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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2022

or

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

Commission File Number 001-36818

TRACON Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**34-2037594** **(IRS Employer Identification No.)**
4350 La Jolla Village Drive, Suite 800, San Diego CA **(Address of principal executive offices)**	**92122** **(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 November 11, 2022 was 22,211,446.

TRACON Pharmaceuticals, Inc.

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ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 17,037	$ 24,072
Prepaid and other assets	983	864
Total current assets	18,020	24,936
Property and equipment, net	51	50
Restricted cash	175	—
Other assets	1,420	1,571
Total assets	$ 19,666	$ 26,557
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,477	$ 10,753
Accrued compensation and related expenses	1,283	1,532
Long-term debt, current portion	—	1,391
Total current liabilities	11,760	13,676
Other long-term liabilities	1,446	1,167
Long-term debt, less current portion	9,095	—
Commitments and contingencies (Note 4)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at September 30, 2022 and December 31, 2021; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 40,000,000 at September 30, 2022 and December 31, 2021; issued and outstanding shares — 21,749,924 and 19,445,903 at September 30, 2022 and December 31, 2021, respectively	22	19
Additional paid-in capital	227,257	219,471
Accumulated deficit	(229,914)	(207,776)
Total stockholders' (deficit) equity	(2,635)	11,714
Total liabilities and stockholders' equity (deficit)	$ 19,666	$ 26,557

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ —	$ —	$ —	$ 346
Operating expenses:				
Research and development	4,097	2,730	10,013	8,082
General and administrative	2,280	4,151	12,049	12,948
Total operating expenses	6,377	6,881	22,062	21,030
Loss from operations	(6,377)	(6,881)	(22,062)	(20,684)
Other expense:				
Interest expense	(58)	(69)	(76)	(269)
Other expense	—	(2)	—	(2)
Total other expense	(58)	(71)	(76)	(271)
Net loss	$ (6,435)	$ (6,952)	$ (22,138)	$ (20,955)
Net loss per share, basic and diluted	$ (0.30)	$ (0.38)	$ (1.08)	$ (1.27)
Weighted-average shares outstanding, basic and diluted	21,469,977	18,533,772	20,455,877	16,514,652

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	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
Stock-based compensation expense	—	—	535	—	535
Issuance of common stock under equity plans	23,461	—	49	—	49
Issuance of common stock and warrants, net of offering costs	1,771,377	1	5,397	—	5,398
Net loss	—	—	—	(6,230)	(6,230)
Balance at June 30, 2022	21,421,798	21	226,000	(223,479)	2,542
Stock-based compensation expense	—	—	481	—	481
Issuance of common stock, net of offering costs	328,126	1	517	—	518
Issuance of common stock warrants in connection with debt financing	—	—	259	—	259
Net loss	—	—	—	(6,435)	(6,435)
Balance at September 30, 2022	21,749,924	$ 22	$ 227,257	$ (229,914)	$ (2,635)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	15,478,787	$ 15	$ 204,166	$ (179,109)	$ 25,072
Stock-based compensation expense	—	—	343	—	343
Issuance of common stock under equity plans	2,024	—	14	—	14
Offering costs	—	—	(8)	—	(8)
Net loss	—	—	—	(5,064)	(5,064)
Balance at March 31, 2021	15,480,811	15	204,515	(184,173)	20,357
Stock-based compensation expense	—	—	417	—	417
Issuance of common stock under equity plans	21,153	1	79	—	80
Net loss	—	—	—	(8,939)	(8,939)
Balance at June 30, 2021	15,501,964	16	205,011	(193,112)	11,915
Stock-based compensation expense	—	—	501	—	501
Issuance of common stock under equity plans	1,703	—	7	—	7
Issuance of common stock, net of offering costs	3,926,702	3	13,389	—	13,392
Net loss	—	—	—	(6,952)	(6,952)
Balance at September 30, 2021	19,430,369	$ 19	$ 218,908	$ (200,064)	$ 18,863

See accompanying notes.

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (22,138)	$ (20,955)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,564	1,261
Depreciation and amortization	12	10
Noncash interest	17	52
Amortization of debt discount	15	18
Amortization of premium/discount on short-term investments	—	(1)
Lease asset amortization and liability accretion, net	47	(41)
Equity ownership license revenue	—	(246)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(316)	(457)
Accounts payable and accrued expenses	(538)	3,364
Accrued compensation and related expenses	(249)	(462)
Net cash used in operating activities	(21,586)	(17,457)
Cash flows from investing activities		
Purchase of property and equipment	(13)	(39)
Proceeds from the maturity of available-for-sale short-term investments	—	4,000
Net cash (used in) provided by investing activities	(13)	3,961
Cash flows from financing activities		
Proceeds from long-term debt	9,960	—
Repayment of long-term debt	(1,680)	(2,100)
Proceeds from sale of common stock and warrants, net of offering costs	6,410	13,265
Proceeds from issuance of common stock under equity plans	49	101
Net cash provided by financing activities	14,739	11,266
Change in cash, cash equivalents, and restricted cash	(6,860)	(2,230)
Cash, cash equivalents, and restricted cash at beginning of period	24,072	32,131
Cash, cash equivalents, and restricted cash at end of period	$ 17,212	$ 29,901

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 September 30, 2022, 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 September 30, 2022, the Company had an accumulated deficit of $229.9 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 September 30, 2022, the Company had cash and cash equivalents of $17.2 million, of which $0.2 million is classified as restricted cash as it is pledged as collateral for the Company’s obligations under its corporate headquarters facility lease. Based on the Company’s current business plan, management believes that there is substantial doubt as to whether existing cash and cash equivalents will be sufficient to meet its obligations as they become due within 12 months from the date the unaudited condensed consolidated financial statements are issued. 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, the Company’s current working capital, anticipated operating expenses and net losses, and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, raise 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, $47.4 million of which remained available for sale as of September 30, 2022. 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 the COVID-19 pandemic and actions taken to slow its spread, as well as adverse macroeconomic developments, such as the 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 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 September 30, 2022, and for the three and nine months ended September 30, 2022 and 2021, 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, 2021, included in its Annual Report on Form 10-K filed with the SEC on March 15, 2022.

