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, 2021

or

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

Commission File Number 001-36818

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

The number of outstanding shares of the registrant's common stock as of October 29, 2021 was 19,445,903.

TRACON Pharmaceuticals, Inc.

FORM 10-Q

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 29,901	$ 32,131
Short-term investments	—	3,999
Prepaid and other assets	1,241	784
Total current assets	31,142	36,914
Property and equipment, net	49	16
Other assets	1,617	508
Total assets	$ 32,808	$ 37,438
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 9,527	$ 6,235
Accrued compensation and related expenses	1,128	1,590
Long-term debt, current portion	2,079	2,718
Total current liabilities	12,734	10,543
Other long-term liabilities	1,211	432
Long-term debt, less current portion	—	1,391
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at September 30, 2021 and December 31, 2020; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 40,000,000 at September 30, 2021 and December 31, 2020; issued and outstanding shares — 19,430,369 and 15,478,787 at September 30, 2021 and December 31, 2020, respectively	19	15
Additional paid-in capital	218,908	204,166
Accumulated deficit	(200,064)	(179,109)
Total stockholders' equity	18,863	25,072
Total liabilities and stockholders' equity	$ 32,808	$ 37,438

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,	
	2021	2020	2021	2020
License revenue	$ —	$ —	$ 346	$ —
Operating expenses:				
Research and development	2,730	1,785	8,082	6,001
General and administrative	4,151	2,063	12,948	6,045
Total operating expenses	6,881	3,848	21,030	12,046
Loss from operations	(6,881)	(3,848)	(20,684)	(12,046)
Other expense:				
Interest expense, net	(69)	(141)	(269)	(412)
Other expense, net	(2)	(3)	(2)	(6)
Total other expense	(71)	(144)	(271)	(418)
Net loss	$ (6,952)	$ (3,992)	$ (20,955)	$ (12,464)
Net loss per share, basic and diluted	$ (0.38)	$ (0.38)	$ (1.27)	$ (1.69)
Weighted-average shares outstanding, basic and diluted	18,533,772	10,509,220	16,514,652	7,366,888

See accompanying notes.

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

	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
Issuances 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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2019	4,051,187	$ 4	$ 165,028	$ (162,334)	$ 2,698
Issuance of common stock under equity plans	2,078	—	(6)	—	(6)
Stock-based compensation expense	—	—	267	—	267
Issuances of common stock, net of offering costs	1,344,673	1	3,719	—	3,720
Issuance of common stock in exchange for services	100,000	—	126	—	126
Net loss	—	—	—	(4,021)	(4,021)
Balance at March 31, 2020	5,497,938	5	169,134	(166,355)	2,784
Issuance of common stock under equity plans	2,450	—	5	—	5
Stock-based compensation expense	—	—	263	—	263
Issuances of common stock, net of offering costs	2,273,427	3	4,399	—	4,402
Net loss	—	—	—	(4,451)	(4,451)
Balance at June 30, 2020	7,773,815	8	173,801	(170,806)	3,003
Stock-based compensation expense	—	—	240	—	240
Issuances of common stock and warrants, net of offering costs	5,908,838	6	16,229	—	16,235
Net loss	—	—	—	(3,992)	(3,992)
Balance at September 30, 2020	13,682,653	$ 14	$ 190,270	$ (174,798)	$ 15,486

See accompanying notes.

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (20,955)	$ (12,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,261	770
Common stock issued for services	—	126
Depreciation and amortization	10	10
Noncash interest	52	99
Amortization of debt discount	18	34
Amortization of premium/discount on short-term investments	(1)	—
Equity ownership license revenue	(246)	—
Lease asset amortization and liability accretion, net	(41)	(17)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(457)	(154)
Accounts payable and accrued expenses	3,364	(1,545)
Accrued compensation and related expenses	(462)	(275)
Net cash used in operating activities	(17,457)	(13,416)
Cash flows from investing activities		
Purchase of property and equipment	(39)	—
Proceeds from the maturity of available-for-sale short-term investments	4,000	—
Net cash provided by investing activities	3,961	—
Cash flows from financing activities		
Repayment of long-term debt	(2,100)	(933)
Proceeds from sale of common stock and warrants, net of offering costs	13,265	24,389
Proceeds from issuance of common stock under equity plans, net of tax withholdings	101	(1)
Net cash provided by financing activities	11,266	23,455
Change in cash and cash equivalents	(2,230)	10,039
Cash and cash equivalents at beginning of period	32,131	16,412
Cash and cash equivalents at end of period	$ 29,901	$ 26,451

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 ex-U.S. 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, 2021, 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, 2021, the Company had an accumulated deficit of $200.1 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. As of September 30, 2021, the Company had cash and cash equivalents of $29.9 million. Based on the Company's current business plan, management believes that existing cash and cash equivalents will be sufficient to fund the Company's obligations for a period in excess of one year from the date of issuance of these financial statements.

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 July 2021, the Company completed an underwritten public offering of 3,926,702 shares of its common stock at an offering price of $3.82 per share. The Company received net proceeds of approximately $13.4 million, after deducting underwriting discounts, commissions and offering-related expenses. In addition, the Company may fund its losses from operations through the common stock purchase agreement the Company entered into with Aspire Capital in October 2019, as amended in April 2020, for the purchase of up to $15.0 million of the Company's common stock over the 30 month period of the purchase agreement, $5.4 million of which remained available for sale as of September 30, 2021 and/or the Capital on Demand™ Sales Agreement (the Sales Agreement) the Company entered into with JonesTrading in December 2020, pursuant to which the Company may sell, at its option, up to an aggregate of $50.0 million of the Company's common stock, all of which remained available for sale as of September 30, 2021. 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, 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, 2021, and for the three and nine months ended September 30, 2021 and 2020, 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, 2020, included in its Annual Report on Form 10-K filed with the SEC on February 25, 2021.

Risks and Uncertainties

COVID-19, a novel strain of coronavirus, has become a global pandemic and has spread to over 100 countries, including the United States. 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.

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.

Use of Estimates

The Company's condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of the Company's 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 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.

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.

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 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 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, 2021 and 2020, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

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,	
	2021	2020
Warrants to purchase common stock	4,810,409	4,991,599
Common stock options and restricted stock units	1,295,808	622,552
ESPP shares	10,757	2,929
	6,116,974	5,617,080

2. Investments and Fair Value Measurements

At September 30, 2021, the Company had no short-term investments and at December 31, 2020, the Company's short-term investments consisted of U.S. treasury securities. 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.

Cash equivalents, which are classified as equity securities, and short-term investments, which are classified as available-for-sale securities, consisted of the following (in thousands):

	September 30, 2021				December 31, 2020			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds included in cash equivalents	$ 5,003	$ —	$ —	$ 5,003	$ 1,002	$ —	$ —	$ 1,002
U.S. treasury securities included in short-term investments	—	—	—	—	3,999	—	—	3,999
Equity securities included in other assets (1)	246	—	—	246	—	—	—	—
	$ 5,249	$ —	$ —	$ 5,249	$ 5,001	$ —	$ —	$ 5,001

(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.

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, 2021				
Money market funds	$ 5,003	$ —	$ 5,003	$ —
At December 31, 2020				
Money market funds and U.S. treasury securities	$ 5,001	$ —	$ 5,001	$ —

3. Long-Term Debt

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

	September 30, 2021	December 31, 2020
Long-term debt	$ 2,100	$ 4,200
Less debt discount, net of current portion	—	(9)
Long-term debt, net of debt discount	2,100	4,191
Less current portion of long-term debt	(2,100)	(2,800)
Long-term debt, net of current portion	$ —	$ 1,391
Current portion of long-term debt	$ 2,100	$ 2,800
Current portion of debt discount	(21)	(82)
Current portion of long-term debt, net	$ 2,079	$ 2,718

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 existing loan with SVB (the 2017 Amended SVB Loan). In accordance with the terms of the 2017 Amended SVB Loan, the Company paid a final payment of $0.3 million associated with the payoff of the 2017 Amended SVB Loan. The transaction was accounted for as a debt modification.

The 2018 Amended SVB Loan provides for interest to be paid at a rate of 9.0% per annum. Interest-only payments were due monthly through June 30, 2019. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at June 30, 2019 divided by 30 months. In April 2020, the Company entered into a deferral agreement with SVB (the Deferral Agreement) for an interest-only payment period of six months, with a corresponding six-month extension to the maturity date to June 2022. All other key terms and conditions of the 2018 Amended SVB Loan remained unchanged and the transaction was accounted for as a debt modification.

At maturity (or earlier prepayment), the Company is required to make a final payment equal to 4.0% of the original principal amount borrowed.

The 2018 Amended SVB Loan is collateralized by substantially all of the Company's assets, other than the Company's intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. Should an event of default occur, including the occurrence of a material adverse change, the Company could be liable for immediate repayment of all obligations under the 2018 Amended SVB Loan. As of September 30, 2021, the Company was in compliance with all covenants and conditions of the 2018 Amended SVB Loan.

In connection with the 2018 Amended SVB Loan, the Company issued SVB a warrant to purchase 5,363 shares of its common stock at an exercise price of $26.10 per share. The warrant is fully exercisable and expires on May 3, 2025. The fair value of the warrant and the final payment related to the 2018 Amended SVB Loan were recorded as debt discounts and are being amortized to interest expense using the effective interest method over the term of the debt, in addition to the remaining unamortized discounts related to the 2017 Amended SVB Loan.

At September 30, 2021, 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
May 13, 2022	1,841	$ 108.60
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
	15,747	

As of September 30, 2021, future minimum principal and interest payments under the 2018 Amended SVB Loan, including the final payment, are as follows (in thousands):

Remaining 2021	$ 742
2022	1,717
	2,459
Less interest and final payment	(359)
Long-term debt	$ 2,100

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 of the license agreements is generally cancelable by the Company, given appropriate prior written notice. At September 30, 2021, potential future milestone payments under these agreements totaled an aggregate of $9.6 million.

5. Stockholders' Equity

Sales of Common Stock

In July 2021, the Company completed an underwritten public offering of 3,926,702 shares of its common stock at an offering price of $3.82 per share. The Company received net proceeds of approximately $13.4 million, after deducting underwriting discounts, commissions and offering-related expenses.

In December 2020, the Company issued and sold 1,612,844 shares of its common stock at an average purchase price of $8.84 per share for net proceeds of $13.6 million in two registered direct offerings with certain institutional investors.

In August 2020, the Company issued and sold 2,633,838 shares of its common stock at an average purchase price of $1.66 per share and warrants to purchase 3,429,696 shares of its common stock at an average purchase price of $1.64 per warrant share with an exercise price of $0.01 per share (the Pre-Funded Warrants) for net proceeds of approximately $10.0 million in a private placement with multiple accredited institutional health care focused funds. In accordance with their terms, the Pre-Funded Warrants may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99% of the Company's total shares outstanding following such exercise. The Pre-Funded Warrants were recorded as a component of stockholders' equity within additional paid-in capital on the consolidated balance sheets.

In October 2019, the Company entered into a Common Stock Purchase Agreement , which was amended in April 2020 (the 2019 Purchase Agreement), with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth in the 2019 Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock solely at the Company's request from time to time during the 30 month period of the agreement and at prices based on the market price at the time of each sale. In consideration for entering into the 2019 Purchase Agreement and concurrently with the execution of the 2019 Purchase Agreement, the Company issued 142,658 shares of its common stock to Aspire Capital. As of September 30, 2021, the Company had sold an aggregate 4.8 million shares of common stock under the 2019 Purchase Agreement with Aspire Capital for net proceeds of $9.6 million.

At-The-Market Issuance Sales Agreement

In December 2020, 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, all of which remains available for sale as of September 30, 2021. Sales of the Company's common stock made pursuant to the JonesTrading Agreement, if any, will be made on the Nasdaq Capital Market under the Company's effective registration statement on Form S-3, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the JonesTrading Agreement, the Company may also sell shares of its common stock through JonesTrading, on the Nasdaq Capital Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading will use its commercially reasonable efforts to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is required to pay JonesTrading 2.5% of gross proceeds for the common stock sold through the Sales Agreement.

Equity Plan Activity

During the three months ended September 30, 2021, the Company issued 1,703 shares of common stock upon the exercise of outstanding stock options, no shares of common stock upon the vesting of restricted stock units, and no shares of common stock in connection with the employee stock purchase plan (the ESPP). During the nine months ended September 30, 2021, the Company issued 3,727 shares of common stock upon the exercise of outstanding stock options, no shares of common stock upon the vesting of restricted stock units, and 21,153 shares of common stock in connection with the ESPP. During the year ended December 31, 2020, the Company issued no shares of common stock upon the exercise of outstanding stock options, 2,078 shares of common stock upon the vesting of restricted stock units, net of shares withheld to settle the employees' minimum statutory tax obligations for income and other related employment taxes, and 4,550 shares of common stock in connection with the ESPP.

Common Stock Warrants

As of September 30, 2021, the Company had the following outstanding warrants for the purchase of common stock:

Expiration	Number of shares	Exercise price
May 13, 2022	1,841	$ 108.60
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
March 27, 2025	176,554	$ 0.10
May 3, 2025	5,363	$ 26.10
August 27, 2027	1,889,513	$ 0.01
August 31, 2027	1,358,993	$ 0.01
	4,810,409	

During the three and nine months ended September 30, 2021, no warrants were exercised. During the year ended December 31, 2020, 181,190 Pre-Funded Warrants were exercised for net proceeds of $2,000.

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,	
	2021	2020	2021	2020
Risk-free interest rate	0.9%	—	0.8%	1.2%
Expected volatility	89%	—	90%	86%
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, 2021 and 2020.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 176	$ 81	$ 447	$ 293
General and administrative	325	159	814	477
	$ 501	$ 240	$ 1,261	$ 770

6. Licenses and Collaborations

3D Medicines and Alphamab

In December 2019, the Company, 3D Medicines Co., Ltd. (3D Medicines), and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb), or nanobody, administered by subcutaneous injection, for the treatment of sarcoma in North America. No consideration was exchanged in the Envafolimab Collaboration Agreement. Given no consideration was exchanged, no value was assigned to the Envafolimab Collaboration Agreement in the accompanying consolidated balance sheets.

Pursuant to the Envafolimab Collaboration Agreement, the Company was granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. The Company is responsible for conducting, and will bear the costs of Phase 1, Phase 2, and Phase 3 or post-approval clinical trials 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 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 the Company 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.

The Company 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 a 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, the Company has 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 the Company as the party responsible for commercialization, and the Company elects and 3D Medicines and Alphamab agree for the Company to not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate the Company for its costs associated with preparing for and conducting commercial activities.

If the Company has the responsibility for commercialization under the Envafolimab Collaboration Agreement, the Company 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, the Company will be entitled to (a) escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if the Company has chosen to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if the Company has 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, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without the Company’s written consent and the parties must negotiate in good faith and agree to fair compensation to be paid to the Company for the value of and opportunity represented by the required 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 the Company elects, or a joint steering committee determines, to cease further development or commercialization of envafolimab, or if the Company fails to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and does not cure such failure within a specified time period, then the Company’s rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

I-Mab

In November 2018, the Company and I-Mab Biopharma (I-Mab) entered into separate strategic collaboration and clinical trial agreements (the I-Mab Collaboration Agreements) for the development of programs for multiple immuno-oncology product candidates, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ004309 Agreement) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the Bispecific Agreement).

No consideration was exchanged in the I-Mab Collaboration Agreements. Given the early preclinical stage of development of these assets as of the agreement date, no value was assigned to the I-Mab Collaboration Agreements in the accompanying consolidated balance sheets.

TJ004309 Agreement

Pursuant to the TJ004309 Agreement, the Company and I-Mab are collaborating on developing the TJ004309 antibody, with the Company bearing the costs of filing an IND and for Phase 1 clinical trials, with the parties sharing costs equally for Phase 2 clinical trials, and with the Company and I-Mab bearing 40% and 60%, respectively, of the costs for pivotal clinical trials. I-Mab will be responsible for the cost of certain non-clinical activities, the drug supply of TJ004309, and any reference drugs used in the clinical trials. Each of the parties also agreed 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 joint steering committee (JSC), as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab out-licenses the rights to TJ004309 to a third party, the Company would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to certain territories outside of Greater China. In the event that I-Mab commercializes TJ004309, the Company would be entitled to receive a royalty percentage 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 the Company would be entitled will escalate based on the phase of development and relevant clinical trial obligations the Company completes 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 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. On April 8, 2020, the Company issued a notice of dispute to I-Mab as the Company believes it may be entitled to receive a payment under the TJ004309 Agreement, although I-Mab has disputed the payment is due. The dispute is before an ICC arbitration tribunal seated in New York City and will be arbitrated under New York law with the hearing set for February 2022. The Company cannot currently estimate the likely outcome of the dispute under the TJ004309 Agreement. In February 2021, May 2021, and July 2021, I-Mab sent the Company notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing the Company a prespecified early 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 the Company 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 the Company to comply with I-Mab's effort to terminate the agreement. The Company disagreed with I-Mab's position, and in May 2021, the Delaware Court of Chancery stayed the lawsuit filed by I-Mab pending a determination of substantive arbitrability from the arbitration tribunal, and subsequently this matter was included in the proceeding before the ICC arbitration tribunal.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party, bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if the Company causes 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 the Company 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 the Company would be entitled to a pre-specified termination fee of $15.0 million and either a low double-digit percentage of non-royalty consideration up to $35.0 million that I-Mab may receive as part of a license to a third party, or an additional payment of $35.0 million 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.

Bispecific Agreement

Pursuant to the Bispecific Agreement, the Company and I-Mab may mutually select through a joint steering committee (JSC) up to five of I-Mab's bispecific antibody 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, while the Company will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and the Company 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, the Company will be responsible for commercializing any approved product candidates in North America and will share profits and losses equally with I-Mab in North America. The Company would also be entitled to 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 the Company's objections after initiating Phase 3 clinical trials, the Company 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 the Company's right of first refusal for any licenses I-Mab may grant to third-parties.

If the Company exercises the option, it 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, the Company 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 the Company obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, the Company 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, the Company 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 Phase 2 proof of concept clinical trial for the collaborative product, the Company 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 Phase 2 proof of concept clinical trial and before completion of pivotal trial for the collaborative product, the Company 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-teen double digits 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 the Company's right to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical trials or after initiating Phase 3 clinical trials and with the Company's concurrence, the Company 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, bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

In March 2020, the Company 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 bispecific antibody (the 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 bispecific antibody 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. On April 8, 2020, the Company issued a notice of dispute regarding possible breach of the Bispecific Agreement related to I-Mab having previously entered into ABL License 1 and ABL License 2. The dispute is before an ICC arbitration tribunal seated in New York City and will be arbitrated under New York law with the hearing set for February 2022. The Company cannot currently estimate the likely outcome of the dispute under the Bispecific Agreement. Until the dispute is concluded, the Company may be unable to provide a timeline as to when or if it will file an IND for a bispecific antibody under the Bispecific Agreement.

Janssen

In September 2016, the Company entered into a license and option agreement with Janssen (the License and Option Agreement) under which Janssen granted the Company a license to technology and intellectual property to develop, manufacture and commercialize two compounds: a small molecule inhibitor of androgen receptor and androgen receptor mutations (the AR Mutant Program or TRC253) which is intended for the treatment of men with prostate cancer, and an inhibitor of NF-kB inducing kinase (the NIK Program or TRC694). Following completion of the pre-clinical development of TRC694, the Company determined the compound did not warrant further development and, in February 2019, issued written notice to terminate the License and Option Agreement with respect to the NIK Program and returned TRC694 and all rights thereto to Janssen. Following completion of the TRC253 Phase 1/2 trial, the Company determined commercialization of TRC253 in prostate cancer in the United States was not viable and, in May 2021, issued written notice to terminate the License and Option Agreement with respect to the AR Mutant Program and returned TRC253 and all rights thereto to Janssen.

No consideration was exchanged for these assets on the acquisition date. Given the early preclinical stage of development of these assets and the low likelihood of success of development through regulatory approval on the acquisition date, no value was previously assigned to these assets in the accompanying consolidated balance sheets.

