price therefor in accordance with this Agreement (each such purchase, an "Additional Accelerated Purchase"). The Company may deliver multiple Additional Accelerated Purchase Notices to the Investor on an Additional Accelerated Purchase Date; provided, however, that the Company may deliver an Additional Accelerated Purchase Notice to the Investor only (i) on a Business Day that is also the Accelerated Purchase Date for an Accelerated Purchase with respect to which the Company properly submitted to the Investor an Accelerated Purchase Notice in accordance with this Agreement on the applicable Purchase Date for a Regular Purchase of a number of Purchase Shares not less than the Regular Purchase Share Limit then in effect in accordance with this Agreement (including, without limitation, giving effect to any automatic increase to the Regular Purchase Share Limit as a result of the Closing Sale Price of the Common Stock exceeding certain thresholds set forth in Section 2(b) above on such Purchase Date and any other adjustments to the Regular Purchase Share Limit, in each case pursuant to Section 2(b) above), and (ii) if all Purchase Shares subject to all prior Regular Purchases, Accelerated Purchases and Additional Accelerated Purchases, including, without limitation, those that have been effected on the same Business Day as the applicable Additional Accelerated Purchase Date with respect to which the applicable Additional Accelerated Purchase relates, in each case have theretofore been received by the Investor as DWAC Shares in accordance with this Agreement. If the Company delivers any Additional Accelerated Purchase Notice directing the Investor to purchase an amount of Purchase Shares that exceeds the Additional Accelerated Purchase Share Amount that the Company is then permitted to include in such Additional Accelerated Purchase Notice, such Additional Accelerated Purchase Notice shall be void *ab initio* to the extent of the amount by which the number of Purchase Shares set forth in such Additional Accelerated Purchase Notice exceeds the Additional Accelerated Purchase Share Amount that the Company is then permitted to include in such Additional Accelerated Purchase Notice (which shall be confirmed in an Additional Accelerated Purchase Confirmation), and the Investor shall have no obligation to purchase such excess Purchase Shares in respect of such Additional Accelerated Purchase Notice; provided, however, that the Investor shall remain obligated to purchase the Additional Accelerated Purchase Share Amount which the Company is permitted to include in such Additional Accelerated Purchase Notice. Within one (1) Business Day after completion of each Additional Accelerated Purchase Date, the Investor will provide to the Company a written confirmation of each Additional Accelerated Purchase on such Additional Accelerated Purchase Date setting forth the applicable Additional Accelerated Purchase Share Amount and Additional Accelerated Purchase Price for each such Additional Accelerated Purchase on such Additional Accelerated Purchase Date (each, an "Additional Accelerated Purchase Confirmation"). Notwithstanding the foregoing, the Company shall not deliver any Additional Accelerated Purchase Notices to the Investor during the PEA Period.

(e) Payment for Purchase Shares. For the Initial Purchase and for each Regular Purchase, the Investor shall pay to the Company an amount equal to the Purchase Amount with respect to such Initial Purchase and such Regular Purchase, respectively, as full payment for such Purchase Shares via wire transfer of immediately available funds on the same Business Day that the Investor receives such Purchase

Shares, if such Purchase Shares are received by the Investor before 1:00 p.m., Eastern time, or, if such Purchase Shares are received by the Investor after 1:00 p.m., Eastern time, the next Business Day. For each Accelerated Purchase and each Additional Accelerated Purchase, the Investor shall pay to the Company an amount equal to the Purchase Amount with respect to such Accelerated Purchase and Additional Accelerated Purchase, respectively, as full payment for such Purchase Shares via wire transfer of immediately available funds on the second Business Day following the date that the Investor receives such Purchase Shares. If the Company or the Transfer Agent shall fail for any reason or for no reason to electronically transfer any Purchase Shares as DWAC Shares in respect of the Initial Purchase, a Regular Purchase, an Accelerated Purchase or an Additional Accelerated Purchase (as applicable) within two (2) Business Days following the receipt by the Company of the Initial Purchase Price, the Purchase Price, the Accelerated Purchase Price and the Additional Accelerated Purchase Price, respectively, therefor in compliance with this Section 2(e), and if on or after such Business Day the Investor purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Investor of such Purchase Shares that the Investor anticipated receiving from the Company in respect of the Initial Purchase, such Regular Purchase, such Accelerated Purchase or such Additional Accelerated Purchase (as applicable), then the Company shall, within two (2) Business Days after the Investor's request, either (i) pay cash to the Investor in an amount equal to the Investor's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "Cover Price"), at which point the Company's obligation to deliver such Purchase Shares as DWAC Shares shall terminate, or (ii) promptly honor its obligation to deliver to the Investor such Purchase Shares as DWAC Shares and pay cash to the Investor in an amount equal to the excess (if any) of the Cover Price over the total Purchase Amount paid by the Investor pursuant to this Agreement for all of the Purchase Shares to be purchased by the Investor in connection with the Initial Purchase, such Regular Purchase, such Accelerated Purchase and such Additional Accelerated Purchase (as applicable). The Company shall not issue any fraction of a share of Common Stock upon the Initial Purchase, any Regular Purchase, any Accelerated Purchase or any Additional Accelerated Purchase. If the issuance would result in the issuance of a fraction of a share of Common Stock, the Company shall round such fraction of a share of Common Stock up or down to the nearest whole share. All payments made under this Agreement shall be made in lawful currency of the United States of America by wire transfer of immediately available funds to such account as the Company (or the Investor, as applicable) may from time to time designate by written notice in accordance with the provisions of this Agreement. Whenever any amount expressed to be due by the terms of this Agreement is due on any day that is not a Business Day, the same shall instead be due on the next succeeding day that is a Business Day.

(f) Compliance with Rules of Principal Market.

(i) Exchange Cap. Subject to Section 2(f)(ii) below, the Company shall not issue or sell any shares of Common Stock pursuant to this Agreement, and the Investor shall not purchase or acquire any shares of Common Stock pursuant to this Agreement, to the extent that after giving effect thereto, the aggregate number of shares of Common Stock that would be issued pursuant to this Agreement and the transactions contemplated hereby would exceed 4,809,486 (such number of shares equal to 19.99% of the shares of Common Stock issued and outstanding immediately prior to the execution of this Agreement), which number of shares shall be (i) reduced, on a share-for-share basis, by the number of shares of Common Stock issued or issuable pursuant to any transaction or series of transactions that may be aggregated with the transactions contemplated by this Agreement under applicable rules of The Nasdaq Stock Market and (ii) appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs after the date of this Agreement (such maximum number of shares, the "Exchange Cap"), unless and until the Company elects to solicit stockholder approval of the issuance of Common Stock as contemplated by this Agreement, and the stockholders of the Company have in fact approved the issuance of Common Stock as contemplated by this Agreement in accordance with the applicable rules of The Nasdaq Stock Market. For the avoidance of doubt, the Company may, but shall be

under no obligation to, request its stockholders to approve the issuance of Common Stock as contemplated by this Agreement; provided, that if stockholder approval is not obtained in accordance with this Section 2(f)(i), the Exchange Cap shall be applicable for all purposes of this Agreement and the transactions contemplated hereby at all times during the term of this Agreement (except as set forth in Section 2(f)(ii) below).

(ii) At-Market Transaction. Notwithstanding Section 2(f)(i) above, the Exchange Cap shall not be applicable for any purposes of this Agreement and the transactions contemplated hereby, solely to the extent that (and only for so long as) the Average Price shall equal or exceed the Base Price (it being hereby acknowledged and agreed that the Exchange Cap shall be applicable for all purposes of this Agreement and the transactions contemplated hereby at all other times during the term of this Agreement, unless the stockholder approval referred to in Section 2(f)(i) is obtained). The parties acknowledge and agree that the Signing Market Price used to determine the Base Price hereunder represents the lower of (i) the official closing price of the Common Stock on The Nasdaq Capital Market (as reflected on Nasdaq.com) on the trading day immediately preceding the date of this Agreement and (ii) the average official closing price of the Common Stock on The Nasdaq Capital Market (as reflected on Nasdaq.com) for the five (5) consecutive trading days ending on the trading day immediately preceding the date of this Agreement.

(iii) General. The Company shall not issue any shares of Common Stock pursuant to this Agreement if such issuance would reasonably be expected to result in (A) a violation of the Securities Act or (B) a breach of the rules and regulations of the Principal Market. The provisions of this Section 2(f) shall be implemented in a manner otherwise than in strict conformity with the terms hereof only if necessary to ensure compliance with the Securities Act, the rules and regulations of the Principal Market.