Risks and Uncertainties

COVID-19, a novel strain of coronavirus (together with its variants, COVID-19), has become a global pandemic. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. While vaccines have become widely available in certain countries, and businesses and economies have reopened, the status of global economic recovery remains uncertain and unpredictable, and will continue to be impacted by developments in the pandemic including any subsequent waves of outbreak or new variant strains of the COVID-19 virus which may require re-closures or other preventative measures. The COVID-19 pandemic may also have long-term effects on the nature of the office environment and remote working, which may present risks for our strategy, operational, talent recruiting and retention, and workplace culture.

The Company has experienced temporary closures of its offices in light of state and local orders and most of its employees continue to work remotely. In addition, the Company's employees have not been able to conduct normal business travel, in particular as part of business development activities or in-person monitoring of clinical trial sites. Potential further impacts to the Company's business include, but are not limited to, additional closures of its facilities or those of its vendors, continued disruptions or restrictions on its employees' ability to travel, disruptions to or delays in ongoing clinical trials, third-party manufacturing supply and other operations, the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, interruptions or delays in the operations of the U.S. Food and Drug Administration or other regulatory authorities, and the Company's ability to raise capital and conduct business development activities.

In addition to the ongoing COVID-19 pandemic, global economic and business activities continue to face widespread macroeconomic uncertainties, including labor shortages, inflation and monetary supply shifts, recession risks and potential disruptions from the Russia-Ukraine conflict. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

Use of Estimates

The Company's unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (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 consolidated balance sheet. 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 Update (ASU) No. 2014-09, Revenue from Contracts with Customers, 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 Accounting Standards Codification 606, Revenue from Contracts with Customers, 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 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 and nine months ended September 30, 2022 and 2021, 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):

	September 30,	
	2022	2021
Warrants to purchase common stock	6,987,785	4,810,409
Common stock options	2,246,310	1,295,808
ESPP shares	16,315	10,757
	9,250,410	6,116,974

2. Financial Instruments and Fair Value Measurements

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

	September 30, 2022				December 31, 2021			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 255	$ —	$ —	$ 255	$ 5,003	$ —	$ —	$ 5,003
U.S. treasury securities	9,921	—	—	9,921	—	—	—	—
Equity securities(1)	246	—	—	246	246	—	—	246
	$ 10,422	$ —	$ —	$ 10,422	$ 5,249	$ —	$ —	$ 5,249
Classified as:								
Cash equivalents				$ 10,001				$ 5,003
Restricted cash				175				—
Other assets				246				246
Total cash equivalents, restricted cash, and other assets				$ 10,422				$ 5,249

(1) The Company's equity securities included in other assets consisted of its investment in a privately held company. The Company recognizes its private company equity securities at cost minus impairments, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. No such impairments or changes were noted for any period presented.

At September 30, 2022 and December 31, 2021, the Company had no short-term investments. The Company classifies all investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies. These investments are carried at amortized cost which approximates fair value. A decline in the market value of any short-term investment below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

Realized gains and losses from the sale of short-term investments, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized and unrealized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations.

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 September 30, 2022				
Money market funds	$ 255	$ —	$ 255	$ —
U.S. treasury securities	9,921	—	9,921	—
	$ 10,176	$ —	$ 10,176	$ —
At December 31, 2021				
Money market funds	$ 5,003	$ —	$ 5,003	$ —

3. 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 2017 Amended SVB Loan).

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 Amended and Restated Loan and Security Agreement with SVB.

At September 30, 2022, 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	

Runway Growth Finance Corp. Loan and Security Agreement

In September 2022, the Company entered into a loan and security agreement with Runway Growth Finance Corp. (the RGC Loan Agreement). The RGC Loan Agreement is a long-term debt facility that provides 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; (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.

Borrowings under the term loan facility bear interest at a variable annual rate equal to the sum of (i) the greater of (a) the rate of interest noted in The Wall Street Journal, Money Rates section, as the "Prime Rate" or (b) 3.5%, plus (ii) 5.0%. The Company is obligated to make interest-only payments monthly in arrears through and including September 30, 2024 and thereafter monthly payments in arrears through the maturity date of September 1, 2026 equal to 1/24th of all outstanding principal plus accrued and unpaid interest.

The Company is obligated to pay a closing fee in the amount of (i) $50,000, which was paid upon the funding of the Term A loan, and (ii) an amount equal to 0.50% of the Term B loan and the Term C loan advanced to the Company, if any, due and payable on the applicable funding date of such Term B loan and Term C loan.

The Company is also obligated to pay a final payment fee equal to 4.25% of the aggregate principal amount of the funded term loans at the earlier to occur of (i) the maturity date, (ii) acceleration of the term loans and (iii) prepayment under the RGC Loan Agreement. The closing fee, other related debt issuance costs, and the final payment fee were recorded as a component of the total debt discount and will be recognized as interest expense over the term of the RGC Loan Agreement using the effective interest method.

The Company has the option to prepay all, but not less than all, of the amounts of outstanding principal, accrued and unpaid interest and any other amounts due and payable under the RGC Loan Agreement, including a final payment fee. If the Company exercises its right to prepay the term loan(s) prior to the maturity date, it is obligated to pay a prepayment fee equal to (a) 3.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs on or prior to the first anniversary date, (b) 2.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the first anniversary date but on or prior to the second anniversary date and (c) 1.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the second anniversary date but prior to the maturity date.

The Company's obligations under the RGC Loan Agreement are collateralized by a first priority security interest in substantially all of its assets other than the intellectual property of the Company. The RGC Loan Agreement also contains customary representations, warranties and covenants that limit, among other things, the ability of the Company to (i) incur indebtedness, (ii) incur liens on its property, (iii) pay dividends or make other distributions, (iv) sell its assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence and during the continuance of an event of default, a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lender may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the RGC Loan Agreement and under applicable law, including, without limitation, termination of its obligations to extend credit to the Company. The RGC Loan Agreement contains customary representations, warranties and covenants, including financial covenants, and also includes customary events of default, including payment defaults, breaches of covenants, change in control and a material adverse effect default. As of September 30, 2022, the Company was in compliance with all covenants and conditions of the RGC Loan Agreement.