Enviro and Kairos

In May 2021, the Company entered into a license and supply agreement with Enviro Therapeutics Inc. (Enviro) and Kairos Pharma, Ltd. (Kairos) under which the Company granted to Enviro access to inactive IND filings for TRC105 in the United States, ownership of existing supplies of TRC105 drug product, and assignment of the Company's patent rights to CD105 technologies, which includes the TRC105 antibody.

In consideration of the transfer and assignment, the Company received a one-time, non-refundable, non-creditable upfront payment in the amount of $0.1 million and equity ownership in Enviro, subject to certain specified reductions. In addition, the Company received anti-dilution protection of its equity ownership in Enviro, subject to certain specified reductions, and is eligible to receive up to a total of $1.0 million in milestone payments upon the achievement of specified financing events, and a single-digit royalty on worldwide net sales of TRC105.

Under the terms of the agreement, Enviro has sole responsibility for funding, developing, seeking regulatory approval for and commercializing TRC105 product candidates. Enviro has the right to grant sublicenses to affiliates and third-party collaborators and in the event Enviro sublicenses any of its rights under the agreement, Enviro would be obligated to pay the Company a single-digit percentage of all consideration received under such sublicense.

The Company assessed this agreement and identified multiple promised goods and services, which included at contract inception: (1) assignment of patent rights to CD105 technologies, (2) access to inactive IND filings for TRC105 in the United States, and (3) transfer of ownership of TRC105 drug product. All performance obligations were satisfied by June 30, 2021, which completed the Company's obligations under the terms of the agreement.

The transaction price included the $0.1 million upfront payment and equity in Enviro valued at $0.2 million, all of which had been fully recognized as revenue as of June 30, 2021. The value of the Company's equity ownership in Enviro was estimated based on the fair value of observable market prices. The remaining $1.0 million of potential financing milestone payments were not considered probable at contract inception or at September 30, 2021, and therefore no amounts have been included in the transaction price for these remaining milestones. In addition, any royalty payments will be recognized when the related sales occur and have therefore also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

7. Leases

The Company's operating lease obligations relate to its corporate headquarters as the Company leases its office space under a non-cancelable operating lease. The Company amended its lease in August 2021 extending the lease term to April 2027. The lease is subject to base lease payments and additional charges for common area maintenance and other costs and includes certain lease incentives and tenant improvement allowances. Operating lease expense was $0.1 million and $0.3 million for the three and nine months ended September 30, 2021, respectively, and $0.1 million and $0.3 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, the Company does not have any finance leases, nor any other operating leases.

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Cash paid within operating cash flows	$ 344	$ 330
ROU assets recognized in exchange for new lease obligations	$ 1,117	$ —

Supplemental balance sheet information related to operating leases was as follows (in thousands, except lease term and discount rate):

	September 30,	
	2021	2020
Reported as:		
Other assets (ROU asset)	$ 1,371	$ 595
Accounts payable and accrued expenses (lease liability)	$ 182	$ 402
Other long-term liabilities (lease liability)	1,211	263
Total lease liabilities	$ 1,393	$ 665
Weighted average remaining lease term	5.6	1.6
Weighted average discount rate	11.3%	11.3%

As of September 30, 2021, the maturities of the Company's operating lease liabilities are as follows (in thousands):

Remaining 2021	$ 117
2022	285
2023	320
2024	334
2025	349
2026	365
Thereafter	123
Total lease payments	1,893
Less imputed interest	(500)
Total operating lease liabilities	$ 1,393

Under the terms of the lease agreement, the Company provided the lessor with an irrevocable letter of credit in the amount of $175,000. The lessor is entitled to draw on the letter of credit in the event of any default by the Company under the terms of the lease.

8. Subsequent Events

Eucure and Biocytogen Collaborative Development and Commercialization Agreement

On October 8, 2021, the Company, Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen), Eucure's controlling affiliate, 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, the Company was 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, renal cell carcinoma (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 the Company's discretion (each upon such substitution, a Substitute Indication). The Company is 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 chemistry, manufacturing and controls activities for YH001. Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to the Company for clinical trials pursuant to the terms of a clinical supply and quality agreement to be separately negotiated.

During a specified period, the Company has 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 will be responsible for commercializing YH001 in North America, including booking of sales revenue in the Initial and Substitute Indications. The Company 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, the Company 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 the Company at cost plus a low double digit markup for commercial sales pursuant to the terms of a commercial supply and quality agreement to be separately negotiated.

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 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 ex-U.S. 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. In December 2020, we announced the dosing of the first patient in the ENVASARC Phase 2 pivotal trial (the ENVASARC trial), which will enroll approximately 160 patients with the sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS). The trial includes one cohort of approximately 80 patients who receive single agent treatment with envafolimab and a second cohort of approximately 80 patients who receive envafolimab in combination with Yervoy® (ipilimumab), a checkpoint inhibitor marketed by Bristol-Myers Squibb (BMS), with the primary endpoint in each of the cohorts being objective response rate (ORR) by blinded central review. Achieving the primary endpoint of ORR could be the basis for accelerated approval of envafolimab by the U.S. Food and Drug Administration (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® (pazopanib) 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. Nine or more objective responses among the 80 patients expected to enroll in cohort A or cohort B would be sufficient to demonstrate that envafolimab or envafolimab combined with Yervoy, respectively, have an ORR that is statistically superior to the 4% ORR reported for Votrient in refractory soft tissue sarcoma.

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 demonstrated partial responses, each with a duration of response of greater than six months. In June and August 2021, the Independent Data Monitoring Committee (IDMC) recommended that the ENVASARC trial proceed as planned following the review of safety data from the more than 20 patients enrolled in the trial at that time.

Assuming sufficient patient responses in line with meeting the ENVASARC trial endpoint, we intend to apply for breakthrough therapy or fast track designation with the FDA for envafolimab for the treatment of soft tissue sarcoma subtypes in the United States in 2021. We expect final response assessment data from the ENVASARC trial in 2022, and, assuming positive data, to submit a biologics license application to the FDA seeking accelerated approval in 2023. Additionally, assuming positive interim data from the ENVASARC trial, we plan to initiate a trial in multiple soft tissue sarcoma subtypes to expand the target patient population.

The initial interim efficacy analysis occurs following the 12-week efficacy scan in the 36th enrolled patient, to allow for determination of the preliminary objective response rate. There must be at least one response among the initial 18 patients enrolled into each cohort to continue enrollment in that cohort per the futility rules of the study. We expect to release data from the initial interim efficacy analysis by the end of this year and to release data from the second interim efficacy analysis following the 12-week efficacy scan in the 92nd enrolled patient in 2022.

In April 2021, a poster highlighting the ENVASARC trial was presented at the American Association for Cancer Research (AACR) virtual meeting, which provided details on the ENVASARC trial design. A poster highlighting the ENVASARC clinical trial design was also presented at the American Society for Clinical Oncology (ASCO) virtual meeting in June 2021.

Our other clinical stage oncology product candidates include YH001, which is a monospecific investigational 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 by Eucure for the treatment of various cancer indications. Cytotoxic T-lymphocyte-associated protein 4, or CTLA-4, is a protein expressed on T-cells that is expressed at high levels on regulatory T-cells ("Tregs") and contributes to the suppressor function of Tregs and acts as a checkpoint to inhibit effector T-cell immune responses to cancer cells. The CTLA-4 inhibitor Yervoy (ipilimumab) marketed by Bristol Myers Squibb has been approved as a single agent in melanoma and approved in combination with other therapies in multiple indications including non-small cell lung cancer, renal cell carcinoma (RCC) and microsatellite instability high colorectal cancer. As of August 9, 2021, YH001 had been dosed to more than 34 patients in China and Australia. No CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma. We intend to initiate a Phase 1/2 clinical trial of YH001 in combination with envafolimab and with doxorubicin chemotherapy, an approved treatment for soft tissue sarcoma, in 2022. Additionally, we plan to initiate trials of YH001 in combination with approved immunotherapy 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 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, TRC102 received ODD from the FDA 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 and further data of the combination of TRC102 and Temodar in lung cancer patients are expected in 2021. We expect further development by the NCI in MGMT deficient glioblastoma based on these data and believe a trial in first line glioblastoma patients of Temodar, radiation therapy and TRC102 is warranted. 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, we also expect further development by the NCI of TRC102 in advanced localized lung cancer patients.

TJ004309, also known as TJD5 or ulilediimab, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) 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 ulilediimab (TJ004309), a differentiated CD73 antibody, in combination with atezolizumab in patients with advanced cancer", ulilediimab was found to be well-tolerated up to 20 mg/kg every three weeks (Q3W) and 15 mg/kg once weekly as a monotherapy and in combination therapy with atezolizumab 1200 mg Q3W 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 partial responses (PR) 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 following treatment with ulilediimab and atezolizumab. We expect completion of the TJ004309 Phase 1 trial in early 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 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 bispecific antibody (the 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. On April 8, 2020, we issued a notice of dispute regarding possible breaches of the TJ004309 Agreement and the Bispecific Agreement. As of the date of this Quarterly Report, these disputes have not been resolved. We believe that based on these transactions, we may be

entitled to receive payments under the TJ004309 Agreement, although I-Mab has disputed the payment is due. The dispute is before an ICC arbitration tribunal seated in New York City and will be arbitrated under New York law with the hearing set for February 2022. We cannot currently estimate the likely outcome of the dispute under the TJ004309 Agreement or the Bispecific Agreement. Until the dispute is concluded, we may be unable to provide a timeline as to when or if we will file an IND for a bispecific antibody under the Bispecific Agreement. Furthermore, our ability to license bispecific product candidates from I-Mab may be more limited than we previously believed. In February 2021, May 2021, and July 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 pending a determination of substantive arbitrability from the arbitration tribunal, and subsequently this matter was included in the proceeding before the ICC arbitration tribunal.

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 - 2021 and 2022 Final Data - 2022
Envafolimab + YH001		
Multiple Soft Tissue Sarcoma Subtypes	Phase 1/2 (planned)	2023 and 2024
TRC102		
Solid Tumors and Lymphomas	Phase 1/2	2021
TJ004309		
Solid Tumors	Phase 1	2022

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 under our credit facility with Silicon Valley Bank (SVB). At September 30, 2021, we had cash and cash equivalents totaling $29.9 million.

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 $16.8 million and $22.7 million for the years ended December 31, 2020 and 2019, respectively. At September 30, 2021, we had an accumulated deficit of $200.1 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 expenses to increase in 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;
- seek regulatory approvals for product candidates that successfully complete clinical trials; and
- incur legal expenses in connection with the arbitration on the TJ004309 Agreement and Bispecific Agreement.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more product candidates, which we expect will take a number of years. If we obtain regulatory approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, and distribution. Accordingly, we will need to raise substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts, developments under our collaboration agreements, including whether and when we receive milestone and other potential payments, and the timing and nature of the regulatory approval process for product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Further, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. As a result of the COVID-19 pandemic and actions taken to slow its spread, 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 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, renal cell carcinoma (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 chemistry, manufacturing and controls 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 within 90 days after the effective date of the YH001 Collaboration Agreement.

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 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 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 to I-Mab as we may be entitled to receive a payment under the TJ004309 Agreement, although I-Mab has disputed the payment is due. The dispute is before an ICC arbitration tribunal seated in New York City and will be arbitrated under New York law with the hearing set for February 2022. We cannot currently estimate the likely outcome of the dispute under the TJ004309 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 February 2021, I-Mab sent us a notice purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified early 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 pending a determination of substantive arbitrability from the arbitration tribunal, and subsequently this matter was included in the proceeding before the ICC arbitration tribunal.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a JSC up to five of I-Mab's bispecific antibody 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 the ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize the 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. On April 8, 2020, we issued a notice of dispute regarding possible breach of the Bispecific Agreement. The dispute is before an ICC arbitration tribunal seated in New York City and will be arbitrated under New York law with the hearing set for February 2022. We cannot currently estimate the likely outcome of the dispute under the Bispecific Agreement. Until the dispute is concluded, we may be unable to provide a timeline as to when or if we will file an IND for a bispecific antibody under the Bispecific Agreement. Furthermore, our ability to license bispecific product candidates from I-Mab may be more limited than we previously believed.

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,	
	2021	2020	2021	2020
	(in thousands)			
Third-party research and development expenses:				
Envafolimab	$ 1,897	$ 270	$ 4,207	$ 506
TRC102	18	109	106	165
TRC253	—	140	166	732
TJ004309	183	459	690	1,133
Total third-party research and development expenses	2,098	978	5,169	2,536
Unallocated expenses	632	807	2,913	3,465
Total research and development expenses	$ 2,730	$ 1,785	$ 8,082	$ 6,001

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

We expect our current level of research and development expenses to increase in 2022 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. As a result of the COVID-19 pandemic and actions taken to slow its spread, many clinical trial sites have temporarily suspended dosing of previously-enrolled patients and/or enrollment of new patients, and patients in clinical trials may choose to not enroll, not participate in follow-up clinical visits or drop out of trials as a precaution against, or as a result of, contracting COVID-19. These events have impacted our clinical trials and those of our collaborators and we cannot predict with certainty the extent to which the COVID-19 pandemic will ultimately delay our clinical trials or those of our collaborators or increase our expenses in completing clinical trials. 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 obtaining and maintaining patents, insurance, occupancy costs, accounting services, and the cost of various consultants.

We anticipate that our general and administrative expenses for the remainder of 2021 will decrease compared to the first half of 2021 given the Delaware Court of Chancery stayed the lawsuit filed by I-Mab but will be higher compared to prior years due to legal related expenses incurred in connection with the continued arbitration on the TJ004309 Agreement and Bispecific Agreement.

Other Income (Expense)

Other income (expense) primarily consists of interest related to our loan agreement with SVB offset in part by interest income from our short-term investments and cash equivalents.

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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these 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, 2020.

Results of Operations

Comparison of the three months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Research and development expenses	2,730	1,785	945
General and administrative expenses	4,151	2,063	2,088
Other expense	(71)	(144)	73

Research and development expenses. Research and development expenses were $2.7 million and $1.8 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $0.9 million was primarily due to the continued enrollment of the ENVASARC trial.

General and administrative expenses. General and administrative expenses were $4.2 million and $2.1 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $2.1 million was primarily due to legal expenses incurred in connection with the arbitration of our dispute with I-Mab regarding the TJ004309 Agreement and Bispecific Agreement.

Other expense. Other expense was $0.1 million for the three months ended September 30, 2021 and 2020.

Comparison of the nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
License revenue	$ 346	$ —	$ 346
Research and development expenses	8,082	6,001	2,081
General and administrative expenses	12,948	6,045	6,903
Other expense	(271)	(418)	147

License revenue. License revenue was $0.3 million for the nine months ended September 30, 2021 and related to revenue recognized under the Enviro license agreement with no corresponding revenue in the comparable period in 2020.

Research and development expenses. Research and development expenses were $8.1 million and $6.0 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $2.1 million was primarily due to the continued enrollment of the ENVASARC trial.

General and administrative expenses. General and administrative expenses were $12.9 million and $6.0 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $6.9 million was primarily due to legal expenses incurred in connection with the lawsuit filed by I-Mab in the Delaware Court of Chancery and arbitration on the TJ004309 Agreement and Bispecific Agreement.

Other expense. Other expense was $0.3 million and $0.4 million for the nine months ended September 30, 2021 and 2020, respectively.

Liquidity and Capital Resources

Our sources of cash liquidity include our cash and cash equivalents. In July 2021, we completed an underwritten public offering which resulted in net proceeds to us of approximately $13.4 million (July 2021 Financing). We believe that our cash and cash equivalents as of September 30, 2021 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. We may also fund our future liquidity needs by selling shares of our common stock under existing common stock purchase agreements, including our common stock purchase agreement with Aspire Capital and our Capital on Demand™ sales agreement with JonesTrading Institutional Services LLC (JonesTrading). In addition to our existing common stock purchase agreements, we periodically consider various other financing alternatives and may, from time to time, seek to take advantage of favorable interest rate environments or other market conditions.

We have incurred losses and negative cash flows from operations since our inception. As of September 30, 2021, we had an accumulated deficit of $200.1 million, and we expect to continue to incur net losses for the foreseeable future. We expect our current level of research and development expenses to increase in 2022 due to the 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. 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.

Common Stock Purchase Agreement with Aspire Capital

In October 2019, as amended in April 2020, we entered into the 2019 Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations of the 2019 Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of our common stock at our request from time to time during the 30 month term of the 2019 Purchase Agreement and at prices based on the market price of our common stock at the time of each sale. In consideration for entering into the 2019 Purchase Agreement and concurrently with the execution of the 2019 Purchase Agreement, we issued to Aspire Capital 142,658 shares of our common stock. As of September 30, 2021, we had sold an aggregate of approximately 4.8 million shares of common stock under the 2019 Purchase Agreement with Aspire Capital for net proceeds of $9.6 million.

ATM Facility

In December 2020, 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, all of which remains available for sale as of September 30, 2021. 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, 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.

Credit Facility with SVB

In May 2018, we entered into a third amendment to our Amended and Restated Loan and Security Agreement with SVB (the 2018 Amended SVB Loan) under which we borrowed $7.0 million, all of which was used to refinance previously outstanding amounts under the loan and security agreement. In connection with the 2018 Amended SVB Loan, we issued warrants to purchase up to 5,363 shares of common stock at an exercise price of $26.10 per share. The warrants are fully exercisable and expire on May 3, 2025.

The 2018 Amended SVB Loan provides for interest to be paid at a rate of 9.0% per annum, with interest-only payments due monthly through June 30, 2019. Thereafter, in addition to interest accrued during such period, the monthly payments include an amount equal to the outstanding principal at June 30, 2019 divided by 30 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 4.0% of the original principal amount of the amounts borrowed. In April 2020, we entered into an agreement with SVB (Deferral Agreement) which granted us an interest-only payment period for six months, with a corresponding six-month extension to the maturity date which is now June 2022. All other material terms and conditions of the 2018 Amended SVB Loan remained unchanged.

The 2018 Amended SVB Loan is collateralized by substantially all of our assets, other than our intellectual property, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be required to immediately repay all obligations

under the 2018 Amended SVB Loan. As of September 30, 2021, we were in compliance with all covenants and conditions of the 2018 Amended SVB Loan.

As of September 30, 2021, the total outstanding balance owed under the 2018 Amended SVB Loan amounted to $2.1 million. As of September 30, 2021, future minimum principal and interest payments under the 2018 Amended SVB Loan, including the final payment, were $2.5 million in the next 12 and 24 months.

Operating Lease Obligations

Our operating lease obligations relate to our corporate headquarters in San Diego, California. In August 2021, we amended our lease, which now expires in April 2027. As of September 30, 2021, future minimum lease payments under this lease were $0.3 million and $0.6 million in 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,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (17,457)	$ (13,416)
Investing activities	3,961	—
Financing activities	11,266	23,455
Decrease in cash and cash equivalents	$ (2,230)	$ 10,039

Operating activities. Net cash used in operating activities was $17.5 million and $13.4 million for the nine months ended September 30, 2021 and 2020, 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 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 $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. Net cash provided by financing activities was $23.5 million during the nine months ended September 30, 2020 and primarily resulted from $10.0 million in net proceeds received from the sale of common stock and Pre-Funded warrants in a private placement, $9.6 million in sales of our common stock under our 2019 Purchase Agreement with Aspire Capital, and $4.8 million in net proceeds through sales of common stock through our ATM facility with JonesTrading, offset by $0.9 million in net repayments on borrowings under our SVB loan agreement.

Funding Requirements

At September 30, 2021, we had cash and cash equivalents totaling $29.9 million. In July 2021, we completed an underwritten public offering which resulted in net proceeds to us of approximately $13.4 million. We believe that our cash and cash equivalents as of September 30, 2021, 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.

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 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 the COVID-19 pandemic delays 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 the COVID-19 pandemic and actions taken to slow its spread, 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 SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports 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, 2021, 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, 2021, 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

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 Note 6, *Collaborations*, of the Notes to Condensed Consolidated Financial Statements, included in Item 1 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, 2020. 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.