(g) Beneficial Ownership Limitation. Notwithstanding anything to the contrary contained in this Agreement, the Company shall not issue or sell, and the Investor shall not purchase or acquire, any shares of Common Stock under this Agreement which, when aggregated with all other shares of Common Stock then beneficially owned by the Investor and its affiliates (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder), would result in the beneficial ownership by the Investor of more than 9.99% of the then issued and outstanding shares of Common Stock (the "Beneficial Ownership Limitation"). Upon the written or oral request of the Investor, the Company shall promptly (but not later than 24 hours) confirm orally or in writing to the Investor the number of shares of Common Stock then outstanding. The Investor and the Company shall each cooperate in good faith in the determinations required hereby and the application hereof. The Investor's written certification to the Company of the applicability of the Beneficial Ownership Limitation, and the resulting effect thereof hereunder at any time, shall be conclusive with respect to the applicability thereof and such result absent manifest error.

3. INVESTOR'S REPRESENTATIONS AND WARRANTIES.

The Investor represents and warrants to the Company that as of the date hereof and as of the Commencement Date:

(a) Organization and Authority; Investment Purpose. The Investor is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, with the requisite power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder and thereunder. The Investor is acquiring the Securities as principal for its own account and not with a view to or for distributing or reselling such Securities or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Securities in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other Persons to distribute or regarding the distribution of such Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting the Investor's right to sell the Securities at any time pursuant to the Registration Statement described herein or otherwise in compliance with applicable federal and state securities laws). The Investor is acquiring the Securities hereunder in the ordinary course of its business.

(b) Accredited Investor Status. The Investor is an "accredited investor" as that term is defined in Rule 501(a)(3) of Regulation D promulgated under the Securities Act.

(c) Reliance on Exemptions. The Investor understands that the Securities are being offered and sold to it in reliance on specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying in part upon the truth and accuracy of, and the Investor's compliance with, the representations, warranties, agreements, acknowledgments and understandings of the Investor set forth herein in order to determine the availability of such exemptions and the eligibility of the Investor to acquire the Securities.

(d) Information. The Investor understands that its investment in the Securities involves a high degree of risk. The Investor (i) is able to bear the economic risk of an investment in the Securities including a total loss thereof, (ii) has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the proposed investment in the Securities and (iii) has had an opportunity to ask questions of and receive answers from the officers of the Company concerning the financial condition and business of the Company and other matters related to an investment in the Securities. Neither such inquiries nor any other due diligence investigations conducted by the Investor or its representatives shall modify, amend or affect the Investor's right to rely on the Company's representations and warranties contained in Section 4 below. The Investor has sought such accounting, legal and tax advice from its own independent advisors as it has considered necessary to make an informed investment decision with respect to its acquisition of the Securities.

(e) No Governmental Review. The Investor understands that no U.S. federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Securities or the fairness or suitability of an investment in the Securities nor have such authorities passed upon or endorsed the merits of the offering of the Securities.

(f) Transfer or Sale. The Investor understands that (i) the Securities may not be offered for sale, sold, assigned or transferred unless (A) registered pursuant to the Securities Act or (B) an exemption exists permitting such Securities to be sold, assigned or transferred without such registration; (ii) any sale of the Securities made in reliance on Rule 144 promulgated under the Securities Act may be made only in accordance with the terms of Rule 144 and further, if Rule 144 is not applicable, any resale of the Securities under circumstances in which the seller (or the Person through whom the sale is made) may be deemed to be an underwriter (as that term is defined in the Securities Act) may require compliance with some other exemption under the Securities Act or the rules and regulations of the SEC thereunder.

(g) Validity; Enforcement. This Agreement has been duly and validly authorized, executed and delivered on behalf of the Investor and is a valid and binding agreement of the Investor enforceable against the Investor in accordance with its terms, subject as to enforceability to general principles of equity and to applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies.

(h) Residency. The Investor is a resident of the State of Illinois.

(i) No Short Selling. The Investor represents and warrants to the Company that at no time prior to the date of this Agreement has any of the Investor, its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any (i) "short sale" (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

4. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

The Company represents and warrants to the Investor that, except as set forth in the disclosure schedules attached hereto, which exceptions shall be deemed to be a part of the representations and warranties made hereunder, as of the date hereof and as of the Commencement Date:

(a) Organization and Qualification. The Company and each of its Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite corporate power and authority to own and use its properties and assets and to carry on its business as currently conducted. Each of the Company and its Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in a Material Adverse Effect and no proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification. The Company has no Subsidiaries except as set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

(b) Authorization; Enforcement; Validity. (i) The Company has the requisite corporate power and authority to enter into and perform its obligations under this Agreement, the Registration Rights Agreement and each of the other Transaction Documents, and to issue the Securities in accordance with the terms hereof and thereof, (ii) the execution and delivery of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby, including without limitation, the issuance of the Commitment Shares (as defined below in Section 5(e)) and the reservation for issuance and the issuance of the Purchase Shares issuable under this Agreement, have been duly authorized by the Company's Board of Directors and no further consent or authorization is required by the Company, its Board of Directors or its stockholders (except as provided in this Agreement), (iii) each of this Agreement and the Registration Rights Agreement has been, and each other Transaction Document shall be on the Commencement Date, duly executed and delivered by the Company and (iv) each of this Agreement and the Registration Rights Agreement constitutes, and each other Transaction Document upon its execution on behalf of the Company, shall constitute, the valid and binding obligations of the Company enforceable against the Company in accordance with their terms, except as such enforceability may be limited by general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of creditors' rights and remedies. The Board of Directors of the Company has approved resolutions (the "Signing Resolutions") authorizing this Agreement, the Registration Rights Agreement and the transactions contemplated hereby. The Signing Resolutions are valid, in full force and effect and have not been modified or supplemented in any respect.

The Company has delivered to the Investor a true and correct copy of minutes of a meeting of the Board of Directors of the Company at which the Signing Resolutions were duly adopted by the Board of Directors or a unanimous written consent adopting the Signing Resolutions executed by all of the members of the Board of Directors of the Company. Except as set forth in this Agreement, no other approvals or consents of the Company's Board of Directors, any authorized committee thereof, or stockholders (except as provided in this Agreement) is necessary under applicable laws and the Company's Certificate of Incorporation or Bylaws to authorize the execution and delivery of the Transaction Documents or any of the transactions contemplated thereby, including, but not limited to, the issuance of the Commitment Shares and the issuance and sale of the Purchase Shares.

(c) Capitalization. As of the date hereof, the authorized capital stock of the Company consists of 60,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, par value $0.001 per share. As of May 4, 2023, 24,059,460 shares of Common Stock were issued and outstanding and no shares of such preferred stock were issued and outstanding. Except as disclosed in the SEC Documents (as defined below), (i) no shares of the Company's capital stock are subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company, (ii) there are no outstanding debt securities, (iii) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional shares of capital stock of the Company or any of its Subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, (iv) there are no agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the Securities Act (except the Registration Rights Agreement), (v) there are no outstanding securities or instruments of the Company or any of its Subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries, (vi) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance of the Securities as described in this Agreement and (vii) the Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. The Company has furnished to the Investor true and correct copies of the Company's Amended and Restated Certificate of Incorporation, as amended and as in effect on the date hereof (the "Certificate of Incorporation"), and the Company's Amended and Restated Bylaws, as amended and as in effect on the date hereof (the "Bylaws"), and summaries of the material terms of all securities convertible into or exercisable for Common Stock, if any, and copies of any documents containing the material rights of the holders thereof in respect thereto that are not disclosed in the SEC Documents.

(d) Issuance of Securities. Upon issuance and payment therefor in accordance with the terms and conditions of this Agreement, the Purchase Shares shall be validly issued, fully paid and nonassessable and free from all taxes, liens, charges, restrictions, rights of first refusal and preemptive rights with respect to the issue thereof, with the holders being entitled to all rights accorded to a holder of Common Stock. Upon issuance in accordance with the terms and conditions of this Agreement, the Commitment Shares shall be validly issued, fully paid and nonassessable and free from all taxes, liens, charges, restrictions, rights of first refusal and preemptive rights with respect to the issue thereof, with the holders being entitled to all rights accorded to a holder of Common Stock. 5,000,000 shares of Common Stock have been duly authorized and reserved for issuance upon purchase under this Agreement as Purchase Shares.