In connection with the funding of the Term A loan, the Company issued Runway Growth Finance Corp. 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' equity (deficit) within additional paid-in capital on the consolidated balance sheets, and will be amortized to interest expense using the effective interest method over the term of the debt. In addition, in connection with the RGC Loan Agreement, additional warrants will be issued upon funding of the other term loan tranches, if any.

Long-term debt and unamortized debt discount balances were as follows (in thousands):

	September 30, 2022	December 31, 2021
Long-term debt	$ 10,000	$ 1,400
Less debt discount, net of current portion	(905)	—
Long-term debt, net of debt discount	9,095	1,400
Less current portion of long-term debt	—	(1,400)
Long-term debt, net of current portion	$ 9,095	$ —
Current portion of long-term debt	$ —	$ 1,400
Current portion of debt discount	—	(9)
Current portion of long-term debt, net	$ —	$ 1,391

Future minimum principal and interest payments under the RGC Loan Agreement, including the final payment, as of September 30, 2022 are as follows (in thousands):

Remaining 2022	$ 316
2023	1,141
2024	2,382
2025	5,736
2026	4,351
	13,926
Less interest and final payment	(3,926)
Long-term debt	$ 10,000

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 September 30, 2022, potential future milestone payments under these agreements totaled an aggregate of $9.6 million.

5. Stockholders' Equity (Deficit)

Sale of Common Stock and Pre-Funded Warrants

In June 2022, the Company issued and sold 841,989 shares of its common stock at a purchase price of $1.32 per share and pre-funded warrants to purchase 2,205,018 shares of its 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 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. The 2022 Pre-Funded Warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital on the consolidated balance sheets. In connection with the Offering, the Company amended two existing pre-funded warrants to purchase shares of the Company's 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 the Company's stockholders of such exercise.

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, $47.4 million of which remains available for sale as of September 30, 2022. 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 and nine months ended September 30, 2022, 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 and nine months ended September 30, 2022, the Company issued 0 shares and 23,461 shares of common stock, respectively, in connection with the employee stock purchase plan (the ESPP). During the year ended December 31, 2021, the Company issued 3,727 shares of common stock upon the exercise of outstanding stock options, 0 shares of common stock upon the vesting of restricted stock units, and 36,687 shares of common stock in connection with the ESPP.

Common Stock Warrants

As of September 30, 2022, 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	1,358,993	$ 0.01
June 21, 2032	2,205,018	$ 0.01
September 2, 2032	150,753	$ 1.99
	6,987,785	

During the three and nine months ended September 30, 2022, the Company issued 0 and 170,668 shares of its common stock upon the cashless exercise of pre-funded warrants to purchase 176,554 shares of common stock, respectively. During the year ended December 31, 2021, no warrants were exercised.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Risk-free interest rate	—	0.9%	1.9%	0.8%
Expected volatility	—	89%	90%	90%
Expected term (in years)	—	6.3	6.2	6.2
Expected dividend yield	—%	—%	—%	—%

Stock compensation expense for the ESPP was immaterial for the three and nine months ended September 30, 2022 and 2021.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 211	$ 176	$ 620	$ 447
General and administrative	270	325	944	814
	$ 481	$ 501	$ 1,564	$ 1,261

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) began dosing in December 2020 at 300mg of envafolimab every three weeks in cohort A, and 300mg of envafolimab every three weeks in combination with Yervoy® at 1mg/kg every three weeks for four doses in cohort B, in the sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS). In December 2021, the independent data monitoring committee (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 objective response rate (ORR) by blinded independent central review (BICR) in each cohort satisfied the prespecified futility rule of having at least one response in each cohort. Envafolimab was well tolerated, with only a single Grade 3 related adverse event reported in 36 patients. Based on the tolerability profile and the significantly higher ORR observed in lower weight patients, the IDMC recommended the trial continue, using a higher dose of envafolimab of 600mg every three weeks. Given the activity demonstrated by higher doses of envafolimab in completed trials, including in the pivotal trial in MSI-H/dMMR cancer that was the basis for approval of envafolimab in China, we agreed with the IDMC guidance and proposed a doubling of the envafolimab dose to 600mg every three weeks to the U.S. Food and Drug Administration (FDA) in an amendment which was cleared without comment. The ENVASARC trial will now assess up to 80 new patients in a cohort of single agent envafolimab at 600mg every three weeks and up to 80 new patients in a cohort of envafolimab at 600mg every three weeks with Yervoy at 1mg/kg every three weeks for four doses. Nine of 80 responses by BICR in either cohort are needed to satisfy the primary objective of the trial which is to statistically exceed the known 4% ORR of Votrient® (pazopanib), the only FDA-approved treatment for patients with refractory UPS or MFS. Achieving the primary endpoint of 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 August and October, we announced that the ENVASARC trial will proceed as planned after the IDMC reviewed three and twelve weeks of safety data, respectively, from more than 20 patients enrolled in the trial as of June 30, 2022. The safety data reviewed included data from more than 10 patients enrolled into cohort C of treatment with single agent envafolimab at 600 mg every three weeks and more than 10 patients enrolled into cohort D of treatment with envafolimab at 600 mg every three weeks in combination with Yervoy (ipilimumab). In July, we dosed the 36th patient in the ENVASARC trial at the 600 mg dose which triggers the initial interim efficacy analysis following the 12-week efficacy scan of the 36th dosed patient to allow for determination of the preliminary ORR, which we expect in the fourth quarter of 2022. There must be at least one response among the initial 18 patients enrolled at 600mg into each cohort to continue enrollment in that cohort per the futility rules of the trial. A second interim efficacy analysis at the 600mg dose 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 2023. 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 rules of the trial.

In September, 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. Assuming sufficient patient responses in line with meeting the ENVASARC trial endpoint, we intend to apply for breakthrough designation following the initial efficacy interim analysis. 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 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.

In June 2021, we received orphan drug designation (ODD) for envafolimab for the treatment of soft tissue sarcoma. The ODD application included data demonstrating that two of five patients with alveolar soft parts sarcoma (ASPS) treated with envafolimab in Phase 1 trials conducted by 3D Medicines and Alphamab demonstrated partial responses (PR), each with a duration of response greater than six months.