Risk Factors Summary

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.
- Our loan and security agreement with Silicon Valley Bank (SVB) 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.
- 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 National Cancer Institute (NCI) to advance clinical development of TRC102 and also depend in part on Case Western 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 for certain sarcoma subtypes 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 YH001 and envafolimab 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.

- 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 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 $16.8 million and $22.7 million for the years ended December 31, 2020 and 2019, respectively. At September 30, 2021, we had an accumulated deficit of $200.1 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.*

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 2022 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, 2021, we had cash and cash equivalents totaling $29.9 million. In July 2021, we completed an underwritten public offering which resulted in net proceeds to us of approximately $13.4 million. Based upon our current operating plan, we believe that our existing cash and cash equivalents 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 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.

Regardless of our expectations, changing circumstances beyond our control, including the COVID-19 pandemic, 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 that could increase our development costs more

than we expect. 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, we entered into a Capital on Demand™ Sales Agreement (JonesTrading Agreement) with JonesTrading Institutional Services LLC (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, all of which remains available for sale as of September 30, 2021. In October 2019, we entered into a Common Stock Purchase Agreement (2019 Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) pursuant to which, upon the terms and subject to the conditions and limitations set forth in the 2019 Purchase Agreement, as amended in April 2020, Aspire Capital committed to purchase up to an aggregate of $15.0 million of shares of our common stock at our request from time to time. As of September 30, 2021, we had sold an aggregate 4.8 million shares of common stock under the 2019 Purchase Agreement with Aspire Capital for net proceeds of $9.6 million. While the JonesTrading Agreement and 2019 Purchase Agreement provide us with additional options to raise capital through sales of our common stock, there can be no guarantee that we will be able to sell shares under either 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 JonesTrading Agreement from time to time, and while Aspire Capital is obligated to purchase shares of our common stock under the 2019 Purchase Agreement, the obligation is subject to our satisfaction of various conditions which we may not be able to meet in the future. If sales are made under either the JonesTrading Agreement or the 2019 Purchase 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 the COVID-19 pandemic and actions taken to slow its spread, 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. 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, 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.

Our loan and security agreement with Silicon Valley Bank, or SVB, 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.

On May 3, 2018, we entered into an amended loan and security agreement with SVB to borrow $7.0 million, all of which was used to refinance amounts outstanding under prior credit facilities with SVB. The agreement, as amended, 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;
- change the nature of our business;
- liquidate or dissolve;
- enter into certain change in control or acquisition transactions;
- incur or assume certain debt;
- grant certain types of liens on our assets;
- maintain certain collateral accounts;

- pay dividends or make certain distributions to our stockholders;
- make certain investments;
- enter into material transactions with affiliates;
- make or permit certain payments on subordinate debt; and
- become an "investment company" as defined under the Investment Company Act of 1940, as amended.

The restrictive covenants of the 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 agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, SVB could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted SVB a security interest under the agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

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. 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 or actions taken to slow its spread, 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 after this offering.

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.

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 and other difficulties in starting or competing our clinical trials due to the COVID-19 pandemic.

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, or 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 National Cancer Institute, or NCI, or other third party clinical trial sponsors, 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, we cannot guarantee that for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression-free survival, the agency will not 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 Biologics License Application, or BLA, or a New Drug Application, or 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 products, 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 verity 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. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. The FDA may also 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 biliary tract cancer, an indication that is outside the scope of our current license agreement with 3D Medicines.

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

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

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

A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma if our interim data 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, or 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 adverse events 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 specifically, 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 sarcoma, microsatellite stable colorectal cancer, renal cell carcinoma (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). 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.

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, bispecific antibody 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 bispecific antibody (the 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. On April 8, 2020, we issued a notice of dispute regarding possible breaches of the TJ004309 and Bispecific Agreements we signed with I-Mab in November 2018. As of the date of this filing, these disputes have not been resolved. We believe that based on these transactions, we may be entitled to receive a payment under the TJ004309 Agreement, although I-Mab has disputed the payment is due. The dispute is before an ICC arbitration tribunal seated in New York City and will be arbitrated under New York law with the hearing set for February 2022. We cannot currently estimate the likely outcome of the dispute under the TJ004309 Agreement or the Bispecific Agreement. Until the dispute is concluded, we may be unable to provide a timeline as to when or if we will file an IND for a bispecific antibody under the Bispecific Agreement. Furthermore, our ability to license bispecific product candidates from I-Mab may be more limited than we previously believed. In February 2021, May 2021, and July 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 pending a determination of substantive arbitrability from the arbitration tribunal, and subsequently this matter was included in the proceeding before the ICC arbitration tribunal.

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 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.

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 sarcoma, microsatellite stable colorectal cancer, renal cell carcinoma, 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. 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 European Union 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 European Union 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 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 U.S. 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 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 European Union, 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. Thus, the ACA will remain in effect in its current form. 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, which ran February 15, 2021 through August 15, 2021. 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. 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, including the Bipartisan Budget Act of 2018, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. In January 2013, the former U.S. President 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.

Recently 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump signed several executive orders that attempt to implement several of the Trump administration proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the former President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN interim final rule. 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, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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;
- 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 bispecific antibody 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) and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives; 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 European Union is governed by the General Data Protection Regulation, or the GDPR. The 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 GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third party transactions, but also to transfers of information within our company, including employee information. The 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 European Union. 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 European Union 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, 2020, we had federal and California net operating loss carryforwards, or NOLs, of approximately $152.5 million and $117.7 million, respectively, which expire in various years beginning in 2030, if not utilized. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal NOLs generated in tax years beginning after 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after 2020 is limited to 80% of taxable income. As of December 31, 2020, we had federal and California research and development and Orphan Drug tax credit carryforwards of approximately $10.3 million and $2.5 million, respectively. The federal research and development and Orphan Drug tax credit carryforwards expire in various years beginning 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, or the 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 (including, without limitation, legislation enacted by California in June 2020 that suspends the use of California NOLs and limits the use of California R&D tax credits for certain years), 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 CARES Act modified certain provisions of the Tax Act and proposals have recently been made in Congress (which have not yet been enacted) to increase the federal income tax rate applicable to corporate income and make other tax law changes that could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. The impact of the Tax Act and CARES Act and any future changes in tax laws on holders of our common stock is also uncertain and could be adverse.

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, has become a global pandemic and many states and municipalities in the United States announced aggressive actions to reduce the spread of the disease, 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. 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 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, 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 adverse events; 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, some of our clinical trial sites have started to slow down or stop further enrollment of new patients in clinical trials, denied access to site monitors and otherwise curtailed certain operations. Similarly, 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. We and our CROs have also made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. 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.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. 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, which are highly uncertain and cannot be predicted with confidence.

Risks Related to Our Common Stock

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

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

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- any delay in submitting a BLA or an NDA for any product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that marketing application;
- failure to successfully develop and commercialize product candidates;
- changes in laws or regulations applicable to product candidates;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors;
- failure to maintain our collaboration and clinical trial agreements;
- failure of 3D Medicines or Alphamab to perform their obligations under our collaboration and clinical trial agreements, or the actions of 3D Medicines or Alphamab or their other partners with respect to envafolimab in other indications or outside North America;
- failure of Eucure and Biocytogen to perform their obligations under our collaborative development and commercialization agreement, or the actions of Eucure or Biocytogen or their other partners with respect to YH001 in other indications or outside North America, or within North America in combination with other Eucure product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- 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, 2020 through October 29, 2021, the closing price of our common stock has ranged between $0.95 and $12.20 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 any of the Nasdaq listing requirements 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, 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, our credit agreement with SVB contains covenants that restrict our ability to pay dividends. 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.

General Risk Factors

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

We are dependent upon our own or third party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, malicious intrusion, or random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our clinical trial data, intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. 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 risks and any security breach of their systems could adversely affect us. A security breach or privacy violation that leads to disclosure or modification of, or prevents access to, patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Any of these events 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 of our obligations to our third party collaborators, and significantly increase our costs to recover or reproduce the data. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

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 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.

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.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business.

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. 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(4)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TRACON Pharmaceuticals, Inc.
3.3(1)	Amended and Restated Bylaws.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(3)	Registration Rights Agreement, dated October 18, 2019, by and between the Registrant and Aspire Capital Fund, LLC.
4.3(5)	Securities Purchase Agreement, dated August 26, 2020, by and between TRACON Pharmaceuticals, Inc. and the purchaser listed on Exhibit A thereto (including the form of Pre-Funded Warrant).
4.4(6)	Securities Purchase Agreement, dated August 28, 2020, by and between TRACON Pharmaceuticals, Inc. and the purchasers listed on Exhibit A thereto (including the form of Pre-Funded Warrant).
4.5(7)	Securities Purchase Agreement, dated December 21, 2020, by and between the Registrant and the purchasers listed on Exhibit A thereto.
4.6(8)	Securities Purchase Agreement, dated December 28, 2020, by and between the Registrant and the purchaser listed on Exhibit A thereto.
10.1*	Collaborative Development and Commercialization Agreement by and among the Registrant, Eucure (Beijing) Biopharma Co., Ltd. and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. dated October 8, 2021.
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

* Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted because they are both not material and the type that the Registrant treats as private or confidential. The Registrant hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

(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 Registration Statement on Form S-1 (File No. 333-201280), as amended.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on October 21, 2019.

(4) Incorporated by reference to the Registrant Current Report on Form 8-K, filed with the SEC on November 6, 2019.

(5) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 27, 2020.

(6) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 31, 2020.

(7) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on December 22, 2020.

(8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on December 29, 2020.

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 3, 2021

/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 3, 2021

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

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE TRACON PHARMACEUTICALS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO TRACON PHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.

COLLABORATIVE DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This **Collaborative Development and Commercialization Agreement** (the "**Agreement**") is entered into on October 8, 2021 (the "**Effective Date**") between **Tracon Pharmaceuticals, Inc.**, a Delaware corporation, with its principal place of business at 4350 La Jolla Village Drive, Suite 800, San Diego, CA, USA ("**Tracon**"), **Eucure (Beijing) Biopharma Co., Ltd.**, a company organized and existing under the laws of the People's Republic of China and having its registered address at 23F, Tower 3, China Central Place, No.77, Jian Guo Road, Chaoyang District, Beijing, China ("**Eucure**"), and, solely with respect to Section 13.15, Eucure's controlling Affiliate **Biocytogen Pharmaceuticals (Beijing) Co., Ltd.**, a company organized and existing under the laws of the People's Republic of China and having its registered address at No.12, Baoshen South Street, Daxing Bio-Medicine Industry Park, 102600 Daxing District, Beijing, China ("**Parent**"). Eucure and Tracon are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

Whereas, Eucure has developed and possesses the rights to a YH001 , and wishes to collaborate with Tracon with respect to the clinical development and commercialization of such monoclonal antibody;

Whereas, Tracon is a biopharmaceutical company engaged in the research, development and future commercialization of pharmaceutical products, including novel targeted therapeutics for oncology applications; and

Whereas, the Parties wish to conduct the development and clinical trials for this antibody, and the Parties agree to share the economic interest in resulting product, all on the terms and conditions set forth herein.

Now Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.

1.1 "**Accounting Standards**" means U.S. generally accepted accounting principles, the People's Republic of China generally accepted accounting principles, or International Financial Reporting Standards, as consistently applied.

1.2 "**Affiliate**" means, with respect to a Party, any corporation, firm, partnership or other entity, which directly or indirectly controls or is controlled by or is under common control with such Party. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, by contract or otherwise.

1.3 "**Agreement**" has the meaning set forth in the preamble.

1.4 "**Antibody**" means Eucure's proprietary YH001 [***], as further described in the Patents listed in Exhibit A.

1.5 "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Regulatory Approvals) of or from any court, arbitration panel, Regulatory Authority, governmental agency, stock exchange (including the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time), or any authority having jurisdiction over or related to subject item or subject person, including GLP, GCP, GMP, the FCPA, Export Control Laws and other laws, in each case as applicable.

1.6 "**BLA**" means a biologics license application for Regulatory Approval of a biologic product.

1.7 "**Business Day**" means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by Applicable Laws to be closed in San Diego, California or Beijing, China.

1.8 "**Calendar Quarter**" means each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30, or December 31.

1.9 "**Calendar Year**" means each successive period of twelve (12) consecutive calendar months ending on December 31.

1.10 "**Change of Control**" means, with respect to a Party: (a) the sale of all or substantially all of such Party's (or any of its controlling Affiliates') assets or business relating to the subject matter of this Agreement; (b) a merger, reorganization or consolidation involving such Party (or a controlling Affiliate thereof) in which the voting securities of such Party (or such controlling Affiliate, as applicable) outstanding immediately prior thereto cease to represent at

least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) the acquisition by a person or entity of more than fifty percent (50%) of the voting equity securities or management control of such Party (or a controlling Affiliate thereof) as a result of a single transaction or a series of related transactions.

1.11 "**Clinical Supply and Quality Agreement**" has the meaning set forth in Section 4.3(a).

1.12 "**CMO**" means a contract manufacturing organization.

1.13 "**CMO Supply Agreement**" means a contract manufacturing and services agreement between Eucure and CMO for the supply of Collaborative Product.

1.14 "**Collaborative Product**" means any pharmaceutical composition or preparation comprising Antibody; *provided*, *however*, Collaborative Product excludes (i) compositions comprising bi-specific or multi-specific antibodies targeting both the same target as Antibody and other different target(s); and (ii) co-formulations of Antibody in a fixed dose combination with one or more other active ingredient(s) having an independent therapeutic effect.

1.15 "**Collaborative Product IP**" means any and all intellectual property rights, including Patents, copyrights, trademarks and Know-How, that are (a) Controlled by Eucure or any of its Affiliates as of the Effective Date or at any time during the Term and (b) (i) claim or cover a Collaborative Product, or (ii) are necessary or useful for the Development, manufacture, marketing, promotion, distribution, use, sale, import or other exploitation of a Collaborative Product. For clarity, Collaborative Product IP includes any and all intellectual property rights that are Controlled by Eucure or any of its Affiliates within the Development IP.

1.16 "**Collaborative Products License**" has the meaning set forth in Section 3.1.

1.17 "**Collaborative Territory**" means the United States, Canada, Mexico and each of their dependent territories.

1.18 "**Commercialize**", "**Commercialized**" or "Commercialization" means any and all activities effective to market, promote, advertise, sell, offer for sale, have sold or otherwise dispose of, transport, distribute, import or export, branding, preparation for the launch and medical education regarding a Collaborative Product, and interacting with Regulatory Authorities in connection with any of the foregoing after all Regulatory Approvals have been obtained in the applicable country or region.

1.19 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party pertaining to a particular objective, the objective, reasonable, diligent, good faith efforts to accomplish such objective in an active and ongoing program as a similarly situated (with respect to size, stage of development, and assets) biotechnology or pharmaceutical company, as the case may be. Such efforts shall be substantially no less than the efforts and resources commonly used by such Party (or a similarly situated biotechnology or pharmaceutical company

for pharmaceutical or biological products, as applicable) to accomplish a similar objective under similar circumstances exercising reasonable business judgment, taking into account the following factors to the extent applicable: stage of development, mechanism of action, efficacy and safety issues, characteristics of competitive products in or anticipated to be in the marketplace, process development, scale-up or manufacturing, Third Party intellectual property rights, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Regulatory Approval, and projected or actual economic return; provided that, with respect to Tracon's obligation to Develop and Commercialize Products, Commercially Reasonable Efforts shall be no less than the efforts expended by Tracon in connection with its other high priority projects. Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Collaborative Product, and it is anticipated that the level of effort may be different for different markets, and may change over time, reflecting changes in the status of each such Collaborative Product and the market(s) involved.

1.20 "**Competing Product**" shall mean any monospecific pharmaceutical product other than the Collaborative Product that contains anti-CTLA-4 monoclonal antibody, whether sold alone or in combination with other products. For clarity, Competing Product shall not include (a) bi-specific or multi-specific agents or oncolytic viruses that have multiple targets and are additionally specific to a target other than CTLA-4, or (b) the specific combination therapy comprising the anti-CTLA-4 monoclonal antibody known as ipilimumab (YERVOY®) that is proprietary to Bristol-Myers Squibb and the anti-PD-L1 antibody known as envafolimab that is proprietary to Tracon, for which Tracon is conducting a Phase 2 Study (NCT No. NCT04480502).

1.21 "**Competing Program**" has the meaning set forth in Section 3.7(a).

1.22 "**Completion**" means, with respect to a clinical trial, the locking of the database that contains the data collected from such clinical trial in a manner consistent with industry standards to enable final data analysis and reporting.

1.23 "**Confidential Information**" means, with respect to a Party, all know-how, data and other information of a financial, commercial, business, operational or technical nature of such Party that is: (a) disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic form; or (b) learned by the other Party pursuant to this Agreement. Notwithstanding anything contained herein to the contrary, (i) the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the Receiving Party with respect thereto) and (ii) all Development IP and Development Data shall be deemed to be the Confidential Information of the Party that owns such Development IP and Development Data (and the owning Party shall be deemed to be the Disclosing Party and the non-owning Party shall be deemed to be the Receiving Party with respect thereto).

1.24 "**Control**" or "**Controlled**" means, with respect to an item of Know-How, Patent or other intellectual property rights, the ability and authority of a Party or its Affiliates, whether

arising by ownership, possession, or pursuant to a license or sublicense (other than by operation of the license and other rights granted in this Agreement) or a right to acquire (by option or otherwise), to grant licenses, sublicenses, or other rights to the other Party under or to such item of Know-How, Patent or other intellectual property rights as provided for in this Agreement, without breaching the terms of any agreement between such Party and any Third Party.

1.25 "**Cost of Goods**" or "**COGS**" means the per unit cost for clinical or commercial supply of Collaborative Product as determined by Eucure's Accounting Standards, as consistently applied. If the Collaborative Product is manufactured by a CMO, the COGS shall be the per unit amount paid to the CMO for the manufacture and supply of the Collaborative Product.

1.26 "**CTLA-4**" means cytotoxic T-lymphocyte-associated protein 4.

1.27 "**Develop**", "**Developed**" or "**Development**" means all activities that relate to the development of a Collaborative Product for use in the Field or that are necessary or useful to obtain or maintain Regulatory Approval for such Collaborative Product, including all non-clinical studies and clinical trials of such Collaborative Product, technology transfer, manufacture process development and manufacture (with respect to Eucure only; for clarity, Development activities conducted by Tracon shall not include any manufacture process development or manufacture activity), labelling, packaging and distribution of such Collaborative Product for use in clinical trials (including placebos and comparators), statistical analyses, and the preparation and submission of regulatory materials and other regulatory activities related to such Collaborative Product.

1.28 "**Development Activities**" means all Development activities performed by or on behalf of either or both Parties pursuant to this Agreement.

1.29 "**Development Costs**" means all costs incurred by or on behalf of either Party or its Affiliates that are reasonably allocable in accordance with such Parties' Accounting Standard, as consistently applied, to the Development of a Collaborative Product in the Field in the Collaborative Territory as delineated herein, which for clarity may include costs for conducting clinical trials in the United Kingdom and European Union as determined by the JSC.

1.30 "**Development Data**" means all data generated by or on behalf of Tracon or its Affiliates in the course of, and as a result of, the performance of the Development Activities and directly relating to the Development of a Collaborative Product in the Field in the Collaborative Territory, including data related to all non-clinical studies and clinical trials of such Collaborative Product, which for clarity may include data from clinical trials in the United Kingdom and European Union as determined by the JSC, technology transfer, manufacture process development, manufacture and distribution of such Collaborative Product for use in clinical trials (including placebos and comparators), statistical analyses, and the preparation and submission of regulatory materials and other regulatory activities related to such Collaborative Product.

1.31 "**Development IP**" means any and all inventions, other than Development Data, that are specific to Collaborative Product or its use and are generated in connection with the

Development of the Collaborative Product in the Field in the Collaborative Territory by or on behalf of Tracon or its Affiliates during the Term, and any and all intellectual property rights therein (including Patents, copyrights, trademarks and Know-How).

1.32 "**Development Plan**" has the meaning set forth in Section 4.1.

1.33 "**Disclosing Party**" has the meaning set forth in Section 9.1.