(e) No Conflicts. The execution, delivery and performance of the Transaction Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the issuance of the Commitment Shares and the reservation for issuance and

issuance of the Purchase Shares) will not (i) result in a violation of the Certificate of Incorporation, any Certificate of Designations, Preferences and Rights of any outstanding series of preferred stock of the Company or the Bylaws or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any of its Subsidiaries is a party, or result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations, the rules of the Principal Market applicable to the Company or any of its Subsidiaries) or by which any property or asset of the Company or any of its Subsidiaries is bound or affected, except in the case of conflicts, defaults, terminations, amendments, accelerations, cancellations and violations under clause (ii), which would not reasonably be expected to result in a Material Adverse Effect. Neither the Company nor its Subsidiaries is in violation of any term of or in default under its certificate or articles of incorporation, any certificate of designation, preferences and rights of any outstanding series of preferred stock of the Company or bylaws or other organizational documents. Neither the Company nor any of its Subsidiaries is in violation of any term of or is in default under any material contract, agreement, mortgage, indebtedness, indenture, instrument, judgment, decree or order or any statute, rule or regulation applicable to the Company or its Subsidiaries, except for possible conflicts, defaults, terminations or amendments that would not reasonably be expected to have a Material Adverse Effect. The business of the Company and its Subsidiaries is not being conducted, and shall not be conducted, in violation of any law, ordinance or regulation of any governmental entity, except for possible violations, the sanctions for which either individually or in the aggregate would not reasonably be expected to have a Material Adverse Effect. Except as specifically contemplated by this Agreement and as required under the Securities Act or applicable state securities laws and the rules and regulations of the Principal Market, the Company is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency in order for it to execute, deliver or perform any of its obligations under or contemplated by the Transaction Documents in accordance with the terms hereof or thereof. Except as set forth elsewhere in this Agreement and with respect to any Form D notice to be filed under Regulation D promulgated under the Securities Act, all consents, authorizations, orders, filings and registrations which the Company is required to obtain pursuant to the preceding sentence shall be obtained or effected on or prior to the Commencement Date. Except as disclosed in the SEC Documents, since one year prior to the date hereof, the Company has not received nor delivered any notices or correspondence from or to the Principal Market, other than notices with respect to listing of additional shares of Common Stock and other routine correspondence. Except as disclosed in the SEC Documents, the Principal Market has not commenced any delisting proceedings against the Company.

(f) SEC Documents; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the twelve months preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "SEC Documents") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Documents prior to the expiration of any such extension. As of their respective dates, the SEC Documents complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable. None of the SEC Documents, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The consolidated financial statements of the Company included or incorporated by reference in the SEC Documents comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the SEC Documents that are not included or incorporated by reference as required; the Company does not have any material liabilities or obligations, direct or contingent (including any off

balance sheet obligations), not described in the SEC Documents (including the exhibits thereto and documents incorporated by reference thereto), which are required to be described in the SEC Documents (including the exhibits thereto and documents incorporated by reference thereto); and all disclosures contained or incorporated by reference in the SEC Documents, if any, regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the SEC) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable. Such consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such consolidated financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. Except as set forth in the SEC Documents, the Company has received no notices or correspondence from the SEC for the one year preceding the date hereof. The SEC has not commenced any enforcement proceedings against the Company or any of its Subsidiaries.

(g) Absence of Certain Changes. Except as disclosed in the SEC Documents, since December 31, 2021, there has been no material adverse change in the business, properties, operations, financial condition or results of operations of the Company or its Subsidiaries. The Company has not taken any steps, and does not currently expect to take any steps, to seek protection pursuant to any Bankruptcy Law nor does the Company or any of its Subsidiaries have any knowledge or reason to believe that its creditors intend to initiate involuntary bankruptcy or insolvency proceedings. The Company is financially solvent and is generally able to pay its debts as they become due.

(h) Absence of Proceedings. Except as disclosed in the SEC Documents, there is no action, suit, proceeding, inquiry or investigation before or brought by any court or governmental agency or body, domestic or foreign, now pending, or, to the knowledge of the Company, threatened, against or affecting the Company or any Subsidiary, which would reasonably be expected to result in a Material Adverse Effect, or which might materially and adversely affect the consummation of the transactions contemplated in this Agreement or any of the other Transaction Documents or the performance by the Company of its obligations hereunder or thereunder.

(i) Acknowledgment Regarding Investor's Status. The Company acknowledges and agrees that the Investor is acting solely in the capacity of arm's length purchaser with respect to the Transaction Documents and the transactions contemplated hereby and thereby. The Company further acknowledges that the Investor is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated hereby and thereby and any advice given by the Investor or any of its representatives or agents in connection with the Transaction Documents and the transactions contemplated hereby and thereby is merely incidental to the Investor's purchase of the Securities. The Company further represents to the Investor that the Company's decision to enter into the Transaction Documents has been based solely on the independent evaluation by the Company and its representatives and advisors.

(j) No General Solicitation; No Integrated Offering. Neither the Company, nor any of its affiliates, nor any Person acting on its or their behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) in connection with the offer or sale of the Securities. Neither the Company, nor or any of its affiliates, nor any Person acting on their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would require registration of the offer and sale of any of the Securities under the Securities Act, whether through integration with prior offerings or otherwise, or cause this offering of the

Securities to be integrated with prior offerings by the Company in a manner that would require stockholder approval pursuant to the rules of the Principal Market on which any of the securities of the Company are listed or designated. To the Company's knowledge, the issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Principal Market.

(k) Intellectual Property Rights. Except where the failure thereof would not reasonably be expected to result in a Material Adverse Effect, (i) the Company and its Subsidiaries own or possess, or reasonably believe they can acquire on reasonable terms, adequate patents, patent rights, licenses, inventions, copyrights, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names or other intellectual property (collectively, "Intellectual Property") necessary to carry on the business now operated by them, and (ii) neither the Company nor any of its Subsidiaries has received any notice of any infringement of or conflict with asserted rights of others with respect to any Intellectual Property or of any facts or circumstances which would render any Intellectual Property invalid or inadequate to protect the interest of the Company or any of its Subsidiaries therein.

(l) Environmental Laws. Except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect: (A) neither the Company nor any of its Subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws"), (B) the Company and its Subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the Company's knowledge threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its Subsidiaries and (D) there are no events or circumstances of which the Company is aware that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its Subsidiaries relating to Hazardous Materials or any Environmental Laws.

(m) Title. Except where the failure thereof would result in a Material Adverse Effect, to the Company's knowledge, (i) the Company and its Subsidiaries have good and marketable title to all real property owned by the Company and its Subsidiaries and good title to all other properties owned by it that are material to the business of the Company, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as do not, singly or in the aggregate, affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company or any of its Subsidiaries; and (ii) all of the leases and subleases material to the business of the Company and its Subsidiaries, considered as one enterprise, and under which the Company or any of its Subsidiaries holds properties described in the SEC Documents, are in full force and effect, and neither the Company nor any Subsidiary has any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any Subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such Subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease.

(n) Insurance. The Company and its Subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by companies of established repute engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it or any Subsidiary will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Effect. During the prior three year period, neither of the Company nor any Subsidiary has been denied any material insurance coverage which it has sought or for which it has applied.

(o) Possession of Licenses and Permits. The Company and each of its Subsidiaries have made all filings, applications, declarations and submissions required by, and own or possess all approvals, licenses, certificates, clearances, consents, exemptions, marks, notifications, orders, authorizations and permits issued by the appropriate local, state, federal or foreign regulatory agencies or bodies, including all such registrations, approvals, certificates, authorizations and permits required by the United States Food and Drug Administration (the "FDA") which are required for the ownership of their respective properties or the conduct of their current respective businesses as described in the SEC Documents (each, a "Governmental License") except where any failures to possess or any noncompliance would not, singly or in the aggregate, have a Material Adverse Effect and neither the Company nor any of its Subsidiaries has received any notice of any revocation, modification or cancellation of, any such Governmental License, which, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect. Where required by applicable laws and regulations of the FDA, the Company has submitted to the FDA an Investigational New Drug Application or amendment or supplement thereto for each clinical trial it has conducted or sponsored or is conducting or sponsoring, except where such failure would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect; all such submissions were in material compliance with applicable laws and rules and regulations when submitted and no material deficiencies have been asserted by the FDA with respect to any such submissions, except any deficiencies which could not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(p) Tax Status. Except as disclosed in the SEC Documents, the Company and each of its Subsidiaries has made or filed all federal and state income and all other material tax returns, reports and declarations required by any jurisdiction to which it is subject or otherwise filed timely extensions (unless and only to the extent that the Company and each of its Subsidiaries has set aside on its books provisions reasonably adequate for the payment of all unpaid and unreported taxes) and has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith and has set aside on its books provision reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply, and except as would not reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, there are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(q) Transactions With Affiliates. Except as set forth in the SEC Documents, none of the officers or directors of the Company and, to the knowledge of the Company, none of the employees of the Company is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(r) Application of Takeover Protections. The Company and its board of directors have taken or will take prior to the Commencement Date all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar business combination anti-takeover provision under the Certificate of Incorporation or the laws of the state of its incorporation which is or could become applicable to the Investor as a result of the transactions contemplated by this Agreement, including, without limitation, the Company's issuance of the Securities and the Investor's ownership of the Securities.