In November 2021, we announced that our partners 3D Medicines and Alphamab had received marketing authorization for envafolimab from the Chinese National Medical Products Association in the indication of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer.

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, 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, and TJ004309, which is a CD73 antibody in Phase 1 clinical development for the treatment of solid tumors, that we licensed from I-Mab Biopharma (I-Mab) in November 2018.

YH001 is an investigational humanized CTLA-4 IgG1 monoclonal antibody that is being developed in two Phase 1 trials 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 (Tregs) and contributes to the suppressor function of Tregs by acting 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 MSI-H/dMMR cancer. As of August 9, 2021, YH001 had been dosed in more than 34 patients in China and Australia. 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, and 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, and we expect data to be presented later this year. No CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma.

In August, 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 expect to initiate dosing in the Phase 1/2 clinical trial in the fourth quarter of 2022. 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 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 trial of chemoradiation with or without TRC102, followed by consolidative durvalumab treatment. The primary objective is to improve the 56% progression free survival 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 2024.

TJ004309, also known as TJD5 or uliledlimab, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate to the immunosuppressive metabolite adenosine. We are developing TJ004309 in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that we entered into in November 2018 (the TJ004309 Agreement). In July 2019, we began enrollment in a Phase 1 clinical trial to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors, and in June 2021 we presented data from the ongoing Phase 1 trial at the ASCO 2021 virtual meeting. In a poster presentation titled "The safety, pharmacokinetics (PK), pharmacodynamics (PD) and clinical efficacy of uliledlimab (TJ004309), a differentiated CD73 antibody, in combination with atezolizumab in patients with advanced cancer," uliledlimab was found to be well-tolerated up to 20mg/kg every three weeks and 15mg/kg once weekly as a monotherapy and in combination therapy with atezolizumab 1200mg every three weeks and no dose limiting toxicity was observed and the maximum tolerated dose was not reached. There was one complete response in a PD-(L)1 naïve patient, two PRs with one PR in a PD-(L)1 naïve patient and one PR in a PD-(L)1 refractory patient, and three cases of stable disease (SD) following treatment with uliledlimab and atezolizumab. We expect to complete the TJ004309 Phase 1 trial by the end of 2022.

We entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) which allows for the development of up to five of I-Mab's proprietary bispecific antibody (the BsAb) 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.

In March 2020, I-Mab issued a press release announcing a strategic partnership with Kalbe Genexine Biologics (KG Bio), whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. In March 2020, we also learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018 (ABL Bio License 1 and ABL Bio License 2). Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce (the ICC) 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 concerning two strategic collaboration and clinical trial agreements with us entered into in November 2018. Those strategic collaboration and clinical trial agreements relate to the development of TJ004309 and 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. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an order of specific performance requiring us to comply with I-Mab's purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On September 29, 2022, the ICC informed us that the International Court of Arbitration extended the time limit for the Tribunal to render a final decision in our ongoing binding arbitration with I-Mab from September 30, 2022 until November 30, 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties are to agree on a schedule for their respective cost submissions. The Tribunal did not indicate when it expects to render its award; however, it did note that it is far along in its deliberations and preparation of a final award. We expect the Tribunal to render its award in the first quarter of 2023.

Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs.

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 - 2022 and 2023 Final Data – 2024
Envafolimab + YH001		
Multiple Soft Tissue Sarcoma Subtypes	Phase 1/2 (planned)	2023 and 2024
TRC102		
Lung Cancer	Randomized Phase 2	2024

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, I-Mab, and Janssen. We continue to evaluate ex-U.S. 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 September 30, 2022, we had cash and cash equivalents totaling $17.2 million, of which $0.2 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 $22.1 million and $21.0 million for the nine months ended September 30, 2022 and 2021, respectively. At September 30, 2022, we had an accumulated deficit of $229.9 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 total expenses to remain relatively constant for the remainder of 2022 as we:

- continue to enroll the ENVASARC trial and initiate a 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, the outcome of our dispute with I-Mab, 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 the COVID-19 pandemic and actions taken to slow its spread, as well as adverse macroeconomic developments, such as the ongoing military conflict between Ukraine and Russia, 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.

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into two separate strategic collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies currently under development by I-Mab.

In the TJ004309 Agreement, we are collaborating with I-Mab on developing TJ004309, and will bear the costs of filing an IND application and for Phase 1 clinical trials, share costs equally for Phase 2 clinical trials, and we will bear 40% and I-Mab 60% of the costs for pivotal clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJ004309 and any reference drugs used in the development activities. We also agreed with I-Mab for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a JSC, as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab licenses rights to TJ004309 to a third party, we would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which we would be entitled escalate based on the phase of development and relevant clinical trial obligations we complete under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration. In March 2020, I-Mab issued a press release announcing a strategic partnership with KG Bio, whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. On April 8, 2020, we issued a notice of dispute regarding possible breach of the TJ004309 Agreement, which resulted in a binding arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal. The latest developments in the dispute with I-Mab are discussed in more detail below following the discussion of the Bispecific Agreement.

The TJ004309 Agreement may be terminated by either 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 TJ004309. I-Mab may also terminate the TJ004309 Agreement if we cause certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case we would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case we would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is “Complete,” as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab’s termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking an order of specific performance requiring us to comply with I-Mab’s effort to terminate the agreement. We disagreed with I-Mab’s position and in May 2021, the Delaware Court of Chancery stayed the lawsuit filed by I-Mab and subsequently this matter was remanded and included in the proceeding before the Tribunal.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a JSC up to five of I-Mab’s BsAb product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab’s right to co-promote an approved product candidate, we will be responsible for commercializing any approved product candidates in North America, and we will share profits and losses equally with I-Mab in North America. We would also be entitled to receive tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical trial for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trial costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical trials, we will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea and any other territories in which I-Mab previously licensed rights to a third party subject to our right of first refusal for any licenses I-Mab may grant to third-parties.