1.34 "**Divest**" or "**Divestiture**" means, with respect to a Competing Program, the sale or transfer of rights to such Competing Program, including all technology, intellectual property, and other assets relating solely thereto, by a Party or its Affiliate to a Third Party in an arm's-length transaction, such that neither such Party nor any of its Affiliates has any right or obligation to engage in any Development, Commercialization, management, governance or decision-making activities in connection with such Competing Program.

1.35 "**Effective Date**" has the meaning set forth in the preamble.

1.36 "**Eucure**" has the meaning set forth in the preamble.

1.37 "**Eucure Combination Therapy**" means a combination therapy comprising the administration of two products: (a) a Collaborative Product for intravenous or subcutaneous administration and (b) an other product (other than a Collaborative Product) comprising at least one (1) other compound, molecule, product or product candidate (that is not the Antibody) consisting of one or more of Eucure's proprietary pipeline compounds, and any other necessary treatment agents.

1.38 "**Eucure Indemnitees**" has the meaning set forth in Section 8.1.

1.39 "**Eucure BLA Submission**" has the meaning set forth in Section 3.6(c).

1.40 "**Eucure Study Report**" has the meaning set forth in Section 3.6(c).

1.41 "**Eucure Territory**" means all territories of the world other than the Collaborative Territory.

1.42 "**European Union**" means the economic, scientific and political organization of European Union member states as it may be constituted from time to time, specifically including any territory that was a European Union member state as of the Effective Date, whether or not such territory is a participating member as of the applicable time.

1.43 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50

U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.44 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.45 "**FDA**" means the U.S. Food and Drug Administration, or any successor Regulatory Authority thereto in the U.S. having substantially the same function.

1.46 "**Field**" means human therapeutic applications of the Collaborative Product administered by intravenous or subcutaneous means for (a) sarcoma, (b) microsatellite stable colorectal cancer ("**mssCRC**"), (c) renal cell carcinoma ("**RCC**"), and (d) K-ras positive non-small cell lung cancer ("**K-ras NSCLC**"), subject to any substitution or addition of Indications pursuant to Section 3.6 or otherwise mutually agreed upon by the Parties; *provided*, *however*, in the event that Tracon exercises the Tracon Option, the Field shall thereafter be the Development and Commercialization of all human and veterinary therapeutic applications of the Collaborative Product administered by intravenous or subcutaneous means for all Indications.

1.47 "**First Commercial Sale**" means the first sale by Tracon or its Affiliate for value for end use or consumption of such Collaborative Product in a country in the Collaborative Territory after the governing Regulatory Authority of such country has granted Regulatory Approval of such Collaborative Product. For clarity, any sale of a Collaborative Product prior to receipt of Regulatory Approval, such as compassionate use, named patient use, clinical trial purposes or other similar uses will not constitute a First Commercial Sale.

1.48 "**GLP**" means the Good Laboratory Practices standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by NMPA or other Regulatory Authority applicable to the Collaborative Territory, as may be updated from time to time, including applicable quality guidelines promulgated under the ICH..

1.49 "**GCP**" means the Good Clinical Practices officially published by the Medicinal Health Regulatory Authority, European Medicines Agency (and any successor agency), the FDA and the ICH that may be in effect from time to time and are applicable to the Development of Collaborative Product.

1.50 "**GMP**" means those laws and regulations applicable in the U.S., United Kingdom, and European Union, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", US Federal Food Drug and Cosmetic Act at 21 C.F.R. (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC that may be in effect from time to time and are applicable to the Development or manufacture of Collaborative Product.

1.51 "**HKEx**" means the Stock Exchange of Hong Kong Limited.

1.52 "**ICC**" has the meaning set forth in Section 12.3(a).

1.53 "**ICH**" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.54 "**IND**" means an investigational new drug application, clinical trial application, clinical trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to commence human clinical trials in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312.

1.55 "**Indication**" means a separate and distinct disease, disorder or condition: (a) which the Collaborative Product is intended to treat or prevent, as evidenced by the protocol for a clinical trial of the Collaborative Product or by the proposed Collaborative Product labeling in a Regulatory Approval application filed with a Regulatory Authority for the Collaborative Product, or (b) which is contained in the Collaborative Product's labeling approved by a Regulatory Authority as part of the Regulatory Approval for the Collaborative Product. The Parties agree that: (i) any genetically defined cancer (*e.g.*, where an explicit genetic mutation is the basis for enrollment in a clinical trial) is a separate Indication from other cancers lacking such genetic characteristic; (ii) the treatment or prevention of the same disease, disorder or condition in different populations (e.g., adult and pediatric or treatment of naïve and relapsed/refractory) shall not be treated as separate Indications; and (iii) with respect to any cancer type, the treatment of different stages within such cancer type based on the size or extent of the primary tumor and whether or not cancer has spread in the body (e.g., different stages in the TNM cancer staging system) shall not be treated as separate Indications.

1.56 "**Infringement**" has the meaning set forth in Section 10.4.

1.57 "**Initiate**" or "**Initiation**" means, with respect to a clinical trial, the first dosing in the first patient in such clinical trial.

1.58 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 2.2(a).

1.59 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1(a).

1.60 "**Know-How**" means tangible and intangible information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), processes, formulations, compounds, products, biological materials, cell lines (it being understood that any rights to use "Know-How" include the rights to use such cell lines), samples of assay components, media, designs, formulas, ideas, programs, software models, algorithms, developments, experimental works, protocols, methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and non-clinical and clinical data and results),

compilations of data, other works of analytical and quality control data, results, descriptions, compositions of matter, regulatory submissions, minutes, correspondence and strategy.

1.61 "**Losses**" has the meaning set forth in Section 8.1.

1.62 "**Net Sales**" shall mean the gross amounts invoiced for sales or other dispositions of a Collaborative Product by Tracon or any of its Affiliates (each, a "**Selling Party**") to Third Parties, less deductions actually incurred, allowed, paid, accrued or otherwise reasonably allocated to such Collaborative Product by the Selling Party in accordance with the Selling Party's Accounting Standards, as consistently applied, for:

(a) trade, cash and quantity discounts or rebates actually allowed or taken;

(b) credits or allowances given or made for rejection of or return of previously sold Collaborative Products or for retroactive price reductions and billing errors or for stocking allowances;

(c) governmental and other rebates (or credits or other equivalents thereof) granted to managed health care organizations, commercial insurance companies, pharmacy benefit managers (or equivalents thereof), distributors, national, state/provincial, local, and other governments, their agencies and purchasers, and reimbursors, or to trade customers;

(d) costs of freight, insurance, and other transportation charges directly related to the distribution of Collaborative Products, to the extent included in gross invoiced sales prices; and

(e) taxes, duties or other governmental charges (including any tax such as a value added or similar tax or government charge other than an income tax) levied on or measured by the billing amount for Collaborative Products, as adjusted for rebates and refunds.

In no event shall any particular amount, identified above, be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of reductions). Sales of a Collaborative Product between a Party and its Affiliates for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Collaborative Product to a Third Party are included in the computation of Net Sales. Sale, disposal or use of such Collaborative Product for Development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, without consideration, shall not be deemed a sale hereunder.

1.63 "**Parent**" has the meaning set forth in the preamble.

1.64 "**Party**" or "**Parties**" has the meaning set forth in the preamble.

1.65 "**Patents**" means (a) patents, re-examinations, reissues, renewals, extensions and term restorations, and foreign counterparts of any of the foregoing, (b) pending applications for patents, including provisional applications, continuations, continuations-in-part, requests for

continued examination, divisional and substitute applications, including inventors' certificates of any of the foregoing, and (c) foreign counterparts of any of the foregoing.

1.66 "**Phase 1 Study**" means a human clinical trial in the U.S. that would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), or its substantial equivalence if such clinical trial is conducted outside the U.S.

1.67 "**Phase 2 Study**" means a human clinical trial in the U.S. that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), or its substantial equivalence if such clinical trial is conducted outside the U.S.

1.68 "**Phase 3 Study**" means a human clinical trial in the U.S. that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), or its substantial equivalence if such clinical trial is conducted outside the U.S.

1.69 "**Pivotal Trial**" means: (a) a Phase 3 Study; or (b) any other human clinical trial that the applicable Regulatory Authority has agreed, whether before first dosing of the first patient in such trial (*e.g.*, pursuant to a special protocol assessment agreement with the FDA) or after first dosing of the first patient in such trial (*e.g.*, based on an interim data analysis), is sufficient to form the primary basis of an efficacy claim in an application for Regulatory Approval, regardless of whether the sponsor of such trial characterizes or refers to such trial as a "Phase 3," "Phase 2b" or "Phase 2b/3" trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context. If a human clinical trial does not constitute a Pivotal Trial at the time of first dosing of the first patient in such trial, but is later determined by the applicable Regulatory Authority to be sufficient to form the primary basis of an efficacy claim in an application for Regulatory Approval, then, for purposes of this Agreement, "Initiation" of such Pivotal Trial shall be deemed to have occurred on the date of such determination by the applicable Regulatory Authority.

1.70 "**Quality Agreement**" has the meaning set forth in Section 4.3(b).

1.71 "**Receiving Party**" has the meaning set forth in Section 9.1.

1.72 "**Regulatory Approval**" means, with respect to a particular country or regulatory jurisdiction, all approvals (including any legally required pricing approvals) that are necessary for the commercial sale of a Collaborative Product in such country or regulatory jurisdiction.

1.73 "**Regulatory Authority**" means any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction, including the FDA.

1.74 "**Representatives**" has the meaning set forth in Section 9.1.

1.75 "**Royalty Term**" has the meaning set forth in Section 6.1(d).

1.76 "**SDEA**" has the meaning set forth in Section 4.5(a).

1.77 "**SEC**" has the meaning set forth in Section 9.3(b).

1.78 "**SFC**" means Securities and Futures Commission of Hong Kong.

1.79 "**Successful Launch Milestone**" has the meaning set forth in Section 6.1(c).

1.80 "**Term**" has the meaning set forth in Section 11.1.

1.81 "**Third Party**" means any person or entity other than a Party or an Affiliate of a Party.

1.82 "**Third Party Claim**" has the meaning set forth in Section 8.1.

1.83 "**Tracon**" has the meaning set forth in the preamble.

1.84 "**Tracon Delay**" shall mean a delay in performance of any Development activity by or on behalf of Tracon that is subject to Tracon's sole decision-making authority and control in violation of the terms and conditions of this Agreement. For clarity, the decision by the JSC to postpone or not to Initiate a clinical trial proposed in the Development Plan due to a change in the competitive landscape will not constitute a Tracon Delay.

1.85 "**Tracon Indemnitees**" has the meaning set forth in Section 8.2.

1.86 "**Tracon IP**" means any and all intellectual property rights, including Patents, copyrights, trademarks and Know-How that are (a) Controlled by Tracon or any of its Affiliates before the Effective Date, (b) developed or acquired by Tracon or any of its Affiliates independent of its performance of the Development Activities, and are not related to Collaborative Product.

1.87 "**Tracon Option**" has the meaning set forth in Section 3.6(c).

1.88 "**U.S.**" shall mean the United States of America and its territories and possessions.

1.89 "**Wind-Down Activities**" has the meaning set forth in Section 11.5(c)(iv).

ARTICLE 2
GOVERNANCE

2.1 Joint Steering Committee.

(a) Establishment. The Parties hereby establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**") to oversee and coordinate the Development Activities and Commercialization of the Collaborative Products in the Collaborative Territory, and to encourage and facilitate the ongoing cooperation and communication between the Parties regarding matters related to such activities.

(b) **Membership**. The JSC shall consist of six (6) members total, with three (3) appointed by Eucure and three (3) appointed by Tracon, each of whom shall have appropriate technical credentials, experience, knowledge, and authority within such Party's organization. Within [***] following the Effective Date, each Party shall designate its initial members to serve on the JSC. Each Party may replace its representatives on the JSC by written notice to the other Party. The Parties shall alternate, on a meeting by meeting basis, in appointing one (1) of their representatives on the JSC to act as the chairperson of the JSC for the meeting. The chairperson shall prepare and circulate agendas prior to each JSC meeting and subsequently, promptly provide to the Parties reasonably detailed drafts of the minutes of each such meeting. The Parties shall promptly discuss any comments on such minutes and finalize the minutes no later than [***] prior to the date of the next JSC meeting. The JSC members of each Party shall, where practical to do so, supply to the JSC members of the other Party copies of materials to be presented at a meeting at least [***] hours in advance of such meeting.

(c) **Responsibilities**. In particular, the JSC shall:

(i) Review and approve the Development Plan for Development of Collaborative Product in the Field in the Collaborative Territory, and semi-annual updates to such Development Plan, including either Party's proposal to substitute or add Indications to be pursued within the Field under the Development Plan pursuant to Section 3.6 and Section 4.1(b);

(ii) Monitor progress of the Development Plan for the Development of Collaborative Product in the Field in the Collaborative Territory, review relevant Development Data and timely share information on progress of such Development with the Parties;

(iii) Review and approve the selection of the CMO for Collaborative Product, if applicable, and monitor the establishment, qualification, compliance, and maintenance of the manufacturing facilities and processes for purposes of pre-clinical (if applicable), clinical, and commercial supply of Collaborative Product; provided that the Parties agree that Mabplex International Ltd. is approved as the CMO as of the Effective Date;

(iv) Review and approve proposals by Tracon for the conduct of clinical trials of a Collaborative Product in the Field at clinical sites in the Collaborative Territory;

(v) Review the Development Plan for Development of Collaborative Product in the Field in the Collaborative Territory, and coordinate the Parties' activities with respect to the Commercialization of Collaborative Products in the Field in the Collaborative Territory;

(vi) Review and approve proposals by Tracon to expand the Field to include additional Indications pursuant to Section 3.6;

(vii) Review and approve proposals by Eucure for additional clinical trials involving Collaborative Product beyond those in the then current Development Plan pursuant to Section 4.1(b);

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

(viii) Serve as a forum for the discussion of any safety, scientific or technical concerns regarding the Development, manufacture or Commercialization of Collaborative Products;

(ix) Review quarterly reports provided by Tracon with respect to the planning for and progress of Commercialization activities for Collaborative Products in the Collaborative Territory pursuant to Section 5.1;

(x) Delegate any functions of the JSC to the JDC pursuant to the consensus of the JSC; and

(xi) Perform such other appropriate activities and functions and making such other appropriate decisions as agreed by the Parties in writing.

(d) JSC Meetings. The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every quarter. Meetings of the JSC may be held in person, or by audio or video teleconference, provided that meetings shall be in person only be mutual agreement of the Parties. JSC meetings shall be chaired by a JSC representative of the Parties on an alternating basis and, if in-person, held at locations selected on an alternating basis by the Parties, with the first in-person JSC meeting to be chaired by a Eucure representative and held at a location to be selected by Eucure. In person meetings shall provide the opportunity for some, but not all, of a Party's members to attend remotely by audio or video teleconference. Each Party shall be responsible for all of its own expenses in connection with participating in the JSC meetings. Each Party may from time to time invite a reasonable number of its representatives, who are not members of the JSC, to attend meetings in a non-voting capacity; *provided* that such participants are bound by confidentiality and non-use obligations consistent with the terms of this Agreement; and *provided further* that each Party shall provide reasonable prior written notice to the other Party if it has invited any Third Party (including any consultant) to attend such a meeting and the attendance of such Third Party shall be subject to the consent of the other Party.

(e) Decision-Making.

(i) All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. No vote of the JSC may be taken unless at least one of each Party's representatives is present for the vote. Each Party shall be responsible for ensuring that, at all times, its representatives on the JSC act reasonably and in good faith in carrying out their respective responsibilities hereunder.

(ii) If the JSC cannot reach consensus with regard to any matter within its authority within [***] after such matter has been brought to the JSC's attention, such matter shall be referred to the Chief Executive Officer of each Party, who shall promptly meet and attempt in good faith to resolve such issue within [***] from the date upon which such matter is referred to them. In the event that such Chief Executive Officers are unable to resolve such issue within [***] of the issue being referred to them, then (i) with respect to all matters solely relating to Development and Commercialization of the Collaborative Product in the Field in the Collaborative

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Territory, Tracon shall have the deciding vote; (ii) with respect to all matters solely relating to manufacture of the Collaborative Product, Eucure shall have the deciding vote; and (iii) with respect to all other matters properly before the JSC and not reserved for consensus of the Parties, Eucure shall have the deciding vote; *provided*, *however*, that, in each case (i)-(iii), (A) Tracon may not use such deciding vote to (x) disadvantage the Development and Commercialization of Collaborative Product in the Eucure Territory in comparison with its development and commercialization in the Field in the Collaborative Territory, (y) determine whether or not to approve the substitution or addition of an Indication pursuant to Section 3.6, or (z) determine whether or not a Tracon Delay has occurred under Section 4.1(d); and (B) Eucure may not use such deciding vote to disadvantage the Development and Commercialization of Collaborative Product in the Field in the Collaborative Territory in comparison with its development and commercialization by Eucure in the Eucure Territory. In all cases where a Party exercises its right to cast a deciding vote to resolve an impasse before the JSC, such Party shall give good faith consideration to the other Party's position, and make reasonable efforts to take such Party's position into account, in making such decision.

(f) Limitations of JSC Authority. The JSC shall only have the powers expressly assigned to it in this Article 2 and elsewhere in this Agreement, and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; or (ii) decide any such issue in a manner that would conflict with the express terms and conditions of this Agreement.

2.2 Joint Development Committee.

(a) General. Within [***] of the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or the "**JDC**") to oversee (i) the execution of the Development Plan, (ii) the progress towards obtaining Regulatory Approvals for the Collaborative Product, (iii) the sharing of information regarding proposed clinical trial sites in the Collaborative Territory, and (iv) such other Development related activities delegated to it by the JSC. Each Party shall appoint three (3) representatives to the JDC, each of whom shall be an officer or employee of the applicable Party having sufficient knowledge regarding Development of the Collaborative Products.

(b) Meetings. While the Parties are developing and conducting Clinical Trials for Collaborative Product in the Collaborative Territory, the JDC shall meet at least once per Calendar Quarter. The Parties shall endeavor to schedule meetings of the JDC at least [***] in advance.

(c) Decisions. All decisions of the JDC on matters for which it has responsibility shall be made unanimously, with each Party's representatives on the JDC collectively having one vote. In the event that the JDC is unable to reach a unanimous decision within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other Party, have such issue submitted to the JSC for resolution in accordance with Section 2.1(e).

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

LICENSE GRANT

3.1 License Grant to Tracon. Subject to the terms and conditions of this Agreement, Eucure hereby grants an exclusive (even with respect to Eucure and its Affiliates), nontransferable, license to Tracon under the Collaborative Product IP and its rights in the Development IP for the Development and Commercialization of the Collaborative Products in the Field in the Collaborative Territory (the "**Collaborative Products License**"). The Collaborative Products License shall include a non-exclusive right to have the Collaborative Product manufactured and supplied pursuant to Sections 4.3 and 5.2, but Tracon shall not itself have the right to manufacture Collaborative Product. For clarity, the licenses granted to Tracon under this Section 3.1 shall not include any rights to any molecule, other than the Antibody, that is proprietary to Eucure, its Affiliates or its (sub)licensees.

3.2 Sublicensing Rights. The Collaborative Products License shall not be sublicensable by Tracon except with the prior written consent of Eucure, in Eucure's sole discretion. In the event the Parties agree to an arrangement whereby Tracon sub-licenses any rights under the Collaborative Products License to a Third Party Licensee in the Field in the Collaborative Territory, the Parties shall use good faith efforts to negotiate the sharing of all proceeds from such sublicense grant, on the basis of each Party's investment in the discovery and Development of Collaborative Product.

3.3 License Grant to Eucure. Tracon hereby grants to Eucure an irrevocable, perpetual, royalty-free, exclusive license, with the right to grant sublicenses, under its rights in all Development Data and Development IP to develop, register, sell, offer to sell, have sold, market and distribute the Collaborative Product in the Eucure Territory or outside the Field in the Collaborative Territory (provided that in the event that the scope of the Field changes, the scope of this license outside the Field shall adjust accordingly), and to make and have made the Collaborative Product anywhere in the world. Upon any expiration or termination of the Agreement (other than by Tracon pursuant to Section 11.2 or Section 11.4), Tracon shall grant Eucure an irrevocable, perpetual, royalty-free, non-exclusive license with the right to grant sublicenses under its rights in all Development Data and Development IP to develop, register, sell, offer to sell, have sold, market and distribute the Collaborative Product in the Collaborative Territory.