(s) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents that will be timely publicly disclosed by the Company, the Company confirms that neither it nor any other Person acting on its behalf has provided the Investor or its agents or counsel with any information that it believes constitutes or might constitute material non-public information which is not otherwise disclosed in the Registration Statement or the SEC Documents. The Company understands and confirms that the Investor will rely on the foregoing representation in effecting purchases and sales of securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Investor regarding the Company, its business and the transactions contemplated hereby, including the disclosure schedules to this Agreement, taken as a whole, is true and correct in all material respects and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that the Investor neither makes nor has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3 hereof.

(t) Foreign Corrupt Practices Act. Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its Subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(u) DTC Eligibility. The Company, through the Transfer Agent, currently participates in the DTC Fast Automated Securities Transfer (FAST) Program and the Common Stock can be transferred electronically to third parties via the DTC Fast Automated Securities Transfer (FAST) Program.

(v) Sarbanes-Oxley. The Company is in compliance in all material respects with all provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications. The Company and each of its Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets that could have a material effect on the Company's financial statements is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Since the end of the Company's most recent audited fiscal year, and except as set forth in the SEC Documents, the Company is not aware of any (1) material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company and its consolidated Subsidiaries employ disclosure controls and procedures that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to the Company's management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding disclosure.

(w) Certain Fees. No brokerage or finder's fees or commissions are or will be payable by the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Investor shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section 4(w) that may be due in connection with the transactions contemplated by the Transaction Documents.

(x) Investment Company. The Company is not, and immediately after receipt of payment for the Securities will not be, an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

(y) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock pursuant to the Exchange Act nor has the Company received any notification that the SEC is currently contemplating terminating such registration. As of the date hereof, the issued and outstanding shares of Common Stock are listed and posted for trading on the Principal Market, and the Company is in compliance in all respects with the current listing requirements of the Principal Market. The Securities will be listed and posted for trading on the Principal Market at or prior to Commencement, with respect to the Commitment Shares, and prior to the time of sale to the Investor pursuant to this Agreement, with respect to the Purchase Shares. Except as disclosed in the SEC Documents, the Company has not, in the twelve (12) months preceding the date hereof, received any notice from any Person to the effect that the Company is not in compliance with the listing or maintenance requirements of the Principal Market.

(z) Accountants. The Company's accountants whose report on the consolidated financial statements of the Company is filed with the Company's most recent Annual Report on Form 10-K filed with the SEC, are and, during the periods covered by their report, were independent public accountants within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company's knowledge, following due inquiry, the Company's accountants are not in violation of the auditor independence requirements of the Sarbanes-Oxley Act with respect to the Company.

(aa) No Market Manipulation. The Company has not, and to its knowledge no Person acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

(bb) Shell Company Status. The Company is not currently, and has never been, an issuer identified in Rule 144(i)(1) under the Securities Act.

(cc) Tests and Preclinical and Clinical Studies. The Company has operated and currently is in compliance with the United States Federal Food, Drug, and Cosmetic Act, all applicable rules and regulations of the FDA and other federal, state, local and foreign governmental bodies exercising comparable authority, except where the failure to so operate or be in compliance would not reasonably be expected to have a Material Adverse Effect. The preclinical and clinical studies conducted by or, to the Company's knowledge, on behalf of the Company that are described in the SEC Documents were, and if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company; the descriptions of the tests and preclinical and clinical studies, and results thereof, conducted by or, to the Company's knowledge on the behalf of the Company contained in the SEC Documents are accurate and complete in all material respects; the Company is not aware of any trials or studies not described or referred to in the SEC Documents, the results of which reasonably call into question the results described or referred to in the SEC Documents; the Company is not in receipt of any notices or correspondence from the FDA or any foreign, state or local governmental body exercising comparable authority that reasonably call into question results of the trials or studies described or referred to in the SEC Documents; and the Company has not received any notice or correspondence from the FDA or any foreign, state or local governmental body exercising comparable authority requiring the termination, suspension, or clinical hold of any tests or preclinical or clinical studies, or such notice or correspondence from any Institutional Review Board or comparable authority requiring the termination or suspension of a clinical study, conducted by or on behalf of the Company, which termination, suspension, or clinical hold would reasonably be expected to have a Material Adverse Effect.

(dd) OFAC. Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person whom the Company has knowledge is currently subject to any U.S. sanctions administered by OFAC.

(ee) Money Laundering Laws. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the applicable rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(ff) Statistical and Market-Related Data. Any statistical and market-related data included and incorporated by reference in the SEC Documents are based on or derived from sources that the Company believes to be reliable and accurate, and, where required, the Company's good faith estimates that are made on the basis of such data from such sources.

(gg) Absence of Labor Disputes. Except as would not result in a Material Adverse Effect, no labor dispute with the employees of the Company or any Subsidiary exists or, to the knowledge of the Company, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or any Subsidiary's principal suppliers, manufacturers, customers or contractors.

(hh) Information Technology. The Company's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems") operate and perform in all material respects as required in connection with the operation of the business of the Company as currently conducted. The Company maintains commercially reasonable controls, policies, procedures, and safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and all personal, personally identifiable, sensitive, confidential or regulated data ("Personal Data") processed and stored thereon, and to the knowledge of the Company, there have been no breaches, incidents, violations, outages, compromises or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company is presently in compliance in all material respects with all applicable laws or statutes and all applicable judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification, except for any such noncompliance that would not have a Material Adverse Effect.

(ii) Accuracy of Exhibits. There are no contracts or documents which are required to be described in the SEC Documents or the documents incorporated by reference therein or to be filed as exhibits thereto which have not been so described and filed as required.

(jj) Smaller Reporting Company Status. As of the Closing Date, the Company was, and as of the Commencement Date, the Company believes in good faith that it will be, a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act.

(kk) No Disqualification Events. None of the Company, any of its predecessors, any affiliated issuer, any director, executive officer, other officer of the Company participating in the offering contemplated hereby, any beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an "Issuer Covered Person") is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "Disqualification Event"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3) under the Securities Act. The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event.

5. COVENANTS.

(a) Filing of Current Report and Registration Statement. The Company agrees that it shall, within the time required under the Exchange Act, file with the SEC a report on Form 8-K relating to the transactions contemplated by, and describing the material terms and conditions of, the Transaction Documents (the "Current Report"). The Company shall also file with the SEC, within ten (10) Business Days from the date hereof, a new registration statement (the "Registration Statement") covering only the resale of the Purchase Shares and all of the Commitment Shares, in accordance with the terms of the Registration Rights Agreement between the Company and the Investor, dated as of the date hereof (the "Registration Rights Agreement"). The Company shall permit the Investor to review and comment upon (1) the final pre-filing draft version of the Current Report at least two (2) Business Days prior to its filing with the SEC, and the Company shall give due consideration to all such comments. The Investor shall use its reasonable best efforts to comment upon the Current Report within one (1) Business Day from the date the Investor receives the final versions thereof from the Company. The Investor shall cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of the Current Report with the SEC.

(b) Form D and Blue Sky. The Company agrees to timely file a Form D with respect to the Securities sold, as required under Regulation D. The Company shall take all such action, if any, as is reasonably necessary in order to obtain an exemption for or to register or qualify (i) the issuance of the Commitment Shares and the sale of the Purchase Shares to the Investor under this Agreement and (ii) any subsequent resale of all Commitment Shares and all Purchase Shares by the Investor, in each case, under applicable securities or "Blue Sky" laws of the states of the United States in such states as is reasonably requested by the Investor from time to time, and shall provide evidence of any such action so taken to the Investor.

(c) Listing/DTC. The Company shall promptly secure the listing of all of the Purchase Shares and Commitment Shares to be issued to the Investor hereunder on the Principal Market and upon each other national securities exchange or automated quotation system, if any, upon which the Common Stock is then listed, and shall use commercially reasonable efforts to maintain, so long as any shares of Common Stock shall be so listed, such listing of all such Securities from time to time issuable hereunder. The Company shall use commercially reasonable efforts to maintain the listing of the Common Stock on the Principal Market and shall use commercially reasonable efforts to comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules and regulations of the Principal Market. Neither the Company nor any of its Subsidiaries shall take any action that would reasonably be expected to result in the delisting or suspension of the Common Stock on the Principal Market. The Company shall promptly, and in no event later than the following Business Day, provide to the Investor copies of any notices it receives from any Person regarding the continued eligibility of the Common Stock for listing on the Principal Market; provided, however, that the Company shall not be required to provide the Investor copies of any such notice that the Company reasonably believes constitutes material non-public information and the Company would not be required to publicly disclose such notice in any report or statement filed with the SEC under the Exchange Act or the Securities Act. The Company shall pay all fees and expenses

in connection with satisfying its obligations under this Section 5(c). The Company shall take all action necessary to ensure that its Common Stock can be transferred electronically as DWAC Shares.