If we exercise our licensing option, we would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, we would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time we obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, we would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, we would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of a Phase 2 proof of concept clinical trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of a Phase 2 proof of concept clinical trial and before completion of a pivotal trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high-teens on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to our rights to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical studies or after initiating Phase 3 clinical studies and with our concurrence, we would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

In March 2020, we learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018. Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning the TJ004309 Agreement and Bispecific Agreement. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On September 29, 2022, the ICC informed us that the International Court of Arbitration extended the time limit for the Tribunal to render a final decision in our ongoing binding arbitration with I-Mab from September 30, 2022 until November 30, 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties are to agree on a schedule for their respective cost submissions. The Tribunal did not indicate when it expects to render its award; however, it did note that it is far along in its deliberations and preparation of a final award. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. As of the date of this Quarterly Report, the TJ004309 Agreement and Bispecific Agreement disputes remain under consideration by the Tribunal, and we expect the Tribunal to render its award in the first quarter of 2023. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Third-party research and development expenses:				
Envafolimab	$ 2,626	$ 1,897	$ 5,599	$ 4,207
YH001	89	—	158	—
TRC102	202	18	313	106
TJ004309	58	183	304	690
Total third-party research and development expenses	2,975	2,098	6,374	5,003
Unallocated expenses	1,122	632	3,639	3,079
Total research and development expenses	$ 4,097	$ 2,730	$ 10,013	$ 8,082

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

We expect our current level of research and development expenses for the remainder of 2022 and in 2023 to increase due to the continued enrollment of the ENVASARC trial and initiation of a 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 duration and scope of impact of the COVID-19 pandemic;
- 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 2022 and in 2023; however, there may be increases to the extent we have to expend additional legal fees in connection with enforcing and collecting any arbitration award from I-Mab.

Other Income (Expense)

Other income (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, 2021.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
		(in thousands)	
Research and development expenses	$ 4,097	$ 2,730	$ 1,367
General and administrative expenses	2,280	4,151	(1,871)
Other expense	(58)	(71)	13

Research and development expenses. Research and development expenses were $4.1 million and $2.7 million for the three months ended September 30, 2022 and 2021, respectively. The increase of $1.4 million was primarily due to the continued enrollment of the ENVASARC trial. We expect research and development expenses to continue to increase in future periods with our continued enrollment of the ENVASARC trial and the initiation of a 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 $4.2 million for the three months ended September 30, 2022 and 2021, respectively. The decrease of $1.9 million was primarily due to legal expenses incurred in 2021 in connection with the arbitration proceeding of our dispute with I-Mab regarding the TJ004309 Agreement and Bispecific Agreement. We expect continued decreases from legal expenses in future periods as we and I-Mab submitted our arbitration post-hearing briefs in May 2022. However, there may be increases to the extent we must expend additional legal fees in connection with enforcing and collecting any arbitration award from I-Mab.

Other expense. Other expense was $0.1 million for the three months ended September 30, 2022 and 2021.

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

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
		(in thousands)	
Research and development expenses	$ 10,013	$ 8,082	$ 1,931
General and administrative expenses	12,049	12,948	(899)
Other expense	(76)	(271)	195

Research and development expenses. Research and development expenses were $10.0 million and $8.1 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of $1.9 million was primarily due to the continued enrollment of the ENVASARC trial. We expect research and development expenses to continue to increase in future periods with our continued enrollment of the ENVASARC trial and initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

General and administrative expenses. General and administrative expenses were $12.0 million and $12.9 million for the nine months ended September 30, 2022 and 2021, respectively. The decrease of $0.9 million was primarily due to legal expenses incurred in 2021 in connection with the arbitration of disputes related to the TJ004309 Agreement and Bispecific Agreement. We expect continued decreases from legal expenses in future periods as we and I-Mab submitted our post-hearing briefs in May 2022. However, there may be increases to the extent we must expend additional legal fees in connection with enforcing and collecting any arbitration award from I-Mab.

Other expense. Other expense was $0.1 million and $0.3 million for the nine months ended September 30, 2022 and 2021, respectively.

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 September 30, 2022 will be sufficient to fund the current requirements of working capital and other financial commitments, including our long-term debt and operating lease obligations, into 2023. 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 unaudited condensed consolidated financial statements are issued.

We may fund our future liquidity needs by selling shares of our common stock under existing common stock purchase agreements, including our 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 September 30, 2022, we had an accumulated deficit of $229.9 million, and we expect to continue to incur net losses for the foreseeable future. We expect our current level of research and development expenses for the remainder of 2022 and in 2023 to increase due to the continued enrollment of the ENVASARC trial and initiation of a 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.

As of the date of this Quarterly Report, the TJ004309 Agreement and Bispecific Agreement disputes with I-Mab remain under consideration by the Tribunal, and we expect their final decision in the first quarter of 2023. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. If the Tribunal does decide to award us certain amounts in the arbitration and we were able to recover some or all of that award, such award and subsequent recovery may materially increase our liquidity.

Runway Growth Finance Corp. Loan and Security Agreement

In September 2022, we entered into a loan and security agreement with Runway Growth Finance Corp. (the RGC Loan Agreement). The RGC Loan Agreement is a long-term debt facility that provides 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; (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.

Borrowings under the term loan facility bear interest at a variable annual rate equal to the sum of (i) the greater of (a) the rate of interest noted in The Wall Street Journal, Money Rates section, as the "Prime Rate" or (b) 3.5%, plus (ii) 5.0%. We are obligated to make interest-only payments monthly in arrears through and including September 30, 2024 and thereafter monthly payments in arrears through the maturity date of September 1, 2026 equal to 1/24th of all outstanding principal plus accrued and unpaid interest.

We were obligated to pay a closing fee in the amount of (i) $50,000, which was paid upon the funding of the Term A loan, and (ii) an amount equal to 0.50% of the Term B loan and the Term C loan advanced to us , if any, due and payable on the applicable funding date of such Term B loan and Term C loan.

We are also obligated to pay a final payment fee equal to 4.25% of the aggregate principal amount of the funded term loans at the earlier to occur of (i) the maturity date, (ii) acceleration of the term loans and (iii) prepayment under the RGC Loan Agreement.