3.4 No Implied Licenses; Negative Covenants; Retained Rights. Except as expressly provided in this Agreement, neither Party shall be deemed to have granted to the other Party (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any intellectual property rights or other information owned by or licensed to such Party or its Affiliates. Eucure hereby covenants that, during the Term, it and its Affiliates shall not engage in (or permit a Third Party to engage in) the Development or Commercialization of a Collaborative Product in the Field in the Collaborative Territory, except the Parties hereby agree as follows: (a) Eucure shall have the right to Develop any Eucure Combination Therapy in the Field in the Collaborative Territory; (b) Eucure shall have the right to Commercialize in the Collaborative Territory any component of the Eucure Combination Therapy other than Collaborative Product, and (c) Eucure shall have the right to conduct clinical trials of Collaborative Product in the Field in the Collaborative Territory as permitted under Section 4.1(b). Notwithstanding the exclusive

license granted by Eucure to Tracon under Section 3.1, Eucure retains the rights under the Collaborative Product IP to directly or indirectly perform its obligations under this Agreement. For clarity, Eucure retains all rights under the Collaborative Product IP outside the scope of the licenses granted to Tracon under Section 3.1. Tracon hereby covenants that it shall not, nor shall it cause or permit any Affiliate or sublicensee to, use or practice, directly or indirectly, any Collaborative Product IP for any purposes other than those expressly permitted by this Agreement.

3.5 Tracon's Rights to Develop in the United Kingdom and European Union. Tracon may from time to time request for the rights to the conduct of a clinical trial in the United Kingdom and European Union for the sole purpose of supporting the Development of Collaborative Products in the Field in the Collaborative Territory. Upon Eucure's receipt of such proposal, the Parties will engage in good faith discussion of such request. Subject to Eucure's grant of its written consent, which Eucure may withhold in its sole discretion, Tracon shall be permitted to Develop Collaborative Product in the United Kingdom and European Union solely through the conduct of such requested trial. Absent written consent from Eucure, Tracon shall have no right to conduct Development of Collaborative Product in the Eucure Territory. For clarity, the Collaborative Products License shall not include the right to Commercialize or seek Regulatory Approval of Collaborative Products in the Eucure Territory.

3.6 Modification or Expansion of Field.

(a) Modification. So long as Tracon is in compliance with and has not breached any of the terms under this Agreement (including without limitations its diligence obligations pursuant to Section 4.1(d)), Tracon shall have the right to propose to substitute an existing Indication in the Field with a new Indication with notice to the JSC and an explanation of Tracon's view of its assessment of the relevant clinical and commercial competitive landscape for such proposed substitute Indication. Upon the approval in writing by Eucure, in its sole discretion, of such proposal by Tracon, the Field shall include such substitute Indication and the replaced Indication shall no longer be part of the Field. Notwithstanding the foregoing, Eucure agrees that the potential Indications listed in Schedule 3.6(a) are pre-approved by Eucure for substitution as an Indication in the Field under this Section 3.6. In connection with any permitted substitution of Indications in the Field, Tracon shall amend the Development Plan to implement such change.

(b) Expansion. Tracon may propose to the JSC to expand the Field to include additional Indications (beyond the Indications as of the Effective Date or any substitutes as permitted in Section 3.6(a)), including proposed amendments to the Development Plan to support such additional Indications. The JSC shall review and determine whether or not to approve such proposal, provided that Eucure's JSC representatives shall not unreasonably withhold such approval, and upon such approval, the Field shall be amended to reflect such addition of Indications.

(c) Tracon Option. Eucure shall promptly notify Tracon (x) upon the completion (delivery of the final study report) of Eucure's multiregional clinical trial ("**MRCT**") Phase 2 Study of YH001 and toripalimab to treat non-small cell lung cancer (NSCLC) and HCC (Hepatocellular carcinoma) (the "**Eucure Study Report**"), (y) of any plans of Eucure, its Affiliates, its sublicensees or permittees for the submission of a BLA in the U.S. with respect to Collaborative Product and/or Eucure Combination Therapy (a "**Eucure BLA Submission**") [***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

prior to such submission, and (z) the occurrence of any such Eucure BLA Submission. Subject to Eucure's prior written approval (which shall be given in writing or deemed denied within [***] of written notice of Tracon's intent to exercise the option), Tracon shall have the option, exercisable upon written notice to Eucure at any time during the period commencing on the [***] anniversary of the Effective Date and ending [***] after the earlier of (i) delivery to Tracon of the Eucure Study Report, or (ii) Eucure's notice to Tracon of a Eucure BLA Submission, to expand the Field to include the Development and Commercialization of all human and veterinary therapeutic applications of the Collaborative Product administered by intravenous or subcutaneous means for all Indications (the "**Tracon Option**") effective upon Tracon's payment to Eucure of an option exercise fee of [***] dollars ($[***]), which payment shall be made concurrently with the delivery of the option exercise notice. If Tracon exercises the Tracon Option before the delivery of the Eucure Study Report, Eucure nonetheless shall retain the right to complete the corresponding MRCT Phase 2 Study at the clinical sites in the Collaborative Territory and shall deliver the Eucure Study Report to Tracon upon its completion.

3.7 Exclusivity.

(a) Subject to Section 3.4(a) during the Term, each Party shall not, and shall cause its Affiliates not to, directly or indirectly, (i) Develop, manufacture or Commercialize, or (ii) authorize (by license or otherwise) any Third Party to Develop, manufacture or Commercialize, any Competing Product in the Field in the Collaborative Territory (a "**Competing Program**"). For clarity, it shall not be a violation of the requirements of this Section 3.7 for a Party to Develop, manufacture or Commercialize a product other than an anti-CTLA-4 antibody where the label for such product directs that it be co-administered with a Third Party's commercially available Competing Product, so long as such Party does not package such Competing Product with such product or otherwise Commercialize such Competing Product.

(b) In the event of (i) a Third Party becomes an Affiliate of such Party as a result of a transaction that does not result in a Change of Control of such Party, and (ii) as of the closing date of such transaction, such Third Party is engaged in the conduct of a Competing Program, then, within [***] after such closing date, such Affiliate shall either: (A) Divest the Competing Program to a Third Party, or (B) discontinue the Competing Program. Prior to such Divestiture or discontinuation during such [***] period, such Affiliate may conduct Competing Program activities without breaching the obligations of Section (a); provided that (x) such activities are conducted independently of the activities pursuant to this Agreement and do not use any Collaborative Product IP, Development Data, Development IP or Tracon IP, and (y) such Party shall, and shall cause its Affiliates to, (A) segregate such Competing Program from the Development, manufacture, Commercialization and other exploitation of Collaborative Product under this Agreement, and (B) establish reasonable firewalls to prevent disclosure of non-public plans or non-public information relating to the Collaborative Product or any Confidential Information of the other Party to any personnel of such Party or its Affiliates who are conducting the Competing Program.

(c) In the event that (i) a Third Party becomes an Affiliate of such Party as a result of a Change of Control of such Party, and (ii) as of the closing date of such Change of Control, such Third Party is engaged in the conduct of a Competing Program, then such new Affiliate may continue to conduct such Competing Program activities without breaching the

obligations of Section 3.7(a); provided that (x) such activities are conducted independently of the activities pursuant to this Agreement and do not use any Collaborative Product IP, Development Data, Development IP or Tracon IP, and (y) such Party shall, and shall cause its Affiliates to, (A) segregate such Competing Program from the Development, manufacture, Commercialization and other exploitation of Collaborative Products under this Agreement, and (B) establish reasonable firewalls to prevent disclosure of non-public plans or non-public information relating to the Collaborative Product or any Confidential Information of the other Party to any personnel of such Party or its Affiliates who are conducting the Competing Program.

ARTICLE 4
DEVELOPMENT; REGULATORY

4.1 Development in the Collaborative Territory.

(a) Overview; Development Plan. As between the Parties and subject to Eucure's fulfillment of its obligations under Section 4.1(c) and Section 4.3, Tracon shall be solely responsible for Development of the Collaborative Product in the Field in the Collaborative Territory, at its sole cost and expense in accordance with a detailed written plan attached hereto as Schedule 4.1(a) (the "**Development Plan**"); *provided*, *further*, notwithstanding anything herein to the contrary Tracon shall not be obligated to commence a clinical trial of Collaborative Product unless the supply for the completion of such clinical trial has been delivered to Tracon or the necessary quantity has been manufactured and allocated for delivery to Tracon. The Development Plan (including any amendments or updates thereto) shall include a reasonably detailed plan setting forth the Development activities to be conducted by or on behalf of Tracon in support of obtaining Regulatory Approval for the Collaborative Product for each of the Indications in the Field in the Collaborative Territory, and shall at a minimum include the following information: (i) tumor type and stage of therapy; (ii) single agent and combinations dosed, control arms, and randomization; (iii) proposed dose and dosing intervals, including dose modifications and therapy for adverse events (including immune related adverse events); (iv) estimated number of patients (in each arm); (v) inclusion and exclusion criteria, such as age, labs, co-morbidities, or previous therapies; (vi) primary and secondary endpoints, including a brief description of how such endpoints will be measured and evaluated; and (vii) the clinical trials to be conducted during the time period covered by such plan, and a budget and a timeline for such clinical trials. The JSC shall review each Development Plan and updates as appropriate no less than once per Calendar Quarter, and the JDC shall oversee and facilitate cooperation and information transfer between the Parties in conducting the activities set forth in the Development Plan.

(b) Eucure Proposals for Additional Clinical Trials. During the Term, Eucure may propose to the JSC that certain additional clinical trials for Collaborative Product for intravenous or subcutaneous administration and involving either Indications or combinations not then included in the Development Plan be pursued under this Agreement. If the JSC approves such proposal, the JSC shall amend the Development Plan (and, if necessary, the Field pursuant to Section 3.6) to include Development of Collaborative Product with respect to such Indications, combinations and proposed clinical trials. If the JSC declines to approve a proposal for additional clinical trials by Eucure pursuant to this Section 4.1(b) for reasons other than reasonable concerns for patient safety, Eucure shall have the right to pursue such proposed clinical trial for Collaborative Product in the Collaborative Territory at its expense; provided that Eucure shall keep

the JSC reasonably informed at each JSC meeting of its plans for, progress of, and the results of such clinical trials.

(c) Technology Transfer; Assistance. Promptly following the Effective Date, Eucure shall provide to the JSC and Tracon, at Eucure's expense, any information Controlled by Eucure that is necessary or reasonably useful for the Development and Commercialization of Collaborative Product in the Field in the Collaborative Territory (including without limitation all INDs filed anywhere in the world with respect to Collaborative Product, all human clinical trial results related to Collaborative Product's effectiveness in the Field or safety, and all existing IND-enabling final reports and all CMC information that is (x) needed to file a BLA for the Collaborative Product in the Field in the Collaborative Territory and (y) Controlled by Eucure or a Third Party contracted by Eucure), pursuant to a technology transfer plan mutually agreed by the Parties. All information will be provided in English. Eucure shall permit Tracon a right to reference any IND or BLA filed by or on behalf of Eucure with respect to Collaborative Product (or for any co-formulation of Antibody with other products, but solely as it relates to Antibody) for the sole purpose of supporting Tracon's IND or BLA for Collaborative Product in the Field in the Collaborative Territory. Eucure shall provide Tracon with reasonable assistance for the conduct, at Tracon's cost and expense, of all IND-enabling and BLA-enabling Development activities for Collaborative Product in the Field in the Collaborative Territory, including, without limitation, transferring to Tracon the pharmacodynamic, pharmacokinetic, immunogenicity, and other bioanalytical assay, methods, and final reports for human plasma sample analysis through all phases of Development and all stability testing and non-clinical bridging studies.

(d) Diligence. Tracon shall use Commercially Reasonable Efforts to Develop Collaborative Products in the Field in the Territory. Without limiting the generality of the foregoing, Tracon shall (i) Initiate a clinical trial for Collaborative Product consistent with the Development Plan within [***] following the later of (A) FDA clearance of the applicable IND and (B) receipt of adequate clinical supply of Collaborative Product at the mutually agreed supply depot pursuant to Section 4.3, and (ii) Initiate clinical trials for Collaborative Product for at least three (3) Indications in the Field before the [***] anniversary of the Completion of Tracon's first clinical trial for a Collaborative Product under the Development Plan. If Tracon fails to meet the clinical milestones in either (i) or (ii) of the foregoing, the JSC shall determine whether such failure is a result of a Tracon Delay. If the JSC determines that Tracon's failure to meet the clinical milestones in either (i) or (ii) of the foregoing is due to a Tracon Delay, or does not otherwise reach consensus with respect to a mitigation plan for such failure, such failure shall be deemed a material breach of this Agreement by Tracon for which Eucure may terminate this Agreement pursuant to Section 11.2 If the JSC determines that Tracon's failure to meet the clinical milestones in either (i) or (ii) of the foregoing is not due to a Tracon Delay, the deadlines set forth in this Section 4.1(d) shall be extended by a reasonable time period; provided that Tracon shall continue to use Commercially Reasonable Efforts to achieve the clinical milestones in either (i) or (ii) of the foregoing as soon as practicable.

(e) Performance Standards. Each party shall perform its activities under the Development Plan in accordance with the terms and conditions of this Agreement and Applicable

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Laws, including GCP and GMP to the extent applicable. If there is any conflict between performance in accordance with Applicable Laws and this Agreement, performance in accordance with Applicable Laws shall prevail.

(f) Eucure Development in the Collaborative Territory. Promptly following Tracon's exercise of the Tracon Option, (i) Eucure shall assign to Tracon all regulatory filings for Collaborative Product in the Field (as expanded pursuant to Tracon's exercise of the Tracon Option) within the Collaborative Territory (except to the extent necessary for Eucure to complete the MRCT Phase 2 Study as contemplated under Section 3.6(c)), (ii) Eucure shall provide Tracon with complete access and right of reference to all data generated by or on behalf of Eucure or its Affiliates in the course of, and as a result of, the Development of Collaborative Product in the Field (as expanded pursuant to exercise of Tracon Option) in the Collaborative Territory, including data related to all non-clinical studies and clinical trials of Collaborative Product in the Field (as expanded pursuant to exercise of Tracon Option) in the Collaborative Territory and related activities concerning manufacture process development, manufacture and distribution of such Collaborative Product for use in clinical trials in the Field (including placebos and comparators), statistical analyses, and the preparation and submission of regulatory materials and other regulatory activities related to such Collaborative Product in the Field, and (iii) Eucure shall permit Tracon to access all other data in the possession or control of Eucure related to Collaborative Product in the Field in support of Tracon's Development and Commercialization of Collaborative Product in the Field in the Collaborative Territory. For clarity, the data in (ii) and (iii) shall be deemed Collaborative Product IP and licensed to Tracon as part of the Collaborative Product License.

4.2 Development in the Eucure Territory. As between the Parties, Eucure shall have the sole right but not the obligation to Develop Collaborative Product in the Eucure Territory, at its sole cost and expense. Eucure shall have the right to access, use and reference all Development Data generated by or on behalf of Tracon or its Affiliates for the Collaborative Product in support of such Development activities in the Eucure Territory. Eucure shall keep Tracon and the JSC reasonably informed regarding the status of all Development Activities for Collaborative Products in the Field in the Eucure Territory.

4.3 Clinical Supply.

(a) As between the Parties, Eucure, itself or through its designees, shall be solely responsible for manufacturing and supplying to Tracon, consistent with the requirements of this Section 4.3, all amounts of Collaborative Product necessary for Tracon to perform all pre-clinical and clinical studies for its Development of Collaborative Products, pursuant to a written clinical supply and quality agreement, which shall be separately negotiated and agreed in good faith by the Parties within [***] after the Effective Date (the "**Clinical Supply and Quality Agreement**"). The price for all Collaborative Product supplied by Eucure to Tracon for Development Activities for Collaborative Product shall be [***] percent ([***]%) of Eucure's COGS for such Collaborative Product, and the Clinical Supply and Quality Agreement will include the terms set forth on **Exhibit B**. Eucure acknowledges and agrees that Tracon's performance of the Development Activities is conditioned upon and subject to Eucure's supply of Collaborative Product in compliance with the terms and conditions of this Agreement and the Clinical Supply

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

and Quality Agreement. While Eucure supplies Collaborative Product for purposes of Development of Collaborative Product both in the Collaborative Territory as well as the Eucure Territory, the requirements for Development in the Field in the Collaborative Territory shall be given equal treatment with respect to requirements for use outside of the Field and/or Collaborative Territory in the event of a shortage or interruption of supply. In all events, Eucure shall not discontinue supplying Collaborative Product to Tracon under the terms of this Agreement so long as Eucure supplies Collaborative Product for any use or to any party. Notwithstanding anything herein to the contrary, until such time as Tracon exercises the Tracon Option with Eucure's approval, Eucure shall bear the cost of the pre-clinical and clinical supply of Collaborative Product to Tracon at the depot in China designated by Tracon pursuant to this Section 4.3.

(b) Eucure shall enter into a CMO Supply Agreement consistent with the terms of this Agreement. The Parties agree that the CMO shall initially be Mabplex International Ltd. which shall manufacture Collaborative Product in China. Eucure shall be responsible for the cost of packaging and shipment of Collaborative Product to a depot in China designated by Tracon in its discretion, and Tracon shall be responsible for, at its cost, the shipment (including export and import) of the Collaborative Product from such China depot to any U.S. depot and to clinical trial sites. The Parties will work together to manage exportation and importation of the Collaborative Product in accordance with importation laws of the U.S., China and other countries as applicable. Eucure shall use Commercially Reasonable Efforts to ensure that the CMO has adequate capabilities and necessary controls in place for the production, testing, and release of cGMP compliant and quality Collaborative Products necessary for all Development Activities and experience in supporting the submission of IND and BLA applications to the FDA with respect to the chemistry-manufacturing-controls activities sections of such IND and BLA applications. With respect to a CMO Supply Agreement with the CMO for Collaborative Product, the supply price in such agreement shall be the COGS for Collaborative Product supplied and charged from such CMO; provided that such price shall not be greater than the price charged by the same CMO to Eucure or its partners in China for supply of Collaborative Product that are manufactured in the same facility in the same period of time. Eucure shall annually provide Tracon with documentation providing the basis for establishment of COGS with respect to clinical supply of Collaborative Product. Eucure shall use Commercially Reasonable Efforts to cause the CMO to supply to Tracon the necessary documentation and information for the chemistry-manufacturing-controls activities section of the IND and BLA and all correspondence with the FDA and other Regulatory Authorities relevant to the supply of Collaborative Products. Tracon shall have conventional inspection and audit rights (which inspection and audit shall be conducted at Tracon's own cost and expense) with respect to the manufacture and supply of Collaborative Products conducted by CMO including the right to participate in all FDA inspections concerning Collaborative Products, as a partner or consultant of Eucure to the extent legally able to do so. The Clinical Supply and Quality Agreements shall provide for the supply of Tracon's requirements for Collaborative Product through the completion of all clinical trials and upon Commercialization of Collaborative Product in the Collaborative Territory. Eucure and Tracon shall enter into a quality agreement with the CMO concerning the manufacture and supply of Collaborative Product (such agreement a "**Quality Agreement**"). Tracon shall have the right to review and approve the Quality Agreement and provide input to Eucure on its terms. Eucure and Tracon shall use Commercially Reasonable Efforts to negotiate the terms and any necessary amendment to the Quality Agreement to include Tracon's input, provide terms that are satisfactory to Tracon, and meet Tracon's needs with respect to interactions with the FDA. Tracon shall have the right to review (at Tracon's own cost and

expense) all source documents that are relevant to Collaborative Product (including master and executed batch records, specifications, and product stability plan/data in English) and to request and participate as a partner or consultant of Eucure in quality audits of the CMO no more than [***], and in inspections by all Regulatory Authorities, with respect to records, processes and facilities relevant to Collaborative Product. In the event that Tracon requests more than [***] audit in a given [***], Eucure shall use Commercially Reasonable Efforts to implement such audit in coordination with the CMO, and Tracon agrees to bear the expense of such additional audit.