(d) Prohibition of Short Sales and Hedging Transactions. The Investor agrees that beginning on the date of this Agreement and ending on the date of termination of this Agreement as provided in Section 11, the Investor and its agents, representatives and affiliates shall not in any manner whatsoever enter into or effect, directly or indirectly, any (i) "short sale" (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

(e) Issuance of Commitment Shares. In consideration for the Investor's execution and delivery of this Agreement, the Company shall cause to be issued to the Investor a total of 599,216 shares of Common Stock (the "Commitment Shares") immediately upon the execution of this Agreement and shall deliver to the Transfer Agent the Irrevocable Transfer Agent Instructions with respect to the issuance of such Commitment Shares. For the avoidance of doubt, all of the Commitment Shares shall be fully earned as of the date of this Agreement, whether or not the Commencement shall occur or any Purchase Shares are purchased by the Investor under this Agreement and irrespective of any subsequent termination of this Agreement.

(f) Due Diligence; Non-Public Information. During the term of this Agreement, the Investor shall have the right, from time to time as the Investor may reasonably deem appropriate and upon reasonable advance notice to the Company to perform reasonable due diligence on the Company during normal business hours. The Company and its officers and employees shall provide information and reasonably cooperate with the Investor in connection with any reasonable request by the Investor related to the Investor's due diligence of the Company. Each party hereto agrees not to disclose any Confidential Information of the other party to any third party and shall not use the Confidential Information for any purpose other than in connection with, or in furtherance of, the transactions contemplated hereby and in full compliance with applicable securities laws. Each party hereto acknowledges that the Confidential Information shall remain the property of the disclosing party and agrees that it shall take all reasonable measures to protect the secrecy of any Confidential Information disclosed by the other party. The Company confirms that neither it nor any other Person acting on its behalf shall provide the Investor or its agents or counsel with any information that constitutes or might constitute material, non-public information, unless a simultaneous public announcement thereof is made by the Company in the manner contemplated by Regulation FD. In the event of a breach of the foregoing covenant by the Company or any Person acting on its behalf (as determined in the reasonable good faith judgment of the Investor), in addition to any other remedy provided herein or in the other Transaction Documents, if the Investor is holding any Securities at the time of the disclosure of material, non-public information, the Investor shall have the right to make a public disclosure, in the form of a press release, public advertisement or otherwise, of such material, non-public information without the prior approval by the Company; provided the Investor shall have first provided notice to the Company that it believes it has received information that constitutes material, non-public information, the Company shall have at least one (1) Business Day to publicly disclose such material, non-public information prior to any such disclosure by the Investor, the Company shall have failed to demonstrate to the Investor in writing within such time period that such information does not constitute material, non-public information, and the Company shall have failed to publicly disclose such material, non-public information within such time period. The Investor shall not have any liability to the Company, any of its Subsidiaries, or any of their respective directors, officers, employees, stockholders or agents, for any such disclosure. The Company understands and confirms that the Investor shall be relying on the foregoing covenants in effecting transactions in securities of the Company.

(g) Purchase Records. The Investor and the Company shall each maintain records showing the remaining Available Amount at any given time and the dates and Purchase Amounts for the Initial Purchase, each Regular Purchase, each Accelerated Purchase and each Additional Accelerated Purchase or shall use such other method, reasonably satisfactory to the Investor and the Company.

(h) Taxes. The Company shall pay any and all transfer, stamp or similar taxes that may be payable with respect to the issuance and delivery of any shares of Common Stock to the Investor made under this Agreement.

(i) Use of Proceeds. The Company will use the net proceeds from the offering as described in the Registration Statement or the SEC Documents.

(j) Other Transactions. The Company shall not enter into, announce or recommend to its stockholders any agreement, plan, arrangement or transaction in or of which the terms thereof would restrict, materially delay, conflict with or impair the ability or right of the Company to perform its obligations under the Transaction Documents, including, without limitation, the obligation of the Company to deliver the Purchase Shares and the Commitment Shares to the Investor in accordance with the terms of the Transaction Documents, for so long as such obligations of the Company are in effect pursuant to the terms of this Agreement.

(k) Integration. From and after the date of this Agreement, neither the Company, nor any of its affiliates will, and the Company shall use its reasonable best efforts to ensure that no Person acting on their behalf will, directly or indirectly, make any offers or sales of any security or solicit any offers to buy any security, under circumstances that would (i) require registration of the offer and sale by the Company to the Investor of any of the Securities under the Securities Act, or (ii) cause this offering of the Securities by the Company to the Investor to be integrated with other offerings by the Company in a manner that would require stockholder approval pursuant to the rules of the Principal Market on which any of the securities of the Company are listed or designated, unless in the case of this clause (ii), stockholder approval is obtained before the closing of such subsequent transaction in accordance with the rules of such Principal Market.

(l) Limitation on Variable Rate Transactions. From and after the date of this Agreement until the later of: (i) the 36-month anniversary of the date of this Agreement and (ii) the 36-month anniversary of the Commencement Date (if the Commencement has occurred), irrespective of any earlier termination of this Agreement, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or any combination of units thereof) in any "equity line of credit", "at-the-market offering", or other substantially similar equity line of credit offering in which, in each case, the Company may offer, issue or sell, and the purchaser is irrevocably bound to purchase, Common Stock or Common Stock Equivalents (or any combination of units thereof) at a future determined price, other than in connection with an Exempt Issuance. The Investor shall be entitled to seek injunctive relief against the Company and its Subsidiaries to preclude any such issuance, which remedy shall be in addition to any right to collect damages, without the necessity of showing economic loss and without any bond or other security being required. "Common Stock Equivalents" means any securities of the Company or its Subsidiaries which entitle the holder thereof to acquire at any time shares of Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, shares of Common Stock. "Exempt Issuance" means the issuance of (a) any Securities issued to the Investor pursuant to this Agreement, and any Common Stock and Common Stock Equivalents issued to the Investor or any affiliate of the Investor pursuant to any other agreement or arrangement between the Company or any of its Subsidiaries, on the one hand, and the Investor or any of its affiliates, on the other hand, if any, (b) any securities issued upon the exercise or exchange of or conversion of any shares of Common Stock or Common Stock Equivalents

owned or held, directly or indirectly, by the Investor or any of its affiliates or designees at any time, (c) any securities, including, without limitation, Common Stock or Common Stock Equivalents (or any combination of units thereof), issuable to the Investor or any of its affiliates or designees pursuant to any other existing or future agreement or arrangement between the Investor or any of its affiliates or designees, on the one hand, and the Company or any of its Subsidiaries, on the other hand, entered into after the date of this Agreement, if any, or (d) shares of Common Stock issued pursuant to an "at-the-market offering" under Rule 415(a)(4) under the Securities Act by the Company exclusively through one or more registered broker-dealer(s) acting as agent(s) of the Company pursuant to a written agreement between the Company and such registered broker-dealer(s) only.

6. TRANSFER AGENT INSTRUCTIONS.

(a) On the date of this Agreement, the Company shall issue irrevocable instructions to the Transfer Agent substantially in the form attached hereto as **Exhibit C** to issue the Commitment Shares in accordance with the terms of this Agreement (the "Irrevocable Transfer Agent Instructions"). The certificate(s) or book-entry statement(s) representing the Commitment Shares, except as set forth below, shall bear the following restrictive legend (the "Restrictive Legend"):

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND COMPLIANCE WITH APPLICABLE STATE SECURITIES LAWS, UNLESS SOLD PURSUANT TO: (1) RULE 144 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR (2) AN OPINION OF HOLDER'S COUNSEL, IN A CUSTOMARY FORM, THAT REGISTRATION IS NOT REQUIRED UNDER SAID ACT OR APPLICABLE STATE SECURITIES LAWS.