We have the option to prepay all, but not less than all, of the amounts of outstanding principal, accrued and unpaid interest and any other amounts due and payable under the RGC Loan Agreement, including a final payment fee. If we exercise our right to prepay the term loan(s) prior to the maturity date, we are obligated to pay a prepayment fee equal to (a) 3.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs on or prior to the first anniversary date, (b) 2.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the first anniversary date but on or prior to the second anniversary date and (c) 1.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the second anniversary date but prior to the maturity date.

Our obligations under the RGC Loan Agreement are collateralized by a first priority security interest in substantially all of our assets other than our intellectual property. The RGC Loan Agreement also contains customary representations, warranties and covenants that limit, among other things, our ability to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence and during the continuance of an event of default, a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lender may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the RGC Loan Agreement and under applicable law, including, without limitation, termination of its obligations to extend credit to us. The RGC Loan Agreement contains customary representations, warranties and covenants, including financial covenants, and also includes customary events of default, including payment defaults, breaches of covenants, change in control and a material adverse effect default.

In connection with the funding of the Term A loan, we issued Runway Growth Finance Corp. 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. In addition, in connection with the RGC Loan Agreement, additional warrants will be issued upon funding of the other term loan tranches, if any.

As of September 30, 2022, the total outstanding balance owed under the RGC Loan Agreement was $10.0 million and future minimum principal and interest payments were $1.2 million and $2.3 million for each of the next 12 and 24 months, respectively.

Registered Direct Offering

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.

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, $47.4 million of which remains available for sale as of September 30, 2022. 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 September 30, 2022, 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:

	Nine Months Ended September 30,	
	2022	**2021**
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (21,586)	$ (17,457)
Investing activities	(13)	3,961
Financing activities	14,739	11,266
Decrease in cash and cash equivalents	$ (6,860)	$ (2,230)

Operating activities. Net cash used in operating activities was $21.6 million and $17.5 million for the nine months ended September 30, 2022 and 2021, 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 $13,000 for the nine months ended September 30, 2022. Net cash provided by investing activities was $4.0 million for the nine months ended September 30, 2021 and was due to maturities of short-term investments.

Financing activities. Net cash provided by financing activities was $14.7 million for the nine months ended September 30, 2022 and primarily resulted from our $10.0 million debt financing with RGC, $6.4 million in net proceeds received from the Offering and periodic issuances and sales of our common stock under the Sales Agreement with JonesTrading, partially offset by $1.7 million in SVB loan repayments. Net cash provided by financing activities was $11.3 million for the nine months ended September 30, 2021 and primarily resulted from $13.4 million raised in connection with an underwritten public offering in July 2021, offset by $2.1 million in net repayments on borrowings under our SVB loan agreement.

Funding Requirements

At September 30, 2022, we had cash and cash equivalents totaling $17.2 million, of which $0.2 million is pledged as collateral for our obligations under our corporate headquarters facility lease. We believe that our cash and cash equivalents as of September 30, 2022, will be sufficient to fund our obligations into 2023. 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, including our collaborations with Eucure, Biocytogen, 3D Medicines, Alphamab, and I-Mab;
- our ability to achieve, and our obligations to make, milestone payments under our collaboration and license agreements;
- the outcome of our disputes with I-Mab with respect to the TJ004309 and Bispecific Agreements, our ability to recover any award resulting from that dispute and the timing of any termination of the TJ004309 Agreement;
- 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 macroeconomic effects, including as a result of 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, 3D Medicines and Alphamab, and I-Mab, 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 macroeconomic developments, such as the COVID-19 pandemic and actions taken to slow its spread, the 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, 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 are responsible for maintaining 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). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's (SEC) rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our Chief Executive Officer and Chief Financial Officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of September 30, 2022, 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 September 30, 2022, 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 disputes and related proceedings with I-Mab, see 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, 2021. 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.
- The COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.
- 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. Additionally, our ability to realize value from any product candidates developed under our agreements with I-Mab Biopharma (I-Mab) will depend in part on I-Mab's activities and willingness to fund future development.

- Our ability to realize value from any product candidates developed under our agreements with I-Mab will depend in part on I-Mab's activities and willingness to fund future development and the timing and outcome of our dispute with I-Mab of which we cannot predict the outcome and could materially adversely affect our ability to operate our business and financial results.
- The RGC Loan Agreement contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.
- We may be unable to adequately maintain and protect our intellectual property rights, including our licenses under collaboration agreements, which could impair the advancement of our product pipeline and our commercial opportunities.
- 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 $22.1 million and $21.0 million for the nine months ended September 30, 2022 and 2021, respectively. At September 30, 2022, we had an accumulated deficit of $229.9 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 increase in the remainder of 2022 and into 2023 due to the continued enrollment of the ENVASARC trial and initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

At September 30, 2022, we had cash and cash equivalents totaling $17.2 million, of which $0.2 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 September 30, 2022 will be sufficient to fund our operating expenses and capital requirements into 2023. We will need additional funding to complete the development and commercialization of product candidates, including envafolimab and YH001. In addition, in November 2018, we entered into separate collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs, 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. 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 macroeconomic developments, such as the COVID-19 pandemic, 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 continue to incur substantial legal expenses in connection with our on-going dispute with I-Mab, including in connection with enforcing and collecting any award from the arbitration process. 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, $47.4 million of which remains available for sale as of September 30, 2022. 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 macroeconomic developments, such as 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.

The RGC Loan Agreement contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.*

In September 2022, we entered into the RGC Loan Agreement that provides 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 on the closing of the RGC Loan 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. The RGC Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease or otherwise dispose of certain parts of our business or property;
- merge or consolidate with another entity;
- incur or assume certain debt;
- incur certain types of liens on our assets;
- make changes to certain collateral accounts or fall below a prespecified amount of liquidity;
- pay dividends or make other distributions to our stockholders;
- make certain loans or investments;
- enter into material transactions with affiliates; and
- voluntarily repay or prepay certain indebtedness.