4.4 Regulatory.

(a) Regulatory Filings. As between the Parties, subject to this Section 4.4(a), Tracon shall be responsible for, at its sole cost and expense, preparing, translating and filing all regulatory materials, and obtaining and maintaining Regulatory Approvals, for the Collaborative Products in the Field in the Collaborative Territory, in compliance with all Applicable Laws. Prior to filing any regulatory materials that incorporates any CMC information for the Collaborative Products, Tracon shall submit a draft of such regulatory materials to Eucure for review and comment, and reasonably incorporate any of Eucure's comments with respect to such CMC information. Tracon shall have the right to cross-reference Eucure's IND for the Collaborative Product in the U.S. in support of Tracon's Development and Commercialization of Collaborative Product for intravenous or subcutaneous administration in the Field in the Collaborative Territory. Eucure shall have the right, but not the obligation, to review and comment on all regulatory filings for any Collaborative Products to any Regulatory Authority in the Collaborative Territory, and Tracon shall reasonably incorporate any such comments in such regulatory filings prior to filing thereof and shall promptly provide copies of any regulatory filings (including all updates thereof) to Eucure. The Parties shall reasonably cooperate with each other in all material respects with respect to such regulatory submissions. Eucure and its Affiliates, licensees and sublicensee in the Eucure Territory or outside the Field in the Collaborative Territory shall have the right to cross-reference the regulatory filings and Regulatory Approvals of the Collaborative Product in the Collaborative Territory to support the Development and Commercialization of the Collaborative Product in the Eucure Territory or outside the Field in the Collaborative Territory.

(b) Interactions with Regulatory Authorities. As between the Parties, subject to this Section 4.4(b), Tracon shall be responsible for, at its sole cost and expense, responding to inquiries and correspondence from the applicable Regulatory Authorities with respect to Collaborative Product in the Field in the Collaborative Territory. Eucure (or its designee) shall have a right to participate (and Tracon may otherwise request Eucure to participate) in meetings with the Regulatory Authorities if it is reasonably likely that there would be discussions on the agenda about the Collaborative Product beyond the scope of Tracon's Development of the Collaborative Product the Collaborative Territory (e.g., CMC matters, clinical data generated by Eucure). Following each substantive communication (whether by phone or in person) with a Regulatory Authority with respect to the Collaborative Product in the Field in the Collaborative Territory, Tracon shall prepare a record of such meeting in accordance with its standard business practices (e.g., written minutes) and provide to Eucure a copy of such record.

(c) Product Recalls. In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Collaborative Product, or in the event a Party reasonably believes that an event, incident or circumstance has occurred impacting product

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

data, quality, safety, or efficacy that may result in the need for a voluntary or mandatory recall, market withdrawal or other corrective action regarding a Collaborative Product, such Party shall promptly so advise the other Party by telephone or email. Tracon shall decide and have control of whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in the Field in any country of the Collaborative Territory and the manner in which any such recall, market withdrawal or corrective action shall be conducted; provided that, Tracon shall (i) give prompt and due consideration to any report by Eucure of any failure of Collaborative Product supplied by or on behalf of Eucure to Tracon to comply with any quality standard set forth in the Clinical Supply and Quality Agreement (or other supply agreement or quality agreement between the Parties); (ii) notify Eucure prior to making any public disclosure of the recall, market withdrawal or corrective action; and (iii) shall keep Eucure regularly informed regarding any such recall, market withdrawal or corrective action. Tracon shall be solely responsible for all costs incurred in connection with any such recall, market withdrawal or corrective action for a Collaborative Product in the Field in the Collaborative Territory, provided that to the extent the recall is a result of the failure of any Collaborative Product supplied by or on behalf of Eucure to Tracon to comply with any quality standard set forth in the Clinical Supply and Quality Agreement (or other supply agreement or quality agreement between the Parties), the costs of the recall shall be borne by Eucure (except to the extent that such costs are exacerbated due to delay or inaction by Tracon after such failure to comply has been reported or become known to Tracon). Eucure shall decide and have control of whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in the Eucure Territory and the manner in which any such recall, market withdrawal or corrective action shall be conducted; provided that Eucure shall notify Tracon prior to making any public disclosure of the recall, market withdrawal or corrective action and shall keep Tracon regularly informed regarding any such recall, market withdrawal or corrective action. Eucure shall be solely responsible for all costs incurred in connection with any such recall, market withdrawal or corrective action for a Collaborative Product in the Eucure Territory.

(d) Power of Attorney. Eucure hereby irrevocably designates and appoints Tracon and its duly authorized officers and agents as Eucure's agent and attorney-in-fact to act for and in Eucure's behalf to execute, deliver, and file any and all letters granting rights of reference to Eucure BLAs with the same legal force and effect as if executed by Eucure if and solely to the extent that Tracon is unable for any reason to secure Eucure's signature on any such letters granting rights of reference that Eucure is required to execute and deliver pursuant to Sections 4.1 or 4.4 above.

4.5 Safety Data Exchange.

(a) Prior to the initiation of the first clinical trial of Collaborative Product by Tracon, the Parties shall negotiate in good faith and enter into a Safety Data Exchange Agreement ("**SDEA**") for the Collaborative Product, with customary terms and conditions consistent with industry standard practices for the Development of the Collaborative Product. With respect to clinical trials being carried out by or on behalf of Tracon and with respect to clinical trials being carried out by or on behalf of Eucure in the Eucure Territory, each Party agrees pursuant to this Agreement, during the Term hereof, to establish and abide by safety data exchange procedures for

individual case safety reports (ICSRs) and safety aggregate reports and any other safety information required, to support each other to meet the regulatory authority requirements in its respective Territory. All such exchanges will be in English. The ICSRs exchange timeline will be set up as following: fatal/ life-threatening serious adverse experiences (SAEs) will be exchanged within [***] of date of awareness; non-fatal/life-threatening SAEs will be exchanged within [***] of date of awareness. The exchange timeline for other safety reports will be also clearly defined in the SDEA. Above terms, which used herein, shall have the meaning as defined in the ICH E2A, B, C, D, E, F and their interpretation in applicable local legislation in both Parties' territories.

(b) Further, no later than [***] before the anticipated launch date of any Collaborative Product in the Collaborative Territory, the Parties shall enter into a separate SDEA, with customary terms and conditions consistent with industry standard practices for the Commercialization of the Collaborative Product. Each SDEA shall include mutually acceptable guidelines and procedures for the receipt, investigation, recording, communication, and exchange of adverse event reports between the Parties, pregnancy reports, and any other information concerning the safety of the Collaborative Product. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws. Furthermore, such agreed procedure shall be consistent with relevant ICH guidelines, except where said guidelines may conflict with existing local regulatory reporting safety reporting requirement, in which case local reporting requirement shall prevail.

ARTICLE 5
COMMERCIALIZATION

5.1 Commercialization in the Collaborative Territory. As between the Parties, Tracon shall be solely responsible for the Commercialization of Collaborative Products in the Field in the Collaborative Territory. Upon procurement of Regulatory Approval of the Collaborative Product for an Indication in the Field in any country in the Collaborative Territory, Tracon shall use Commercially Reasonable Efforts to Commercialize the Collaborative Product for such Indication in the Field in such country. Tracon shall book all sales of Collaborative Products in the Field in the Collaborative Territory during the Term. No less than [***] prior to the anticipated First Commercial Sale of the Collaborative Product in the Field in the Collaborative Territory and each anniversary of the First Commercial Sale thereafter, Tracon shall provide Eucure with a written report that summarizes, in reasonable detail, the Commercialization activities performed during such time period. Additionally, Tracon shall report to the JSC on a quarterly basis regarding its planning for and the progress of Commercialization activities with respect to the Collaborative Product in the Field in the Collaborative Territory.

5.2 Commercial Supply.

As between the Parties, Eucure, itself or through its designees, will be solely responsible for Manufacturing Collaborative Product for all commercial uses in the Collaborative Territory. Eucure shall use Commercially Reasonable Efforts to supply, or cause to be supplied, to Tracon all amounts of Collaborative Product necessary for Tracon to Commercialize Collaborative Product in the Field in the Collaborative Territory, at Eucure's COGS for such Collaborative

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Product plus a [***] percent ([***]%) markup. No later than [***] prior to the anticipated First Commercial Sale of the Collaborative Product in the Field in the Collaborative Territory, the Parties shall negotiate in good faith and enter into a written commercial supply and quality agreement, which will be consistent with the terms of this Agreement and include customary terms and conditions consistent with industry standard practices for such a commercial supply arrangement.

(a) Eucure shall enter into CMO Supply Agreements with one or more CMOs for the supply of Collaborative Product in quantities sufficient for the Commercialization of Collaborative Product in the Field in the Collaborative Territory, which arrangements shall be on terms reasonably acceptable to Tracon. Eucure shall be responsible for the shipment of Collaborative Product to a Tracon designated depot in the U.S.; The Parties will work together to manage importation of the Collaborative Product in accordance with importation laws of the U.S., China and other countries as applicable. For clarity, upon Eucure's entry into a CMO Supply Agreement with a CMO for Collaborative Product, the COGS for Collaborative Product shall be the supply price in such agreement; provided that such COGS amount shall not be greater than the price charged by same CMO to Eucure or its partners in China for supply of Collaborative Product that are manufactured in the same facility in the same time period. Eucure shall annually provide Tracon with documentation providing the basis for establishment of COGS with respect to commercial supply of Collaborative Product. Within [***] of commercial launch of Collaborative Product in the Field in the Collaborative Territory, Eucure shall use Commercially Reasonable Efforts to establish a second source of commercial supply of such Collaborative Product by entering into a second CMO Supply Agreement with a CMO on terms that are reasonably acceptable to Tracon. In the event that the CMO supplies Collaborative Product for purposes of Commercialization of Collaborative Product in both the Collaborative Territory and the Eucure Territory, the requirements for Commercialization in the Collaborative Territory shall be given equal treatment with respect to requirements for use outside of the Field and/or in the Eucure Territory in the event of a shortage or interruption of supply.

(b) **Substitute Supply**. In the event of an uncured material breach of Eucure's obligation to supply Collaborative Product as required under this Agreement (or any failure to supply at least [***] ([***]%) of the aggregate amount of firm orders for Collaborative Product placed by Tracon in accordance with its binding forecast during a [***] period, the details of which will be set forth in the commercial supply agreement between the Parties as contemplated in this Section 5.2), (i) Tracon shall have the right to enter into a direct supply agreement with a CMO of its choosing for the supply of all of its requirements for the Development and Commercialization of Collaborative Product, and (ii) Eucure shall provide to such CMO, at Eucure's expense, any information Controlled by Eucure that is necessary or reasonably useful to enable such CMO to manufacture Collaborative Product.

5.3 **Pricing**. As between the Parties, Tracon shall have the sole right to make all decisions regarding the pricing of the Collaborative Product in the Field in the Collaborative Territory; provided that, if Tracon sells the Collaborative Product in a "bundle" with one or more other products or services at a discount to the purchaser, then Tracon shall not disproportionately or unreasonably discount such Collaborative Product relative to the other products or services composing such bundle. As between the Parties, Eucure shall have the sole right to make all

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

decisions regarding the pricing of the Collaborative Product in the Eucure Territory. Notwithstanding anything in this Agreement express or implied to the contrary, Eucure shall not have any right to direct, control, or approve Tracon's decisions regarding the pricing of Collaborative Products for the Collaborative Territory. Tracon shall inform Eucure of the results of any pricing approval and update thereof, through the JSC, provided that the provision to Eucure of such information shall be for informational purposes only.

5.4 No Diversion.

(a) Tracon shall not, and shall ensure that its Affiliates do not, either directly or indirectly, promote, market, distribute for sale, import for sale, sell or have sold the Collaborative Product, including via internet or mail order, into countries of the Eucure Territory. As to such countries of the Eucure Territory (which are exclusively reserved for Eucure), Tracon shall not, and shall ensure that its Affiliates do not: (i) establish or maintain any branch, warehouse or distribution facility for sale of the Collaborative Product in such countries, (ii) engage in any advertising or promotional activities relating to the Collaborative Product that are directed primarily to customers or other purchasers of the Collaborative Product located in such countries, (iii) solicit orders for the Collaborative Product from any prospective purchaser located in such countries, or (iv) sell or distribute for sale the Collaborative Product to any person in the Collaborative Territory who intends to sell or has in the past sold the Collaborative Product in such countries. If Tracon receives any order for the Collaborative Product from a prospective purchaser located in a country in the Eucure Territory, Tracon shall immediately refer that order to Eucure and Tracon will not accept any such orders. Tracon shall not deliver or tender for sale (or cause to be so delivered or tendered) the Collaborative Product into a country in the Eucure Territory. Tracon shall not, and shall ensure that its Affiliates do not, restrict or impede in any manner Eucure's exercise of its retained exclusive rights in the Collaborative Product in the Eucure Territory.

(b) Eucure shall not, and shall ensure that its Affiliates and sub-licensees do not, either directly or indirectly, promote, market, distribute for sale, import for sale, sell or have sold the Collaborative Product in the Field, including via internet or mail order, into countries within the Collaborative Territory. As to such countries within the Collaborative Territory, Eucure shall not, and shall ensure that its Affiliates and sub-licensees do not: (i) establish or maintain any branch, warehouse or distribution facility for sale of the Collaborative Product in the Field in such countries, (ii) engage in any advertising or promotional activities relating to the Collaborative Product in the Field that are directed primarily to customers or other purchasers of the Collaborative Product located in such countries, (iii) solicit orders for the Collaborative Product in the Field from any prospective purchaser located in such countries, or (iv) sell or distribute for sale the Collaborative Product to any person in the Eucure Territory who intends to sell or has in the past sold the Collaborative Product in the Field in such countries within the Collaborative Territory. If Eucure receives any order for the Collaborative Product in the Field from a prospective purchaser located in a country within the Collaborative Territory, Eucure shall immediately refer that order to Tracon and Eucure shall not accept any such orders. Eucure shall not deliver or tender for sale (or cause to be so delivered or tendered) the Collaborative Product in the Field into a country within the Collaborative Territory. Eucure shall not, and shall ensure that its Affiliates

and sub-licensees do not, restrict or impede in any manner Tracon's exercise of its exclusive rights in the Collaborative Product in the Field within the Collaborative Territory.

ARTICLE 6
FINANCIAL PROVISIONS

6.1 Royalties.

(a) Royalty Rate. Subject to the remainder of this Section 6.1, on a country-by-country basis, during the Royalty Term, Tracon shall pay a royalty to Eucure on Net Sales of Collaborative Product in the Collaborative Territory, as calculated by multiplying the Net Sales amount with the applicable royalty rate set forth in the table below.

Calendar Year Net Sales Threshold	Royalty rate through the end of the first full Calendar Year following First Commercial Sale of Collaborative Product in the Collaborative Territory	Royalty rate for all periods after the first full Calendar Year of following First Commercial Sale of Collaborative Product in the Collaborative Territory
Up to $[***]	[***]%	[***]%
Above $[***] and up to $[***]	[***]%	[***]%
Above $[***] and up to $[***]	[***]%	[***]%
Above $[***]	[***]%	[***]%

(b) Royalty Payments and Reports. The royalty set forth in this Section 6.1 shall be payable within [***] following the end of each Calendar Quarter. No later than the end of such [***] period, Tracon shall provide to Eucure a report summarizing the amount of Net Sales of Collaborative Product sold in the Field, on a country-by-country basis, in the Collaborative Territory and the amount of royalty owed with respect to such Net Sales for such Calendar Quarter.

(c) Successful Launch Milestone. If the total Net Sales for Collaborative Product in the Collaborative Territory in the first full Calendar Year following First Commercial Sale exceeds [***] dollars ($[***]) ("**Successful Launch Milestone**"), Tracon shall indicate the achievement of such Successful Launch Milestone in the applicable royalty report for the Calendar Quarter in which such Successful Launch Milestone is achieved, and concurrently make a one-time payment of [***] dollars ($[***]) to Eucure. If the Successful Launch Milestone is not met with respect to such first Calendar Year following First Commercial Sale, Tracon shall have no payment obligation with respect to this Section 6.1(c).

(d) Royalty Term. Royalties under this Section 6.1 shall be payable, on a country-by country basis, starting from the First Commercial Sale of the Collaborative Product in such country and until the latest of (i) expiration of the last to expire of the Patents within the Collaborative Product IP covering the Collaborative Product or its use in the Field in such country, (ii) expiration of marketing or regulatory exclusivity for the Collaborative Product in such country,

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

and (iii) ten years from First Commercial Sale of such Collaborative Product in such country in the Collaborative Territory (the "**Royalty Term**").

6.2 Currency; Exchange Rate. All payments to be made under this Agreement shall be made in US Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from the receiving Party. When conversion of payments from any foreign currency is required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange for the currency of the country from which such payments are payable as published by *The Wall Street Journal*, Western U.S. Edition during the quarter for which a payment is due. The payment of such interest shall not limit the Party entitled to payment from exercising any other rights it may have as a consequence of the lateness of any payment.

6.3 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of prime reported in *The Wall Street Journal*, Western U.S. Edition on the due date of the payment plus [***] percent ([***]%) per annum, or the maximum rate allowable by Applicable Laws, whichever is less.

6.4 Financial Records; Audit.

(a) Tracon shall keep, and require its Affiliates, to keep, reasonably detailed, fair and true books of accounts and records for the purpose of determining the amounts payable to Eucure pursuant to this Agreement. Eucure shall keep, and require the CMO, to keep, reasonably detailed, fair and true books of accounts and records for the purpose of determining the amounts of COGS for Collaborative Product. In each case, such books and records shall be kept for at least [***] following the end of the year to which they pertain.

(b) Tracon shall allow an independent certified public accountant selected by Eucure and reasonably acceptable to Tracon to audit its records for such year to verify the accuracy of any financial report furnished by Tracon and any amounts to be paid under this Agreement for the preceding [***]. Such audits may be exercised during normal business hours and no more frequently than once per calendar year upon reasonable prior written notice to Tracon. The cost of such any audit shall be borne by Eucure, unless the audit discloses an underpayment by Tracon of more than [***] percent ([***]%) of the amount of payments due under this Agreement for the period under audit, in which case, Tracon shall bear the cost of such audit.

(c) Eucure shall allow an independent certified public accountant selected by Tracon and reasonably acceptable to Eucure to audit its records to verify the accuracy of COGS as stated by Eucure for the preceding [***]. Such audits may be exercised during normal business hours and no more frequently than [***] per [***] upon reasonable prior written notice to Eucure. The cost of such any audit shall be borne by Tracon, unless the audit discloses an overpayment by Tracon of more than [***] percent ([***]%) of the amount of payments due under this Agreement for the period under audit, in which case, Eucure shall bear the cost of such audit.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

(d) Any amounts shown to be owed but unpaid, or overpaid and in need of refund, by Tracon shall be paid or refunded (as the case may be) within [***] after the accountant's report, plus interest (as set forth in Section 6.3) from the original due date on any amounts underpaid (but interest shall not apply to overpayments). In the event that any audit of COGS establishes that the COGS charged by Eucure for Collaborative Product exceeded the actual COGS, Eucure shall refund Tracon the excess amount charged for Collaborative Product within [***] after the accountant's report, plus interest (as set forth in Section 6.3) from the date of Tracon's overpayment for such Collaborative Product.

6.5 Tax.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income, including any payments received, as contemplated in this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to take all such action as shall avoid or reduce tax withholding or similar obligations in respect of any payments made by a Party to the other Party under this Agreement and take advantage of any applicable double taxation agreement or treaty. Eucure shall deliver to Tracon an Internal Revenue Service Form W-8BEN-E claiming the benefits of the income tax convention between the United States and The People's Republic of China within [***] after the Effective Date.