(b) On the earlier of (i) the Commencement Date and (ii) such time that the Investor shall request, provided all conditions of Rule 144 under the Securities Act are met, the Company shall, no later than one (1) Business Day following the delivery by the Investor to the Company or the Transfer Agent of one or more legended book-entry statements representing the Commitment Shares (which book-entry statements the Investor shall promptly deliver on or prior to the first to occur of the events described in clauses (i) and (ii) of this sentence), as directed by the Investor, issue and deliver (or cause to be issued and delivered) to the Investor, as requested by the Investor, either: (A) a book-entry statement representing such Commitment Shares that is free from all restrictive and other legends or (B) a number of shares of Common Stock equal to the number of Commitment Shares represented by the book-entry statement(s) so delivered by the Investor as DWAC Shares. The Company shall take all actions to carry out the intent and accomplish the purposes of the immediately preceding sentence, including, without limitation, delivering all such legal opinions, consents, certificates, resolutions and instructions to the Transfer Agent, and any successor transfer agent of the Company, as may be requested from time to time by the Investor or necessary or desirable to carry out the intent and accomplish the purposes of the immediately preceding sentence. On the Commencement Date, the Company shall issue to the Transfer Agent, and any subsequent transfer agent, (i) irrevocable instructions in the form substantially similar to those used by the Investor in substantially similar transactions (the "Commencement Irrevocable Transfer Agent Instructions") and (ii) the notice of effectiveness of the Registration Statement in the form attached as an exhibit to the Registration Rights Agreement (the "Notice of Effectiveness of Registration Statement"), in each case to remove the legend described in Section 6(a) above from the Commitment Shares and to issue the Purchase

Shares in accordance with the terms of this Agreement and the Registration Rights Agreement. All Purchase Shares and Commitment Shares to be issued from and after Commencement to or for the benefit of the Investor pursuant to this Agreement shall be issued only as DWAC Shares. The Company represents and warrants to the Investor that, while this Agreement is effective, no instruction other than the Commencement Irrevocable Transfer Agent Instructions and the Notice of Effectiveness of Registration Statement referred to in this Section 6(b) (or similar instructions as required by the Transfer Agent in connection with each issuance of Purchase Shares) will be given by the Company to the Transfer Agent with respect to the Purchase Shares or the Commitment Shares from and after Commencement, and the Purchase Shares and the Commitment Shares covered by the Registration Statement shall otherwise be freely transferable on the books and records of the Company. If the Investor effects a sale, assignment or transfer of the Purchase Shares, the Company shall permit the transfer and shall promptly instruct the Transfer Agent (and any subsequent transfer agent) to issue DWAC Shares in such name and in such denominations as specified by the Investor to effect such sale, transfer or assignment. The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Investor. Accordingly, the Company acknowledges that the remedy at law for a breach of its obligations under this Section 6 will be inadequate and agrees, in the event of a breach or threatened breach by the Company of the provisions of this Section 6, that the Investor shall be entitled, in addition to all other available remedies, to an order and/or injunction restraining any breach and requiring immediate issuance and transfer, without the necessity of showing economic loss and without any bond or other security being required. The Company agrees that if the Company fails to fully comply with the provisions of this Section 6(b) within five (5) Business Days of the Investor providing the deliveries referred to above, the Company shall, at the Investor's written instruction, purchase such shares of Common Stock containing the restrictive legend from the Investor at the greater of the (i) purchase price paid for such shares of Common Stock (as applicable) by the Investor and (ii) the Closing Sale Price of the Common Stock on the date of the Investor's written instruction.

7. CONDITIONS TO THE COMPANY'S RIGHT TO COMMENCE SALES OF SHARES OF COMMON STOCK.

The right of the Company hereunder to commence sales of the Purchase Shares on the Commencement Date is subject to the satisfaction of each of the following conditions:

(a) The Investor shall have executed each of the Transaction Documents and delivered the same to the Company;

(b) The Registration Statement covering the resale of the Purchase Shares and all of the Commitment Shares shall have been declared effective under the Securities Act by the SEC, and no stop order with respect to the Registration Statement shall be pending or threatened by the SEC; and

(c) The representations and warranties of the Investor shall be true and correct in all material respects as of the date hereof and as of the Commencement Date as though made at that time.

8. CONDITIONS TO THE INVESTOR'S OBLIGATION TO PURCHASE SHARES OF COMMON STOCK.

The obligation of the Investor to buy Purchase Shares under this Agreement is subject to the satisfaction of each of the following conditions on or prior to the Commencement Date and, once such conditions have been initially satisfied, there shall not be any ongoing obligation to satisfy such conditions after the Commencement has occurred:

(a) The Company shall have executed each of the Transaction Documents and delivered the same to the Investor;

(b) The Company shall have issued or caused to be issued to the Investor (i) one or more book-entry statements representing the Commitment Shares free from all restrictive and other legends or (ii) a number of shares of Common Stock equal to the number of Commitment Shares as DWAC Shares, in each case in accordance with Section 6(b);

(c) The Common Stock shall be listed or quoted on the Principal Market, subject only to customary listing conditions, trading in the Common Stock shall not have been within the last 365 days suspended by the SEC, the Principal Market, and all Securities to be issued by the Company to the Investor pursuant to this Agreement shall have been approved for listing or quotation on the Principal Market in accordance with the applicable rules and regulations of the Principal Market, subject only to any standard listing conditions for transactions of this nature;

(d) The Investor shall have received the opinions and negative assurances of the Company's counsel, dated as of the Commencement Date, substantially in the forms heretofore agreed by the parties hereto;

(e) The representations and warranties of the Company shall be true and correct in all material respects (except to the extent that any of such representations and warranties is already qualified as to materiality in Section 4 above, in which case, the portion of such representations and warranties so qualified shall be true and correct without further qualification) as of the date hereof and as of the Commencement Date as though made at that time (except for representations and warranties that speak as of a specific date, which shall be true and correct as of such date) and the Company shall have performed, satisfied and complied with the covenants, agreements and conditions required by the Transaction Documents to be performed, satisfied or complied with by the Company at or prior to the Commencement Date. The Investor shall have received a certificate, executed by the CEO, President or CFO of the Company, dated as of the Commencement Date, to the foregoing effect in the form attached hereto as **Exhibit A**;

(f) The Board of Directors of the Company shall have adopted the Signing Resolutions which shall be in full force and effect without any amendment or supplement thereto as of the Commencement Date;

(g) As of the Commencement Date, the Company shall have reserved out of its authorized and unissued Common Stock, solely for the purpose of effecting purchases of Purchase Shares hereunder, 5,000,000 shares of Common Stock;

(h) The Commencement Irrevocable Transfer Agent Instructions and the Notice of Effectiveness of Registration Statement each shall have been delivered to and acknowledged in writing by the Company and the Company's Transfer Agent (or any successor transfer agent);

(i) The Company shall have delivered to the Investor a certificate evidencing the incorporation and good standing of the Company in the State of Delaware issued by the Secretary of State of the State of Delaware as of a date within ten (10) Business Days of the Commencement Date;

(j) The Company shall have delivered to the Investor a certified copy of the Certificate of Incorporation as certified by the Secretary of State of the State of Delaware within ten (10) Business Days of the Commencement Date;

(k) The Company shall have delivered to the Investor a secretary's certificate executed by the Secretary of the Company, dated as of the Commencement Date, in the form attached hereto as **Exhibit B**;

(l) The Registration Statement covering the resale of the Purchase Shares and all of the Commitment Shares shall have been declared effective under the Securities Act by the SEC, and no stop order with respect to the Registration Statement shall be pending or threatened by the SEC. The Company shall have prepared and filed with the SEC, not later than one (1) Business Day after the effective date of the Registration Statement, a final and complete prospectus (the preliminary form of which shall be included in the Registration Statement) and shall have delivered to the Investor a true and complete copy thereof, provided that the Company will be deemed to have furnished such prospectus to the Investor to the extent they are filed on the SEC's Electronic Data Gathering, Analysis and Retrieval system. Such prospectus shall be current and available for the resale by the Investor of all of the Securities covered thereby. The Current Report shall have been filed with the SEC as required pursuant to Section 5(a). All reports, schedules, registrations, forms, statements, information and other documents required to have been filed by the Company with the SEC at or prior to the Commencement Date pursuant to the reporting requirements of the Exchange Act shall have been filed with the SEC within the applicable time periods prescribed for such filings under the Exchange Act;

(m) No Event of Default has occurred, or any event which, after notice and/or lapse of time, would become an Event of Default has occurred;

(n) All federal, state and local governmental laws, rules and regulations applicable to the transactions contemplated by the Transaction Documents and necessary for the execution, delivery and performance of the Transaction Documents and the consummation of the transactions contemplated thereby in accordance with the terms thereof shall have been complied with, and all consents, authorizations and orders of, and all filings and registrations with, all federal, state and local courts or governmental agencies and all federal, state and local regulatory or self-regulatory agencies necessary for the execution, delivery and performance of the Transaction Documents and the consummation of the transactions contemplated thereby in accordance with the terms thereof shall have been obtained or made, including, without limitation, in each case those required under the Securities Act, the Exchange Act, applicable state securities or "Blue Sky" laws or applicable rules and regulations of the Principal Market, or otherwise required by the SEC, the Principal Market or any state securities regulators;

(o) No statute, regulation, order, decree, writ, ruling or injunction shall have been enacted, entered, promulgated, threatened or endorsed by any federal, state or local court or governmental authority of competent jurisdiction which prohibits the consummation of or which would materially modify or delay any of the transactions contemplated by the Transaction Documents; and

(p) No action, suit or proceeding before any federal, state, local or foreign arbitrator or any court or governmental authority of competent jurisdiction shall have been commenced or threatened, and no inquiry or investigation by any federal, state, local or foreign governmental authority of competent jurisdiction shall have been commenced or threatened, against the Company, or any of the officers, directors or affiliates of the Company, seeking to restrain, prevent or change the transactions contemplated by the Transaction Documents, or seeking material damages in connection with such transactions.