The restrictive covenants of the RGC Loan Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the RGC Loan Agreement. An event of default will also occur upon the occurrence of, among other things, a material adverse effect on our business, operations, properties, assets or condition (financial or otherwise) , which could potentially include receipt of negative results in clinical trials, a material impairment in the perfection or priority of the lien in any collateral or value of such collateral, or a material adverse effect on the prospect of our repayment of any portion of the amounts we owe under the RGC Loan Agreement or in the ability of RGC to enforce its rights and remedies. In the case of a continuing event of default under the RGC Loan Agreement, RGC, on behalf of all lenders, could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted a security interest under the RGC Loan Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the RGC Loan Agreement are secured by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge arrangement. Should an event of default or continuing event of default occur or if RGC elects to exercise its rights or remedies in accordance with the RGC Loan Agreement, including accelerating any payments or proceeding against any collateral, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

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 COVID-19 actions taken to slow its spread or adverse macroeconomic developments, such as 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, 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, the COVID-19 pandemic has 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 the COVID-19 pandemic and other macroeconomic 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. 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 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 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 if the interim data from the ENVASARC trial is positive, 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 if our interim data with the 600mg dose from the ENVASARC trial is positive, 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, or cGMPs, and current good clinical practices, or 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.

Our ability to realize value from any product candidates developed under our agreements with I-Mab will depend in part on I-Mab's activities and willingness to fund future development and the timing and outcome of our dispute with I-Mab of which we cannot predict the outcome and could materially adversely affect our ability to operate our business and financial results.*

Pursuant to the terms of our strategic collaboration and clinical trial agreements with I-Mab, we are largely responsible for clinical development activities and I-Mab is responsible for pre-clinical development and manufacturing activities. Consequently, our ability to realize value or generate any revenues from the development of product candidates in collaboration with I-Mab will depend in part on I-Mab's willingness and ability to successfully complete pre-clinical development and manufacturing activities, in addition to funding agreed-upon portions of the costs of clinical development. We have limited control over the amount and timing of resources that I-Mab will dedicate to its respective efforts, and have limited rights in the event that I-Mab determines to cease development or manufacturing activities or funding for any product candidate under the collaboration. We could also encounter disagreements with I-Mab over the timing and scope of development or manufacturing of any product candidates or payments owed under the collaboration or which, if any, BsAb product candidates are selected for development. For example, in March 2020, I-Mab issued a press release announcing a strategic partnership with Kalbe Genexine Biologics (KG Bio), whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. In March 2020, we also learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018 (ABL Bio License 1 and ABL Bio License 2). Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning two strategic collaboration and clinical trial agreements with us entered into in November 2018. Those strategic collaboration and clinical trial agreements relate to the development of TJ004309 and 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. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an order of specific performance requiring us to comply with I-Mab's purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On September 29, 2022, the ICC informed us that the International Court of Arbitration extended the time limit for the Tribunal to render a final decision in our ongoing binding arbitration with I-Mab from September 30, 2022 until November 30, 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties are to agree on a schedule for their respective cost submissions. The Tribunal did not indicate when it expects to render its award; however, it did note that it is far along in its deliberations and preparation of a final award. We expect the Tribunal to render its award in the first quarter of 2023. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, which could materially adversely affect our ability to operate our business and our financial results, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs, as well as distract our management over an extended period. Until these disputes are concluded, we will be unable to provide a timeline as to when or if we will file an IND for a BsAb under the Bispecific Agreement. Furthermore, our ability to license bispecific product candidates from I-Mab may be more limited than we previously believed.

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. Under our collaboration and clinical trial agreement with I-Mab for TJ004309, we are prohibited from developing other biologic product candidates targeting the same indications for which TJ004309 is being developed, which increases our reliance on the success of I-Mab's activities with respect to TJ004309 and could limit our ability to collaborate with others with respect to biologic product candidates in certain indications. 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 Good Clinical Practice requirements (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, or 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. Several patent applications covering our product candidates have been filed recently. 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. Regarding the development of TJ004309 in North America, we hold a non-exclusive license from I-Mab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309.

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, envafolimab and associated intellectual property have been licensed from 3D Medicines and Alphamab, and TJ004309 and associated intellectual property have been licensed from I-Mab.

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 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 2031 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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. No legislation or administrative actions have been finalized to implement 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. 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. 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, 3D Medicines and Alphamab with respect to envafolimab, and I-Mab with respect to TJ004309 and potential BsAb candidates. 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 TJ004309, if I-Mab licenses rights to TJ004309 to a third party, while we would be entitled to receive varying portions of royalty and non-royalty payments from I-Mab, we would have no further rights to develop, commercialize or realize value from TJ004309. 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 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, 2021, we had U.S. federal and California net operating loss carryforwards (NOLs) of approximately $179.4 million and $144.4 million, respectively, certain of which begin to expire in 2030, if not utilized. As of December 31, 2021, we had $96.2 million of U.S. federal NOLs that were generated in tax years beginning after 2017 that will carryforward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of taxable income. As of December 31, 2021, we had U.S. federal and California research and development and Orphan Drug tax credit carryforwards of approximately $11.8 million and $2.7 million, respectively. The federal research and development and Orphan Drug tax credit carryforwards will begin expiring in 2031, if not utilized. The California research and development 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, or the CARES Act, modified certain provisions of the Tax Act and the recently enacted Inflation Reduction Act of 2022, or the Inflation Reduction Act, 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 Inflation Reduction Act 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 shareholders.

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 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, geopolitical developments such as the conflict between Ukraine and Russia, and increasing 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.

The COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.*

COVID-19, a novel strain of coronavirus (together with its variants, COVID-19), has become a global pandemic and many states and municipalities in the United States announced aggressive actions to reduce the spread of COVID-19, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions). For example, on March 19, 2020, the Executive Department of the State of California issued Executive Order N-33-20, ordering all individuals in the State of California to stay at their place of residence except as needed to maintain continuity of operations of the federal critical infrastructure sectors. Since then, almost all of our employees have been telecommuting, which has impacted certain of our operations and may continue to do so over the long term. We may experience further limitations on employee resources in the future, including because of sickness of employees or their families. While vaccines have become widely available in certain countries, and businesses and economies have reopened, the status of global economic recovery remains uncertain and unpredictable, and will continue to be impacted by developments in the pandemic including any subsequent waves of outbreak or new variant strains of the COVID-19 virus which may require re-closures or other preventative measures. The COVID-19 pandemic may also have long-term effects on the nature of the office environment and remote working, which may present risks for our strategy, operational, talent recruiting and retention, and workplace culture.