(c) Payment of Tax. To the extent a Party is required by Applicable Laws to deduct and withhold taxes on any payment to the other Party, the paying Party shall pay the amounts of such taxes to the proper tax authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable such other Party to claim such payment of taxes.

ARTICLE 7
REPRESENTATIONS, WARRANTIES AND COVENANTS

7.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, to the other Party that, as of the Effective Date:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **No Conflict**. It is not a party to any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement.

7.2 **Additional Representations and Warranties of Eucure**. Eucure represents and warrants to Tracon that, as of the Effective Date:

(a) Eucure (i) has the right to grant the Collaborative Products License that it purports to grant in Section 3.1 and all other rights granted to Tracon herein; (ii) has not granted and will not grant any right to any Third Party that would conflict with or adversely affect such Collaborative Products License or rights; and (iii) possesses all necessary rights in intellectual property for the Development and Commercialization of Collaborative Product in the Collaborative Territory;

(b) neither Eucure nor any of its Affiliates has granted any license or right to obtain any license to any Third Party to the Collaborative Product IP in the Field in the Collaborative Territory;

(c) there are no actual, pending, or to Eucure's knowledge, alleged or threatened, adverse actions, suits, proceedings, or claims against Eucure (or facts providing the basis for such an action, suit, proceeding or claim) involving the Collaborative Product or the Collaborative Product IP, nor has Eucure received any written communication from any Third Party, including, without limitation, any Regulatory Authority or other government agency, threatening such action, suit or proceeding;

(d) neither Eucure nor any of its Affiliates has filed any regulatory filing for the Collaborative Product in the Field in the Collaborative Territory except as identified in Schedule 7.2(d);

(e) all tangible or recorded information and data provided by or on behalf of Eucure to Tracon related to the Collaborative Product is true, accurate and complete in all material respects, and Eucure has not failed to disclose, or failed to cause to be disclosed, any such information or data related to the Collaborative Product in its Control that would cause the information and data that has been disclosed to be misleading in any material respect;

(f) Eucure is not debarred or disqualified under the United States Federal Food, Drug and Cosmetic Act or comparable Applicable Laws in the Territory, and it has not employed or used the services of any person who is debarred or disqualified in connection with activities relating to any pharmaceutical products; and

(g) there are no legal claims, judgments or settlements against or owed by Eucure or any of its Affiliates, or pending or, to Eucure's knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations.

7.3 Additional Representations and Warranties of Tracon. Tracon represents, warrants, and covenants to Eucure that, as of the Effective Date:

(a) Tracon shall conduct the Development Activities performed by it pursuant to the Development Plan in a competent and professional manner and the personnel assigned to perform Development Activities rendered by Tracon under this Agreement shall be qualified and professionally capable of performing the Development Activities;

(b) Tracon is not debarred or disqualified under the United States Federal Food, Drug and Cosmetic Act or comparable Applicable Laws in the Territory, and it has not employed or used the services of any person who is debarred or disqualified in connection with activities relating to any pharmaceutical products; and

(c) there are no legal claims, judgments or settlements against or owed by Tracon or any of its Affiliates, or pending or, to Tracon's knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations.

7.4 Eucure Covenants. In addition to any covenants made by Eucure elsewhere in this Agreement, Eucure hereby covenants to Tracon as follows:

(a) All Collaborative Product supplied to Tracon will meet approved specifications and be provided with a certificate of analysis indicating that drug substance and drug product meets specifications and has at least [***] of stability under refrigerated conditions, and that no Collaborative Product has been out of specification in ongoing stability testing.

(b) Eucure will not knowingly employ or use the services of any person who is debarred or disqualified in connection with activities relating to Development of Collaborative Product; and, in the event that Eucure becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to Eucure with respect to any activities relating to the Collaborative Product, Eucure will immediately notify Tracon in writing and Eucure will cease employing, contracting with, or retaining any such person to perform any services relating to such Collaborative Product;

(c) Eucure will not, in connection with the performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including Eucure, nor will Eucure directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or

entity or any other person in connection with the performance of Eucure's obligations under this Agreement;

(d) Eucure and its employees and contractors, in connection with the performance of Eucure's obligations under this Agreement, shall not knowingly cause Tracon to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws;

(e) Eucure has a policy or practice in place against corruption and bribery and in connection with the performance of its obligations under this Agreement, Eucure shall comply and shall cause its and its Affiliates' employees to comply with Eucure's such policy or practice; and

(f) Eucure shall comply in all material aspects with all Applicable Laws in the course of performing its obligations and exercising its rights under this Agreement, and immediately notify Tracon if it has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of its obligations under this Agreement.

7.5 Tracon Covenants. In addition to any covenants made by Tracon elsewhere in this Agreement, Tracon hereby covenants to Eucure as follows:

(a) Tracon will not knowingly employ or use the services of any person who is debarred or disqualified in connection with activities relating to the Collaborative Product; and in the event that Tracon becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to Tracon with respect to any activities relating to the Collaborative Product; Tracon will immediately notify Eucure in writing and Tracon will cease employing, contracting with, or retaining any such person to perform any services relating to such Collaborative Product;

(b) Tracon will not, in connection with the performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including Tracon, nor will Tracon directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other person in connection with the performance of Tracon's obligations under this Agreement;

(c) Tracon and its employees and contractors, in connection with the performance of Tracon's obligations under this Agreement, shall not knowingly cause Eucure to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws;

(d) Tracon has a policy or practice in place against corruption and bribery and in connection with the performance of its obligations under this Agreement, Tracon shall comply

and shall cause its and its Affiliates' employees to comply with Tracon's such policy or practice; and

(e) Tracon shall comply in all material aspects with all Applicable Laws in the course of performing its obligations and exercising its rights under this Agreement, immediately notify Eucure if it has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of its obligations under this Agreement.

7.6 Performance by Affiliates and Subcontractors. The Parties recognize that each Party may perform some or all of its obligations or exercise some or all of its rights under this Agreement through one or more Affiliates or subcontractors; *provided*, in each case, that (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such delegation or subcontracting, and (b) each such Affiliate, subcontractor, licensee or sublicensee undertakes in writing obligations of confidentiality and non-use regarding Confidential Information and ownership of intellectual property rights which are substantially the same as those undertaken by the parties pursuant to Article 9; and *provided, further*, that such Party shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor, licensee or sublicensee.

7.7 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 7, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL SUCH REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. Each Party understands that Collaborative Product is the subject of ongoing research and development and that neither Party can assure that the Collaborative Product can successfully complete clinical trials, nor that the Collaborative Product can be successfully Developed and Commercialized in the Field in the Territory.

ARTICLE 8
INDEMNIFICATION; LIMITATION OF LIABILITY

8.1 Indemnification by Tracon. Tracon hereby agrees to defend, hold harmless and indemnify each of Eucure, its Affiliates and their agents, shareholders, directors, officers, employees and consultants, and the successors and assigns of any of the foregoing (the "**Eucure Indemnitees**") from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys' fees (collectively "**Losses**"), incurred by any Eucure Indemnitee as a result of any suits, claims, actions and demands brought by a Third Party (each, a "**Third Party Claim**") arising directly or indirectly out of (a) any breach of any representations, warranties, covenants or agreements by Tracon under this Agreement, or (b) the negligence or willful misconduct of any Tracon Indemnitee, or (c) the research, development, manufacture, use,

handling, storage, sale or other disposition of the Collaborative Product by Tracon or its Affiliates, licensees or sublicensees; provided that, Tracon's obligation to indemnify the Eucure Indemnitees pursuant to this Section 8.1 shall not apply to the extent that any such Losses arise from any activities for which Eucure is obligated to indemnify Tracon Indemnitees under Section 8.2.

8.2 Indemnification by Eucure. Eucure hereby agrees to defend, hold harmless and indemnify Tracon, its Affiliates and their agents, directors, officers, employees and consultants, and the successors and assigns of any of the foregoing (the "**Tracon Indemnitees**") from and against any and all Losses incurred by any Tracon Indemnitee as a result of any Third Party Claims arising directly or indirectly out of (a) any breach of any representations, warranties, covenants or agreements by Eucure under this Agreement, (b) the negligence or willful misconduct of Eucure Indemnitees, or (c) the research, development, manufacture, use, handling, storage, sale or other disposition of the Collaborative Product by Eucure or its Affiliates, licensees or sublicensees; provided that, Eucure's obligation to indemnify the Tracon Indemnitees pursuant to the foregoing sentence shall not apply to the extent that any such Losses arise from any activities for which Tracon is obligated to indemnify Eucure Indemnitees under Section 8.1.

8.3 Procedure. The indemnified Party shall provide the indemnifying Party with prompt notice of the claim giving rise to the indemnification obligation pursuant to this Article 8 and the exclusive ability to defend (with the reasonable cooperation of the indemnified Party) or settle any such claim; *provided, however*, that the indemnifying Party shall not enter into any settlement for damages other than monetary damages without the indemnified Party's written consent, such consent not to be unreasonably withheld. The indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party. If the Parties cannot agree as to the application of Sections 8.1 and 8.2 to any particular Third Party Claim, the Parties may conduct separate defenses of such Third Party Claim. Each Party reserves the right to claim indemnity from the other Party in accordance with Sections 8.1 and 8.2 above upon resolution of the underlying claim, notwithstanding the provisions of this Section 8.3 requiring the indemnified Party to tender to the indemnifying Party the exclusive ability to defend such claim or suit. The failure to deliver written notice to the indemnifying Party within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the indemnifying Party of its indemnification obligations under this Article 8 if and to the extent the indemnifying Party is actually prejudiced thereby.

8.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS ARTICLE 8 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 8.1 OR 8.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9.

8.5 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice in the region(s) where the Party operates and reasonable in light of its obligations under this Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 9
CONFIDENTIALITY

9.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (in such capacity, the "**Receiving Party**") agrees that, for the Term and for a period of [***] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party (in such capacity, the "**Disclosing Party**"). Pursuant to Section 10.1, Development Data should be deemed as Confidential Information of Eucure. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates', employees, directors, officers, agents, consultants, advisors (including legal, accounting, or other professional advisors) and other representatives (collectively the "**Representatives**") do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party may disclose Confidential Information only to the Representatives on a need-to-know basis. The Receiving Party will have executed or shall execute appropriate written agreements with its Representatives sufficient to enable it to comply with all the provisions of this Agreement, or the Representatives shall be bound by written confidentiality obligations no less stringent as those obligations imposed on the Receiving Party under this Agreement, and Receiving Party shall be responsible for the acts and or omissions of such Representative with regards to or any breach of the confidentiality obligations herein by such Representatives. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information and will cooperate with Disclosing Party in every reasonable way to help Disclosing Party regain possession of the Confidential Information and prevent its further unauthorized use or disclosure. The foregoing confidentiality and non-use obligations shall not apply to any portion of the Confidential Information that the Receiving Party can demonstrate by competent written proof:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party by a Third Party who has a legal right to make such disclosure; or

(e) is subsequently independently discovered or developed by the Receiving Party without the aid, application, or use of the Disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

9.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 9.1, the Receiving Party may disclose the Disclosing Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary for (i) the Development, manufacture or Commercialization of the Collaborative Product, including obtaining and maintaining Regulatory Approval or patent protection, pursuant to the terms of this Agreement; or (ii) the prosecuting or defending litigation as contemplated by this Agreement; or

(b) such disclosure is reasonably necessary: (i) to the Receiving Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, provided that in each such case on the condition that such directors, attorneys, independent accountants and financial advisors are bound in writing by confidentiality and non-use obligations consistent with those contained in this Agreement; or (ii) to actual or potential investors, acquirers, licensors, licensees, collaborators or other business partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, license or collaboration; *provided* that in each such case on the condition that such disclosures are bound in writing by confidentiality and non-use obligations consistent with those contained in the Agreement;

(c) such disclosure is required by Applicable Laws, including judicial or administrative process (such as vetting process of securities listing), and/or by competent securities regulators and stock exchanges, including but not limited to the SEC, the HKEx and the SFC. Confidential Information that is disclosed under this Section 9.2(c) shall remain otherwise subject to the confidentiality and non-use provisions of this Article 9, and the Party disclosing Confidential Information pursuant to Applicable Laws may disclose, but only to the extent so required, and shall take all steps reasonably necessary and practicable, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 9.2(a)(ii) or Section 9.2(c), it will, except where impracticable, give reasonable advance written notice to the other Party of such disclosure to allow the other Party a reasonable opportunity to seek a protective order or equivalent and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any

event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any disclosure under this Section 9.2 shall not relieve such Party of its obligations as the Receiving Party contained herein.

9.3 Public Announcements.

(a) Publicity. Subject to the rest of this Article 9, no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Laws.

(b) Press Releases. As soon as practicable following the Effective Date, the Parties shall issue a joint press release announcing the execution of this Agreement in substantially the form attached hereto as **Exhibit C**. Except as required by Applicable Laws (including disclosure requirements of the U.S. Securities and Exchange Commission ("**SEC**"), the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited ("**Listing Rules**") of HKEx, or any other stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed*; provided* that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Article 9 and which do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

(c) Filing of this Agreement. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC, the HKEx or any other stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; *provided* that each Party will ultimately retain control over what information to disclose to the SEC, the HKEx, or any other stock exchange or other governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the HKEx or any other stock exchange or other governmental agency.

9.4 Publication. At least [***] prior to a Party or any of its Affiliates, licensees or sublicensees, publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes any data or results generated from the Development of the Collaborative Product in the Field in the Collaborative Territory that has not been previously published, such Party shall provide to the other Party a draft copy thereof for its review and approval (unless such Party is required by Applicable Law to publish such Know-How sooner, in which case such Party shall provide such draft copy to the other Party as much in advance of such publication as possible). The publishing Party shall consider in good faith any comments provided by the other Party during such [***] period. The review period shall be extended for an additional [***] if a representative of the non-publishing Party can demonstrate a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. By mutual agreement of the Parties, this period may be further extended. In addition, the publishing Party shall, and shall cause its Affiliates, licensees or sublicensees, as applicable, at the other Party's reasonable request, remove therefrom any Confidential Information of such other Party. The contribution of each Party shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate.

9.5 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 9 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

9.6 Equitable Relief. Each Party acknowledges that a breach of this Article 9 cannot be reasonably or adequately compensated in damages in an action at law and that such a breach shall cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein.

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 Ownership. As between the Parties, and subject to the licenses granted under this Agreement, (a) Eucure is the sole owner of all rights, title and interest in and to the Collaborative Product IP (other than Development IP), (b) Tracon is the sole owner of all rights, title and interest in and to the Tracon IP, (c) Eucure and Tracon shall jointly own all rights, title and interest in and to the Development IP and Development Data. Upon generation of Development Data or the conception or reduction to practice of any Development IP by a Party, such Party shall promptly notify the other Party thereof. Each of Tracon and Eucure agree and hereby irrevocably transfer and assign to the other sufficient rights to vest joint ownership in the Development Data and Development IP. Each Party shall perform and, if necessary, obligate its personnel to perform any and all other reasonable acts necessary to assist the other Party in obtaining, maintaining,

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

implementing, securing and perfecting such any and all rights hereof, including but not limited to executing the necessary documents by such Party and/or its personnel.

10.2 Prosecution and Maintenance.

(a) Collaborative Product IP. Eucure shall be solely responsible for, and shall have the sole rights in relation to, the preparation, filing, prosecution and maintenance of any Patents and other intellectual property rights within the Collaborative Product IP (other than Development IP), at its sole cost and expense.

(b) Development IP. The Parties shall collaborate with respect to the prosecution and maintenance of any Patents within the Development IP. The prosecuting Party shall inform the non-prosecuting Party as to the material correspondence received from the applicable patent office in the course of prosecution and maintenance of any Patents within the Development IP reasonably prior to any deadline or action with any patent office, shall furnish to the non-prosecuting Party copies of the draft responses reasonably in advance of such deadline, and shall reasonably take into account the non-prosecuting Party's comments. The prosecuting Party shall keep the non-prosecuting Party reasonably informed of progress with regard to the prosecution and maintenance of any Patents within the Development IP and shall provide to the non-prosecuting Party copies of all material patent office submissions within a reasonable amount of time following submission thereof by the prosecuting Party. In the event that the prosecuting Party desires to abandon or cease the prosecution or maintenance of any Patents within the Development IP in any country in the Territory, or decides not to file any Patents within the Development IP in any country in the Territory, the prosecuting Party shall provide reasonable prior written notice to the non-prosecuting Party of such intention to abandon or not to file (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Patent within the Development IP in the relevant patent office). In such case, upon written notice to the prosecuting Party from the non-prosecuting Party, the non-prosecuting Party may elect to file or continue the prosecution and maintenance of any such Patent in the applicable country, at its sole cost and expense and by counsel of its own choice.

(c) Cooperation of the Parties. Each Party agrees to cooperate fully in the prosecution and maintenance of the Patents within the Development IP pursuant to Section 10.2(b). The non-prosecuting Party shall provide reasonable cooperation in the prosecution and maintenance of such Patents at the prosecuting Patent's sole cost and expense, including but not limited to: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to enable the prosecuting Party to apply for and to prosecute patent applications in any country as permitted by Section 10.2(b), and (ii) promptly informing the other Party of any matters coming to such Party's attention that may materially adversely affect the prosecution and maintenance of any such patent applications.

10.3 Defense of Third Party Claims. In the event that any Third Party asserts that the Commercialization of Collaborative Product in the Collaborative Territory infringes any Third

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Party intellectual property rights, the Party first having notice of the assertion shall promptly notify the other Party and the Parties promptly meet to consider the claim or assertion and the appropriate course of action, including entering into an "identity of interest agreement" wherein such Parties agree to their shared mutual interest in the outcome of such potential dispute, as appropriate. The Parties shall discuss and agree on how best to mitigate or control the defense of any such claim or assertion; provided that, if either Party or any of its Affiliates have been individually named as a defendant in such claim or assertion, the other Party shall be allowed to join in such action, at its own expense. The Parties shall keep each other informed of the status of and of their respective activities regarding any claim or assertion under this Section 10.3; provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.3 may be undertaken by a Party without the consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed.

10.4 Infringement by Third Parties. In the event either Party becomes aware of any Third Party infringement of the Collaborative Product IP in the Field in the Collaborative Territory (an "**Infringement**"), such Party shall promptly notify the other Party and the Parties shall confer in good faith regarding strategy for abating such infringement in view of its potential effect upon the Commercialization of Collaborative Products in the Field in the Collaborative Territory. As between the Parties, Tracon shall have the first right to bring an action for infringement of the Collaborative Product IP in the Field in the Collaborative Territory, at its sole cost and expense, and any recovery realized as a result of any such action or proceeding, whether by way of settlement or otherwise, shall first be used to reimburse the Parties for their costs in connection with such enforcement action and the balance shall be treated as Net Sales. Eucure shall have the right (but not the obligation), at its own expense, to participate in any such Infringement action and to be represented in any such suit, proceeding, or action by counsel of its own choice. If Tracon does not elect to bring an enforcement action against such Infringement or does not bring such enforcement action within [***] after receiving notice of such Infringement, Eucure shall have the right but not the responsibility to bring an enforcement action against such Infringement, at its sole cost and expense, and any recovery shall first be used to reimburse the Parties for their costs in connection with such enforcement action and the balance shall retained by Eucure. Each Party shall cooperate at the enforcing Party's expense with any enforcement action brought against an Infringement and, additionally, shall have the right to participate in such action with its own counsel at its own expense subject to the foregoing right of reimbursement from any recoveries from such action.

ARTICLE 11
TERM AND TERMINATION

11.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 11, shall remain in effect until the earlier of (a) the date that the Parties cease Development and Commercialization of all Collaborative Products in the Field in the Collaborative Territory pursuant to this Agreement; or (b) on a country-by-country basis, the expiration of the Royalty Term in such country of the Collaborative Territory (the

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

"**Term**"). In the event the Agreement expires in a country pursuant to this Section 11.1(b), the licenses granted herein shall become non-exclusive, perpetual and fully paid-up in such country.

11.2 Termination for Breach. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party, if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, such breaching party fails to cure such material breach within sixty (60) days (or twenty-five (25) days with respect to any payment breach) from the date of such notice. Any right to terminate under this Section 11.2, other than with respect to any payment breach, shall be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 12 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Article 12.