9. INDEMNIFICATION.

In consideration of the Investor's execution and delivery of the Transaction Documents and acquiring the Securities hereunder and in addition to all of the Company's other obligations under the Transaction Documents, the Company shall defend, protect, indemnify and hold harmless the Investor and all of its affiliates, stockholders, members, officers, directors and employees and any of the foregoing Person's agents or other representatives (including, without limitation, those retained in connection with the transactions contemplated by this Agreement) (collectively, the "Indemnitees") from and against any

and all actions, causes of action, suits, claims, losses, costs, penalties, fees, liabilities and damages, and reasonable expenses in connection therewith (irrespective of whether any such Indemnitee is a party to the action for which indemnification hereunder is sought), and including reasonable and documented attorneys' fees and disbursements (the "Indemnified Liabilities"), incurred by any Indemnitee as a result of, or arising out of, or relating to (a) any misrepresentation or breach of any representation or warranty made by the Company in the Transaction Documents or any other certificate, instrument or document executed by the Company and contemplated hereby or thereby, (b) any breach of any covenant, agreement or obligation of the Company contained in the Transaction Documents or any other certificate, instrument or document executed by the Company and contemplated hereby or thereby, or (c) any cause of action, suit or claim brought or made against such Indemnitee and arising out of or resulting from the execution, delivery, performance or enforcement of the Transaction Documents or any other certificate, instrument or document executed by the Company and contemplated hereby or thereby, other than, in the case of clause (c), with respect to Indemnified Liabilities which directly and primarily result from the fraud, gross negligence or willful misconduct of an Indemnitee. The indemnity in this Section 9 shall not apply to amounts paid in settlement of any claim if such settlement is effected without the prior written consent of the Company, which consent shall not be unreasonably withheld, conditioned or delayed. To the extent that the foregoing undertaking by the Company may be unenforceable for any reason, the Company shall make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable law. Payment under this indemnification shall be made within thirty (30) days from the date Investor makes written request for it provided that the Investor shall promptly reimburse the Company for any portion of such payment that a court of competent jurisdiction determines by final and non-appealable judgment that any such Indemnitee was not entitled to receive hereunder. A certificate containing reasonable detail as to the amount of such indemnification submitted to the Company by Investor shall be conclusive evidence, absent manifest error, of the amount due from the Company to Investor. If any action shall be brought against any Indemnitee in respect of which indemnity may be sought pursuant to this Agreement, such Indemnitee shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Indemnitee. Any Indemnitee shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnitee, except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of such separate counsel, a material conflict on any material issue between the position of the Company and the position of such Indemnitee, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel.

10. EVENTS OF DEFAULT.

An "Event of Default" shall be deemed to have occurred at any time as any of the following events occurs:

(a) the effectiveness of a registration statement registering the resale of the Securities lapses for any reason (including, without limitation, the issuance of a stop order or similar order) or such registration statement (or the prospectus forming a part thereof) is unavailable to the Investor for resale of any or all of the Securities to be issued to the Investor under the Transaction Documents, and such lapse or unavailability continues for a period of ten (10) consecutive Business Days or for more than an aggregate of thirty (30) Business Days in any 365-day period, but excluding a lapse or unavailability where (i) the Company terminates a registration statement after the Investor has confirmed in writing that all of the Securities covered thereby have been resold or (ii) the Company supersedes one registration statement with another registration statement, including (without limitation) by terminating a prior registration statement when it is effectively replaced with a new registration statement covering Securities (provided in the case of this clause (ii) that all of the Securities covered by the superseded (or terminated) registration statement that have not theretofore been resold are included in the superseding (or new) registration statement);

(b) the suspension of the Common Stock from trading on the Principal Market for a period of one (1) Business Day, provided that the Company may not direct the Investor to purchase any shares of Common Stock during any such suspension;

(c) the delisting of the Common Stock from The Nasdaq Capital Market, provided, however, that the Common Stock is not immediately thereafter trading on the New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market, the NYSE American, the NYSE Arca, or OTC Markets (or nationally recognized successor to any of the foregoing);

(d) the failure for any reason by the Transfer Agent to issue Purchase Shares to the Investor within two (2) Business Days after the Commencement Date, Purchase Date, Accelerated Purchase Date or Additional Accelerated Purchase Date, as applicable, on which the Investor is entitled to receive such Purchase Shares;

(e) the Company breaches any representation, warranty, covenant or other term or condition under any Transaction Document if such breach would reasonably be expected to have a Material Adverse Effect and except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues for a period of at least five (5) Business Days;

(f) if any Person commences a proceeding against the Company pursuant to or within the meaning of any Bankruptcy Law;

(g) if the Company, pursuant to or within the meaning of any Bankruptcy Law, (i) commences a voluntary case, (ii) consents to the entry of an order for relief against it in an involuntary case, (iii) consents to the appointment of a Custodian of it or for all or substantially all of its property, or (iv) makes a general assignment for the benefit of its creditors or is generally unable to pay its debts as the same become due;

(h) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (i) is for relief against the Company in an involuntary case, (ii) appoints a Custodian of the Company or for all or substantially all of its property, or (iii) orders the liquidation of the Company or any Subsidiary;

(i) if at any time the Company is not eligible to transfer its Common Stock electronically as DWAC Shares; or

(j) if at any time after the Commencement Date, the Exchange Cap is reached (to the extent such Exchange Cap is applicable pursuant to Section 2(f) hereof), and the stockholder approval referred to in Section 2(f)(i) has not been obtained in accordance with the applicable rules of The Nasdaq Stock Market.

In addition to any other rights and remedies under applicable law and this Agreement, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would reasonably be expected to become an Event of Default has occurred and is continuing, the Company shall not deliver to the Investor the Initial Purchase Notice, any Regular Purchase Notice, any Accelerated Purchase Notice or any Additional Accelerated Purchase Notice.

11. TERMINATION

This Agreement may be terminated only as follows:

(a) If pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company which is not discharged within 90 days, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors (any of which would be an Event of Default as described in Sections 10(f), 10(g) and 10(h) hereof), this Agreement shall automatically terminate without any liability or payment to the Company (except as set forth below) without further action or notice by any Person.

(b) In the event that (i) the Company fails to file the Registration Statement with the SEC within the period specified in Section 5(a) hereof in accordance with the terms of the Registration Rights Agreement or (ii) the Commencement shall not have occurred on or before June 30, 2023, due to the failure to satisfy the conditions set forth in Sections 7 and 8 above with respect to the Commencement, then, in the case of clause (i) above, this Agreement may be terminated by the Investor at any time prior to the filing of the Registration Statement and, in the case of clause (ii) above, this Agreement may be terminated by either party at the close of business on June 30, 2023 or thereafter, in each case without liability of such party to the other party (except as set forth below); provided, however, that the right to terminate this Agreement under this Section 11(b) shall not be available to any party if such party is then in breach of any covenant or agreement contained in this Agreement or any representation or warranty of such party contained in this Agreement fails to be true and correct such that the conditions set forth in Section 7(c) or Section 8(e), as applicable, could not then be satisfied.

(c) At any time after the Commencement Date, the Company shall have the option to terminate this Agreement for any reason or for no reason by delivering notice (a "Company Termination Notice") to the Investor electing to terminate this Agreement without any liability whatsoever of any party to any other party under this Agreement (except as set forth below). The Company Termination Notice shall not be effective until one (1) Business Day after it has been received by the Investor.

(d) This Agreement shall automatically terminate on the date that the Company issues and sells and the Investor purchases the full Available Amount as provided herein, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement (except as set forth below).

(e) If, for any reason or for no reason, the full Available Amount has not been purchased in accordance with Section 2 of this Agreement by the Maturity Date, this Agreement shall automatically terminate on the Maturity Date, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement (except as set forth below).

Except as set forth in Sections 11(a) (in respect of an Event of Default under Sections 10(f), 10(g) and 10(h)), 11(d) and 11(e), any termination of this Agreement pursuant to this Section 11 shall be effected by written notice from the Company to the Investor, or the Investor to the Company, as the case may be, setting forth the basis for the termination hereof. The representations and warranties and covenants of the Company and the Investor contained in Sections 3, 4, 5, and 6 hereof, the indemnification provisions set forth in Section 9 hereof and the agreements and covenants set forth in Sections 10, 11 and 12 shall survive the execution and delivery of this Agreement and any termination of this Agreement. No termination of this Agreement shall (i) affect the Company's or the Investor's rights or obligations under (A) this Agreement with respect to a pending Initial Purchase or any pending Regular Purchases, Accelerated Purchases or Additional Accelerated Purchases (as applicable) and the Company and the Investor shall complete their respective obligations with respect to a pending Initial Purchase and any pending Regular Purchases, Accelerated Purchases and Additional Accelerated Purchases (as applicable) under this Agreement and (B) the Registration Rights Agreement, which shall survive any such termination, or (ii) be deemed to release the Company or the Investor from any liability for intentional misrepresentation or willful breach of any of the Transaction Documents.