The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 may negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain. In addition, travel restrictions, quarantine requirements and shutdowns in business operations as a result of the pandemic have limited our ability to pursue our business development strategy with respect to China-based biopharmaceutical companies seeking U.S. drug development expertise. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, and our operations may be further limited or curtailed.

As COVID-19 continues to spread and new variants emerge, we may experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and trial procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed AEs; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. Our ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, including, without limitation, the effectiveness of government policies, vaccine mandates, vaccine shortages and administration rates, the emergence of new strains or variants of the virus, and other factors that are not foreseeable. Such developments are highly uncertain and cannot be predicted with confidence. Despite the increased availability of vaccines, due to the continuing and evolving nature of the COVID-19 pandemic and the potential for periods of increases in case numbers and emergence and spread of virus variants in markets and communities in which we, our collaborators, our manufacturers and our suppliers operate, as well as where our clinical trial participants are located, it is not possible for us to accurately predict the duration or magnitude of the adverse impacts of the pandemic and its effects on our business, results of operations or financial condition. Further, to the extent the COVID-19 pandemic and other recent global events adversely affects our business, results of operations, or financial condition, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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;
- the results of our dispute with I-Mab;
- 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 events, such as general political, health and economic conditions, including 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, 2021 through November 11, 2022, the closing price of our common stock has ranged between $1.30 and $11.65 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, for example, if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, 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.

A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company.

In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

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. Additionally, the RGC Loan Agreement contains covenants that restrict our ability to pay dividends or make other distributions. Any return to stockholders will therefore be limited to the appreciation of their stock.

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 changing 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, and other adverse business impacts.*

In the ordinary course of business, we process personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities also subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

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, and consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act). The California Consumer Privacy Act of 2018, or CCPA, imposes obligations on businesses to which it applies. These obligations include, without limitation, providing specific disclosures in privacy notices, affording California residents certain rights related to their personal data, and requiring businesses subject to the CCPA to implement certain measures to effectuate California residents' personal data rights. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). In addition, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. Other states have enacted data privacy laws. For example, Virginia passed its Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, and Utah passed the Consumer Privacy Act, all of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to 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 the personal data of individuals located, respectively, within the European Economic Area, or EEA, and the United Kingdom, or UK. Violators of these laws face significant penalties. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines up to €20 million or 4% of the annual global revenue, whichever is greater. The EU GDPR also provides for private litigation related to the processing of personal data that can be brought by classes of data subjects or consumer protection organizations authorized at law to represent the data subjects' interests.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfers laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to provide an adequate level of personal data protection. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual clauses are a valid mechanism to transfer personal data outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, laws in Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. In addition to European restrictions on cross-border personal data transfers, other jurisdictions have enacted or are considering similar cross-border personal data transfer laws and local personal data residency laws, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. Inability to import personal data to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. These obligations may be subject to differing applications and interpretations, which may be inconsistent among jurisdictions or in conflict. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and those of any third parties that process personal data on our behalf. In addition, these obligations may even require us to change to our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third-parties upon whom we rely may fail to comply such obligations that impacts our compliance posture.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related 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 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 revision or restructuring our operations.

If our information technology systems or data is or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations and harm to our reputation.*

In the ordinary course of our business, we, or the third parties upon which we rely, may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets. We may rely upon third-party service providers and technologies to operate critical business systems to process confidential and personal information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to business partners, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported 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 cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be 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), 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. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of 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. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. The COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Additionally, past or future business transactions (such as acquisitions or integrations), if any, 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.

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. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. A security incident could disrupt our (and third parties upon whom we rely) ability to conduct our clinical development activities. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and 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 may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. 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 disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing 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 products, deter new customers from using our products, 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.

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

The RGC Loan Agreement provides that, so long as it remains effective, we shall not pay any dividends or make any distribution or payment in respect of our equity interests, subject to limited exceptions.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

We previously announced that the ICC had extended the time limit for the Tribunal to render its Award in our ongoing binding arbitration with I-Mab until November 30, 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties are to agree on a schedule for their respective cost submissions. The Tribunal did not indicate when it expects to render its award; however, it did note that it is far along in its deliberations and preparation of a final award. We expect the Tribunal to render its award in the first quarter of 2023.

This disclosure is provided in this Part II, Item 5 in lieu of disclosure under Item 8.01 of Form 8-K.

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(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.
4.3(4)	Form of Common Warrant dated March 27, 2018.
4.4(5)	Form of Pre-Funded Warrant.
4.5(5)	Form of Amended and Restated Pre-Funded Warrant 1.
4.6(5)	Form of Amended and Restated Pre-Funded Warrant 2.
4.7(6)	Form of Common Stock Warrant Agreement and Warrant Certificate.
4.8(6)	Form of Preferred Stock Warrant Agreement and Warrant Certificate.
4.9(7)	Form of Warrant to Purchase Common Stock..
10.1(7)	Loan and Security Agreement by and among the Company, each other party thereto as a borrower from time to time, the lenders from time to time party thereto and Runway Growth Finance Corp., dated as of September 2, 2022.

Exhibit Number	Description of Document
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.
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

(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 Registration Statement on Form S-3, filed with the SEC on March 16, 2022.
(7) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on September 6, 2022.

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: November 14, 2022	/s/ Charles P. Theuer, M.D., Ph.D.
	Charles P. Theuer, M.D., Ph.D. *President and Chief Executive Officer* *(Principal Executive Officer)*
Date: November 14, 2022	/s/ Scott B. Brown, CPA
	Scott B. Brown, CPA Chief Financial Officer *(Principal Financial and Accounting Officer)*

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: November 14, 2022

/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: November 14, 2022

/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 September 30, 2022, 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: November 14, 2022

/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 September 30, 2022, 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: November 14, 2022

/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.