11.3 Termination for Convenience or Good Reason.

(a) Either Party shall have the right to terminate this Agreement upon sixty (60) days advance written notice to the other Party if the terminating Party reasonably determines, based upon additional information that becomes available or an analysis of the existing information at any time, that the medical risk/benefit of Collaborative Product is so unfavorable that it would be incompatible with the welfare of patients to Develop or Commercialize or to continue to Develop or Commercialize Collaborative Product. Prior to any such termination, the terminating Party shall comply with such internal review and management approval processes as it would normally follow in connection with the termination of the development and commercialization of its own products for safety reasons and shall present and discuss the findings of such internal review for approval by the JSC.

(b) If Eucure does not grant prior approval for Tracon's exercise of the Tracon Option under Section 3.6(c), then Tracon shall have the right, in its discretion, to terminate this Agreement for convenience upon thirty (30) days written notice to Eucure during the ninety (90) days period after Eucure denies approval for the exercise of the Tracon Option; *provided*, *further* that if such notice of termination is given within twelve (12) months of the Effective Date, (x) Eucure shall reimburse Tracon for all costs and expenses incurred by Tracon in the course of performing the Development Activities, and (y) notwithstanding the provisions of Sections 11.5(c)(iii) and (iv), Eucure shall bear the cost of the Wind-Down Activities and Eucure shall reimburse Tracon for its costs and expenses incurred to provide all cooperation and assistance requested or required by Eucure pursuant to Section 11.5(c)(iii).

11.4 Termination for Bankruptcy. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party, if the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of substantially all of its assets, or if such other Party proposes a written agreement of composition or extension of substantially all of its debts, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within ninety (90) days after the

filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment of substantially all of its assets for the benefit of creditors.

11.5 Effect of Termination.

(a) In the event of any termination of the Agreement other than by Tracon pursuant to Section 11.2 or 11.4, the Collaborative Products License shall terminate.

(b) In the event of a termination of the Agreement by Tracon pursuant to Section 11.2 or 11.4, the Collaborative Products License shall continue in the Field and in the Collaborative Territory, provided that (i) such license shall remain exclusive during the Royalty Term and non-exclusive thereafter; (ii) Tracon shall have the right to have the Collaborative Product manufactured for its Development and Commercialization requirements in the Field and in the Collaborative Territory; and (iii) in addition to those provisions of the Agreement that survive pursuant to Section 11.6, during the Royalty Term, Articles 6, and 10, and Sections 3.1, 3.2, 3.4, 3.7, 4.1(a), 4.1(c), 4.1(e), 4.1(f), 4.4, 4.5, 5.1(except for the second and last sentences thereof), 5.3, 5.4, 7.5, and 7.6, shall additionally survive such termination; (iv) Section 2.1 shall survive solely with respect to the information sharing function of the JSC which shall no longer have a decision-making or approval role; and (v) the Collaborative Product License shall terminate if Tracon materially breaches any provision that so survives (including its obligations to make payment under Article 6) and fails to cure such breach within sixty (60) days after receipt of a notice of such breach from Eucure.

(c) In the event of termination pursuant to Section 11.3, by mutual agreement of the Parties, or by Eucure pursuant to Section 11.2 or 11.4, the following terms shall apply:

(i) Development Data. Tracon shall, within a period of [***] following the effective date of such termination, provide Eucure access to, and transfer to Eucure, all Development Data for Collaborative Product in its possession as of the effective date of such termination.

(ii) Regulatory Filings. Tracon shall promptly transfer and assign to Eucure all regulatory filings (including Regulatory Approval) for the Collaborative Product in the Field in the Collaborative Territory that are held by Tracon or its Affiliates. Upon Eucure's request, Tracon shall provide Eucure with reasonable assistance and cooperation regarding any inquiries and correspondence with Regulatory Authorities relating to the Collaborative Product in the Field in the Collaborative Territory.

(iii) Transition to Eucure. Upon Eucure's request, Tracon shall and shall cause its Affiliate to reasonably cooperate with Eucure to facilitate the orderly transition of the Development (including any ongoing clinical trials) and Commercialization of the Collaborative Product in the Field in the Collaborative Territory to Eucure, including (1) assigning or terminating as appropriate, upon request of Eucure (and subject to any necessary Third Party

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

consent), any agreements or arrangements with Third Party vendors (including distributors) to Develop, promote, distribute, sell or otherwise Commercialize the Collaborative Product; (2) to the extent that Tracon or its Affiliate is performing any activities described above in (1), reasonably cooperating with Eucure to transfer such activities to Eucure or its designee, and continuing to perform such activities on Eucure's behalf for a reasonable time after termination until such transfer is completed. Eucure shall reimburse Tracon for the cost and expense incurred to provide all such cooperation and assistance requested or required by Eucure pursuant to this Section 11.5(c)(iii), unless the Agreement is terminated by Tracon pursuant to Section 11.3 or by Eucure pursuant to Section 11.2 or 11.4, in which case Tracon shall bear its costs to provide such cooperation and assistance.

(iv) Wind-Down Activities. Tracon, in consultation with Eucure, will promptly wind-down any of Tracon's ongoing Development and Commercialization activities (including any clinical studies) for Collaborative Product that Eucure does not request transition to Eucure under clause (iii) above in an orderly manner consistent with accepted pharmaceutical industry norms and ethical practices ("**Wind-Down Activities**"). If the Agreement is terminated pursuant to Section 11.3, the cost and expense of the Wind-Down Activities shall be borne by the terminating Party. If the Agreement is terminated by the mutual agreement of the Parties, the Parties shall share equally the costs and expenses of the Wind-Down Activities or as otherwise mutually agreed. If the Agreement is terminated by Eucure pursuant to Section 11.2 or 11.4, Tracon shall bear the costs and expenses of the Wind-Down Activities, absent mutual agreement to the contrary.

11.6 Survival. Expiration or termination of this Agreement shall not relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. Without limiting the foregoing, the following provisions, including the Parties' rights and obligations thereunder, shall survive any expiration or termination of this Agreement: Articles 1, 8, 9, 12, and 13 and Sections 3.3, 6.4, 7.7, 10.1, 11.5, and 11.6 and those which, by their nature, are intended to survive.

ARTICLE 12
DISPUTE RESOLUTION

12.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 12 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

12.2 Internal Resolution. With respect to all disputes arising between the Parties under this Agreement, including, without limitation, any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement or any failure of the parties toreach consensus where consensus is required under the Agreement, if the Parties are unable to resolve such dispute within [***] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers of the Parties for attempted resolution by good faith negotiations within [***] after such notice is received.

12.3 Binding Arbitration.

(a) Claims. If the Chief Executive Officers of the Parties are not able to resolve any disputed matter within [***] and either Party wishes to pursue the matter, each such dispute, controversy or claim shall be finally resolved by binding arbitration before a panel of three neutral experts with relevant industry experience, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration proceeding shall be administered by the International Court of Arbitration of the International Chamber of Commerce (the "**ICC**") in accordance with its then existing arbitration rules or procedures regarding commercial or business disputes, and the panel of arbitrators shall be selected in accordance with such rules. The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in New York, NY. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of arbitration without the prior written consent of both Parties.

(b) Arbitrators' Award. The arbitrators shall, within [***] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall not be authorized to award any damages expressly excluded pursuant to Section 8.4. The decision or award rendered by the arbitrators shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction. Either Party may apply for interim injunctive relief with the arbitrators until the arbitration award is rendered or the controversy is otherwise resolved.

(c) Costs. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however,* that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the tribunal and the arbitrators.

(d) Court Actions. Nothing contained in this Agreement shall deny either Party the right to seek, upon good cause, injunctive or other equitable relief from a court of competent jurisdiction in the context of an emergency or prospective irreparable harm, and such an action

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

may be filed and maintained notwithstanding any ongoing dispute resolution discussions or arbitration proceedings.

ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement; Amendment. This Agreement, including the Exhibits attached hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

13.2 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement, other than obligations to make payments when due, to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues, the nonperforming Party takes reasonable efforts to remove the condition and provided that the nonperforming Party has not caused such condition to occur. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the nonperforming Party, including without limitation, an act of God or terrorism, involuntary compliance with any regulation, law or order of any government, war, civil commotion, epidemic or pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. If a force majeure persists for more than [***], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

13.3 Bankruptcy Code. All licenses and rights granted under this Agreement will be deemed licenses of rights to intellectual property for purposes of Section 365(n) of the United States Bankruptcy Code or any analogous provisions in any other country or jurisdiction and a licensee or sublicensee under this Agreement will retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

13.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by reputable overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at the address specified below or such other address as may be specified by such Party in writing in accordance with this Article 13. Notice shall be deemed to have been sufficiently given for all purposes upon the earliest

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

of (a) the date of actual receipt, if hand-delivered, or sent by facsimile with electronic confirmation of receipt, or a reputable courier service, or (b) [***] after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Tracon:	TRACON Pharmaceuticals, Inc. 4350 La Jolla Village Dr., Suite 800 San Diego, CA 92121 USA Attention: Chief Business Officer Fax: +1 858-550-078
with a copy to:	Pillsbury Winthrop Shaw Pittman LLP 12255 El Camino Real, Suite 300 San Diego, CA 92130 United States Attn: Richard L. Blaylock Email: not permitted
If to Eucure:	Eucure (Beijing) Biopharma Co., Ltd. 23F, Tower 3, China Central Place, No.77, Jian Guo Road Chaoyang District, Beijing, China Attention： Dr. Chaoshe Guo, VP of Business Development Email: [***]
with a copy to:	Cooley LLP 4401 Eastgate Mall, San Diego, CA 92121, United States Attn:James Lu Email: [***]

13.5 No Strict Construction; Headings. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

13.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to an Affiliate or to a successor to substantially all of the business of such Party (whether by merger, sale of stock, sale of assets or other transaction) or as expressly permitted herein. Any permitted successor or assignee of rights or obligations hereunder shall, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the foregoing shall be null, void and of no legal effect.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

13.7 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.8 **No Third Party Beneficiaries**. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except as expressly provided with respect to the Eucure Indemnitees and the Tracon Indemnitees.

13.9 **Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.10 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

13.11 **Independent Contractors**. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

13.12 **Interpretations**. In this Agreement, unless otherwise specified:

(a) "includes" and "including" shall mean respectively includes and including without limitation;

(b) the word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction is mutually exclusive;

(c) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(d) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(e) all references to days, quarters and years in this Agreement shall mean calendar days, quarters and years, respectively, unless otherwise specified; and

(f) the Exhibits attached hereto form part of the operative provision of this Agreement and references to this Agreement shall include references to such Exhibits.

13.13 **English Language**. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. To the extent this Agreement requires a Party to provide to the other Party information, correspondence, notice or other documentation, such Party shall provide such information, correspondence, notice or other documentation in the English language and also a copy of the original of such information, correspondence, notice or other documentation if such original is not in the English language.

13.14 **Governing Law**. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of State of New York, U.S., without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

13.15 **Guaranty**. To induce Tracon to enter into this agreement, Parent hereby absolutely, unconditionally and irrevocably guarantees to Tracon the due and punctual observance, performance and discharge of the obligations of Eucure (payment and otherwise) under this Agreement. The provisions of Section 12 and 13 shall apply *mutatis mutandis* to this guarantee by Parent as if Parent were a Party.

13.16 **Counterparts**. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

In Witness Whereof, the Parties have executed this Collaborative Development and Commercialization Agreement in triplicate originals by their duly authorized officers as of the Effective Date.

Tracon Pharmaceuticals, Inc.

By: /s/ Charles Theuer, M.D. Ph.D.

Name: CHARLES THEUER, M.D. Ph.D.

Title: President and CEO

Eucure (Beijing) Biopharma Co., Ltd

By: /s/ Yuelei Shen

Name: Yuelei Shen

Title: President and CEO

With respect to Section 13.15:

Biocytogen Pharmaceuticals (Beijing) Co., Ltd

By: /s/ Yuelei Shen

Name: Yuelei Shen

Title: President and CEO

Exhibit A
Patents describing Antibody

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Exhibit B

Clinical Supply and Quality Agreement Terms

[***]

Exhibit C
[Press Release]

TRACON Pharmaceuticals and Eucure Biopharma, a Subsidiary of Biocytogen, Announce Partnership for Development of Clinical Stage CTLA-4 Antibody YH001

YH001 is a potential best-in-class CTLA-4 antibody with enhanced ADCC and CDC effector functions

YH001 is currently being dosed in multiple Phase 1 oncology trials sponsored by Eucure Biopharma in Australia and China

TRACON intends to initiate a Phase 1 trial of YH001 in combination with envafolimab in soft tissue sarcoma as well as to study YH001 in multiple other selected tumor types

San Diego, CA – October 11, 2021 – TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics and utilizing a cost efficient, CRO-independent product development platform to partner with ex-U.S. companies to develop and commercialize innovative products in the U.S., announced today that it has entered into a collaborative partnership agreement with Eucure Biopharma, a subsidiary of Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen), and a China-based clinical stage biopharmaceutical company primarily focused on the research and development of biologics, for the development of YH001, a CTLA-4 antibody with enhanced ADCC and CDC effector functions, for development in multiple oncology indications, including soft tissue sarcoma, in North America.

Under the terms of the agreement, TRACON will be responsible for the clinical development and commercialization of YH001 in multiple oncology indications in North America, with the majority of the development activities expected to occur in the U.S. TRACON will bear the costs of clinical trials and Eucure Biopharma will supply YH001. TRACON will be responsible for commercializing YH001 in multiple oncology indications in North America and will owe Eucure Biopharma escalating double digit royalties on net sales.

YH001 was developed to potently inhibit CTLA-4 binding to the CD80/CD86 receptors and deplete regulatory T cells through enhanced ADCC and CDC effector functions. YH001 demonstrated superior activity *in vitro* and in transgenic syngeneic tumor models compared to ipilimumab (Yervoy®), both as a single agent and when combined with a PD-(L)1 antibody.

“We are focused on advancing a dual checkpoint inhibitor strategy focused on the PD-(L)1 and CTLA-4 pathways, that we expect to leverage in sarcoma by combining YH001 with envafolimab, our novel, single-domain PD-L1 antibody, in sarcoma. Going forward, we intend to use YH001 rather than Yervoy in our future dual checkpoint inhibition trials in sarcoma, which we anticipate will result in meaningful cost savings from not needing to purchase Yervoy at retail prices.” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Moreover, we expect to study YH001 in other solid tumors in combination with PD-(L)1 antibodies, including in patients who have progressed on prior PD-(L)1 treatment.”

“We believe that this collaboration with TRACON has potential to provide cancer patients in the United States with a best-in-class CTLA-4 checkpoint inhibitor. YH001 was optimized using Biocytogen’s discovery labs and proprietary transgenic mouse models to inhibit CTLA-4 binding and to deplete regulatory cells.

In our ongoing Phase 1 clinical trials, YH001 has been tolerable as a single agent and in combination with the PD-1 antibody toripalimab," said Dr. Yuelei Shen, CEO of Biocytogen and Eucure Biopharma.

About YH001

YH001 is an IgG1 antibody against CTLA-4 that has shown enhanced antibody dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) *in vitro*. In preclinical studies YH001 demonstrated superior T cell activation and superior tumor growth inhibition activity compared to ipilimumab. YH001 also demonstrated superior activity compared to ipilimumab in human transgenic mouse tumor models when combined with a PD-(L)1 antibody. In these models, single agent YH001 depleted regulatory T cells and increased CD8+ T cells in tumor tissue. YH001 is being dosed as a single agent in a Phase 1 trial in China (NCT04699929) and in combination with the PD-1 antibody toripalimab in a Phase 1 trial in Australia (NCT04357756). In July 2021, the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug application to initiate multiple phase II clinical trials for YH001 in the United States.

About Envafolimab

Envafolimab (KN035), a novel, single-domain antibody against PD-L1, is the first subcutaneously injected PD-(L)1 inhibitor to be studied in pivotal trials. Envafolimab is currently being studied in the ENVASARC Phase 2 pivotal trial in the U.S. sponsored by TRACON, as well as in a Phase 2 pivotal trial as a single agent in MSI-H/dMMR advanced solid tumor patients and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines. Alphamab Oncology and 3D Medicines submitted an NDA to the NMPA in China for envafolimab in MSI-H/dMMR cancer that was accepted for review in December 2020 and granted priority review in January 2021. In the Phase 2 MSI-H/dMMR advanced solid tumor trial, the confirmed objective response rate (ORR) by blinded independent central review in MSI-H/dMMR colorectal cancer (CRC) patients treated with envafolimab who failed a fluoropyrimidine, oxaliplatin and irinotecan was 32%, which was similar to the 28% confirmed ORR reported in the Opdivo package insert in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin, and irinotecan and the 33% confirmed ORR reported for Keytruda in MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan in cohort A of KEYNOTE-164.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient, CRO independent, product development platform. The Company's clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and

commercial capabilities in the U.S. To learn more about TRACON and its product pipeline, visit TRACON's website at www.traconpharma.com.

About Eucure Biopharma

Eucure Biopharma, a subsidiary of Biocytogen, is a China based innovative biotechnology company with global vision, specializing in developing innovative antibody drugs with independent intellectual property rights. Relying on a strong clinical development team with extensive experience, the company has established a product pipeline for more than 10 targets. At present, three products have received clinical trial approvals in the US and China including that two products have obtained the phase II clinical approval from the FDA and have initiated the global phase II clinical trial, two products have entered the phase I clinical trial in China, four products have entered Phase I clinical stages in Australia. These lay a solid foundation for the development of Eucure Biopharma. As a wholly owned subsidiary of Biocytogen, Eucure Biopharma is focused on clinical development. Biocytogen is an international biotechnology company driven by innovative technology and committed to becoming the global birthplace of new drugs, with a mission to focus on technological innovation, continuously produce new drugs, and safeguard human health. For more information, please visit www.eucure.com.

About Biocytogen

Biocytogen Pharmaceuticals (Beijing) Co., Ltd. is a global biotech company that drives the research and development of new drugs with innovative technologies. The company is committed to becoming a global headstream of new drugs and bringing the benefits to patients around the world as its mission. Based on the fully human antibody RenMab™ and RenLite™ mice for fully human antibodies production with robust humoral responses, highly diverse antibody repertoire and superior affinity, Biocytogen has integrated its platforms in single-cell antibody discovery, gene editing, large-scale animal model supply, and screening to form a new approach to streamline the entire drug development process. Biocytogen actively promotes the independent and cooperative development of new drugs. For more, please visit http://en.biocytogen.com.cn/

Forward-Looking Statements

Statements made in this press release regarding matters that are not historical facts are “forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's and Eucure’s plans to further develop YH001, potential benefits of the collaboration between TRACON and Eucure, expectations regarding the timing, design and scope of clinical trials, potential payments and activities under the collaboration with Eucure, expected development milestones, and potential benefits of YH001 and TRACON’s product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON’s expected timelines, if at all; the impact of the COVID-19 pandemic; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that the collaboration agreement with Eucure Biopharma is subject to early termination; potential changes in regulatory requirements in the United States and foreign countries;

TRACON's reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON's filings with the Securities and Exchange Commission under the heading "Risk Factors". All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

TRACON Contacts:

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
(212) 915-2578
britchie@lifesciadvisors.com

Biocytogen and Eucure Biopharma Contacts:

Company Contact:
Chaoshe Guo
Vice President, Business Development and Licensing
Biocytogen Pharmaceuticals (Beijing) Co., Ltd.
Chaoshe.guo@bbctg.com.cn

Investor Contact:
Yongliang Wang
Deputy General Manager
Biocytogen Pharmaceuticals (Beijing) Co., Ltd.
Yongliang.wang@bbctg.com.cn

Schedule 3.6(a)

Pre-approved Substitute Indications

bladder cancer
endometrial cancer
melanoma

Schedule 4.1(a)

Development Plan

[***]

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 3, 2021

/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 3, 2021

/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, 2021, 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 3, 2021

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

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

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, 2021, 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 3, 2021

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

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.