12. MISCELLANEOUS.

(a) Governing Law; Jurisdiction; Jury Trial. The corporate laws of the State of Delaware shall govern all issues concerning the relative rights of the Company and its stockholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement, the Registration Rights Agreement and the other Transaction Documents shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the State of Illinois, County of Cook, for the adjudication of any dispute hereunder or under the other Transaction Documents or in connection herewith or therewith, or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

(b) Counterparts. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile signature or signature delivered by e-mail in a ".pdf" format data file, including any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com, www.echosign.adobe.com, etc., shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original signature.

(c) Headings. The headings of this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

(d) Severability. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction.

(e) Entire Agreement. The Transaction Documents supersede all other prior oral or written agreements between the Investor, the Company, their affiliates and Persons acting on their behalf with respect to the subject matter thereof, and this Agreement, the other Transaction Documents and the instruments referenced herein contain the entire understanding of the parties with respect to the matters covered herein and therein and, except as specifically set forth herein or therein, neither the Company nor the Investor makes any representation, warranty, covenant or undertaking with respect to such matters. The Company acknowledges and agrees that is has not relied on, in any manner whatsoever, any representations or statements, written or oral, other than as expressly set forth in the Transaction Documents.

(f) Notices. Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt when delivered personally; (ii) upon receipt when sent by email (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); or (iii) one Business Day after deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and email addresses for such communications shall be:

If to the Company:

TRACON Pharmaceuticals, Inc.
4350 La Jolla Village Drive, Suite 800
San Diego, California 92122
Telephone:
E-mail:
Attention: Scott B. Brown, CFO

With a copy to (which shall not constitute notice or service of process):

Cooley LLP
10265 Science Center Drive
San Diego, California 92121
Telephone: (858) 550-6045
E-mail: mbrowne@cooley.com
Attention: Matthew Browne, Esq.

If to the Investor:

Lincoln Park Capital Fund, LLC
440 North Wells, Suite 410
Chicago, IL 60654
Telephone:
E-mail:
Attention: Josh Scheinfeld/Jonathan Cope

With a copy to (which shall not constitute notice or service of process):

Dorsey & Whitney LLP
51 West 52nd Street
New York, NY 10019
Telephone: (212) 415-9214
E-mail: marsico.anthony@dorsey.com
Attention: Anthony J. Marsico, Esq.

If to the Transfer Agent:

American Stock Transfer & Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Telephone:
Attention:

or at such other address and/or email address and/or to the attention of such other Person as the recipient party has specified by written notice given to each other party three (3) Business Days prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent, waiver or other communication, (B) mechanically or electronically generated by the sender's email account containing the time, date, and recipient email address and an image of the first page of such transmission or (C) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of personal service, receipt by email or receipt from a nationally recognized overnight delivery service in accordance with clause (i), (ii) or (iii) above, respectively.

(g) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns. The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Investor; provided, however, that any transaction, whether by merger, reorganization, restructuring or consolidation, financing or otherwise, whereby the Company remains the surviving entity immediately after such transaction shall not be deemed an assignment. The Investor may not assign its rights or obligations under this Agreement.

(h) No Third Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns and, except as set forth in Section 9, is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

(i) Publicity. The Company shall afford the Investor and its counsel with the opportunity to review and comment upon, shall consult with the Investor and its counsel on the form and substance of, and shall give due consideration to all such comments from the Investor or its counsel on, any press release, SEC filing or any other public disclosure by or on behalf of the Company relating to the Investor, its purchases hereunder or any aspect of the Transaction Documents or the transactions contemplated thereby, not less than 24 hours prior to the issuance, filing or public disclosure thereof; provided, however, that this provision shall not apply to any portion of any Form 10-K or Form 10-Q that does not relate to the Investor, its purchases hereunder or any aspect of the Transaction Documents or the transactions contemplated hereby. The Investor must be provided with a final version of any portion of such press release, SEC filing or other public disclosure relating to the Investor, its purchases hereunder or any aspect of the Transaction Documents or the transactions contemplated hereby at least 24 hours prior to any release, filing or use by the Company thereof. The Company agrees and acknowledges that its failure to fully comply with this Section 12(i) shall constitute a Material Adverse Effect.

(j) Further Assurances. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other party may reasonably request in order to consummate and make effective, as soon as reasonably possible, the Commencement, and to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

(k) No Financial Advisor, Placement Agent, Broker or Finder. The Company represents and warrants to the Investor that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. The Investor represents and warrants to the Company that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. The Company shall be responsible for the payment of any fees or commissions, if any, of any financial advisor, placement agent, broker or finder engaged by the Company relating to or arising out of the transactions contemplated hereby. The Company shall pay, and hold the Investor harmless against, any liability, loss or expense (including, without limitation, reasonable attorneys' fees and out of pocket expenses) arising in connection with any claim by any financial advisor, placement agent, broker or finder engaged by the Company related to the transactions contemplated by this Agreement.

(l) No Strict Construction. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party. In addition, each and every reference to share prices and shares of Common Stock in this Agreement shall be subject to adjustment as provided in this Agreement for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

(m) Remedies, Other Obligations, Breaches and Injunctive Relief. The Investor's remedies provided in this Agreement, including, without limitation, the Investor's remedies provided in Section 9, shall be cumulative and in addition to all other remedies available to the Investor under this Agreement, at law or in equity (including a decree of specific performance and/or other injunctive relief), no remedy of the Investor contained herein shall be deemed a waiver of compliance with the provisions giving rise to such remedy and nothing herein shall limit the Investor's right to pursue actual damages for any failure by the Company to comply with the terms of this Agreement. The parties acknowledges that a breach by any other party of its obligations hereunder will cause irreparable harm to the non-breaching party and that the remedy at law for any such breach may be inadequate. The parties therefore agrees that, in the event of any such breach or threatened breach, the non-breaching party shall be entitled, in addition to all other available remedies, to an injunction restraining any breach, without the necessity of showing economic loss and without any bond or other security being required.

(n) Enforcement Costs. If: (i) this Agreement is placed by the Investor in the hands of an attorney for enforcement or is enforced by the Investor through any legal proceeding; (ii) an attorney is retained to represent the Investor in any bankruptcy, reorganization, receivership or other proceedings affecting creditors' rights and involving a claim under this Agreement; or (iii) an attorney is retained to represent the Investor in any other proceedings whatsoever in connection with this Agreement, then the Company shall pay to the Investor, as incurred by the Investor, all reasonable costs and expenses including reasonable attorneys' fees incurred in connection therewith, in addition to all other amounts due hereunder. If this Agreement is placed by the Company in the hands of an attorney for enforcement or is enforced by the Company through any legal proceeding, then the Investor shall pay to the Company, as incurred by the Company, all reasonable costs and expenses, including attorney's fees incurred in connection therewith, in addition to all other amounts due hereunder.

(o) Amendment and Waiver; Failure or Indulgence Not Waiver. No provision of this Agreement may be amended or waived by the parties from and after the date that is one (1) Business Day immediately preceding the initial filing of the Registration Statement with the SEC. Subject to the immediately preceding sentence, (i) no provision of this Agreement may be amended other than by a written instrument signed by both parties hereto and (ii) no provision of this Agreement may be waived other than in a written instrument signed by the party against whom enforcement of such waiver is sought. No failure or delay in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege.

*** Signature Page Follows ***

IN WITNESS WHEREOF, the Investor and the Company have caused this Agreement to be duly executed as of the date first written above.

THE COMPANY:

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles P. Theuer, M.D., Ph.D.
Name: Charles P. Theuer, M.D., Ph.D.
Title: Chief Executive Officer

INVESTOR:

LINCOLN PARK CAPITAL FUND, LLC
BY: LINCOLN PARK CAPITAL, LLC
BY: ROCKLEDGE CAPITAL CORPORATION

By: /s/ Josh Scheinfeld
Name: Josh Scheinfeld
Title: President

EXHIBITS

Exhibit A	Form of Officer's Certificate
Exhibit B	Form of Secretary's Certificate
Exhibit C	Form of Letter to Transfer Agent

Exhibit 31.1

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

I, Charles P. Theuer, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRACON Pharmaceuticals, 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 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 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 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.

Date: May 10, 2023

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Scott B. Brown, CPA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRACON Pharmaceuticals, 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 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 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 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.

Date: May 10, 2023

/s/ Scott B. Brown, CPA
Scott B. Brown, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with Rule 13a-14(b) and 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant for the period ended March 31, 2023, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 10, 2023

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of TRACON Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott B. Brown, CPA, Chief Financial Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with Rule 13a-14(b) and 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant for the period ended March 31, 2023, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 10, 2023

/s/ Scott B. Brown, CPA
Scott B. Brown, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of TRACON Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.