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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

OR

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

Commission File Number: 001-33038

Alaunos Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**84-1475642**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

8030 El Rio Street
Houston, TX 77054
(346) 355-4099
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TCRT	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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large Accelerated Filer	☐	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 ☒

As of August 10, 2022, the number of outstanding shares of the registrant's common stock, $0.001 par value, was 216,174,542 shares.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are all statements contained in this Quarterly Report that are not historical fact, and in some cases can be identified by terms such as: "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "target," "will" and other words and terms of similar meaning.

These statements are based on management's current beliefs and assumptions and on information currently available to management. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- our ability to raise substantial additional capital to continue as a going concern, fund our planned operations and repay our existing indebtedness;
- estimates regarding our expenses, use of cash, timing of future cash needs and anticipated capital requirements;
- the development of our product candidates, including statements regarding the initiation, timing, progress and results of our preclinical studies, clinical trials and research and development programs;
- our ability to advance our product candidates through various stages of development, especially through pivotal safety and efficacy trials;
- the risk that final trial data may not support interim analysis of the viability of our product candidates;
- our expectation regarding the safety and efficacy of our product candidates;
- the timing, scope or likelihood of regulatory filings and approvals from the U.S. Food and Drug Administration, or FDA, or equivalent foreign regulatory agencies for our product candidates and for which indications;
- our ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements;
- our ability to enter into partnerships or strategic collaboration agreements and our ability to achieve the results and potential benefits contemplated from relationships with collaborators;
- our ability to maintain and establish collaborations and licenses;
- our expectation of developments and projections relating to competition from other pharmaceutical and biotechnology companies or our industry;
- our estimates regarding the potential market opportunity for our product candidates;
- the anticipated rate and degree of commercial scope and potential, as well as market acceptance of our product candidates for any indication, if approved;
- the anticipated amount, timing and accounting of contract liabilities, milestones and other payments under licensing, collaboration or acquisition agreements, research and development costs and other expenses;
- our intellectual property position, including the strength and enforceability of our intellectual property rights;
- our ability to attract and retain qualified employees and key personnel; and
- our expectations regarding the impact of the COVID-19 pandemic, including the expected duration of disruption to key clinical trial activities, limitations on travel, quarantine and social distancing protocols, diversion of healthcare resources away from the conduct of our clinical trials, and other immediate and long-term impacts and effects on our business and operations.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law,

we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Quarterly Report to "Alaunos," the "Company," "we," "us" or "our" refer to Alaunos Therapeutics, Inc., and its subsidiaries.

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. We own the trademarks Alaunos™, Ziopharm® and hunTR™ as well as the graphic trademark found on our website. Other trademarks, service marks and trade names appearing in this Quarterly Report are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Quarterly Report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

Our business faces significant risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report. Some of the more significant risks include the following:

- We will require substantial additional financial resources to continue as a going concern, continue ongoing development of our product candidates and pursue our business objectives; if we are unable to obtain these additional resources when needed, we may be forced to delay or discontinue our planned operations, including clinical testing of our product candidates.
- Our plans to develop and commercialize non-viral adoptive cellular therapies based on T-cell receptor, or TCR, therapies can be considered as new approaches to cancer treatment, the successful development of which is subject to significant challenges.
- Our current product candidates are based on novel technologies and are supported by limited clinical data and we cannot assure you that our current and planned clinical trials will produce data that supports regulatory approval of one or more of these product candidates.
- We will need to attract, recruit and retain qualified personnel, and we will continue to rely on key scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.
- Our existing indebtedness, together with our other financial obligations and contractual commitments, could adversely affect our financial condition and restrict our future operations. For instance, if we fail to achieve certain clinical milestones or equity raise requirements, we will be required to deposit a significant amount of cash into an account to be held as collateral.
- If we are unable to obtain the necessary United States or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.
- Our product candidates are in various stages of clinical trials, which are very expensive and time-consuming. We cannot be certain when we will be able to submit a Biologics License Application, or BLA, to the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.
- Our cell-based immuno-oncology product candidates rely on the availability of reagents, specialized equipment, and other specialty materials and infrastructure, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.
- If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.
- Our immuno-oncology product candidates may face competition in the future from biosimilars.
- If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired.
- Our stock price has been, and may continue to be, volatile.
- Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our clinical research organizations, or CROs, shippers and others.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Alaunos Therapeutics, Inc.

BALANCE SHEETS
(unaudited)

(in thousands, except share and per share data)

	June 30, 2022	December 31, 2021
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 60,011	$ 76,054
Receivables	—	1,111
Prepaid expenses and other current assets	1,350	1,666
Total current assets	61,361	78,831
Property and equipment, net	9,671	10,941
Right-of-use asset	2,357	4,420
Deposits	42	42
Other non-current assets	500	631
Total assets	$ 73,931	$ 94,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 474	$ 1,368
Current portion of long-term debt	20,051	7,868
Accrued expenses	5,725	6,076
Lease liability, current	525	729
Total current liabilities	26,775	16,041
Long-term debt	4,472	16,250
Lease liability, non-current	2,476	4,518
Other non-current liabilities	28	—
Total liabilities	$ 33,751	$ 36,809
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock $0.001 par value; 420,000,000 shares authorized, 216,174,542 shares issued and outstanding at June 30, 2022 and 350,000,000 shares authorized, 216,127,443 shares issued and outstanding at December 31, 2021	216	216
Additional paid-in capital	902,536	900,693
Accumulated deficit	(862,572)	(842,852)
Total stockholders' equity	40,180	58,057
Total liabilities and stockholders' equity	$ 73,931	$ 94,865

The accompanying notes are an integral part of these financial statements.

Alaunos Therapeutics, Inc.

STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	5,937	13,570	11,518	26,906
General and administrative	3,429	9,069	6,935	17,296
Gain on lease modification	(133)	—	(133)	—
Total operating expenses	9,233	22,639	18,320	44,202
Loss from operations	(9,233)	(22,639)	(18,320)	(44,202)
Interest expense	(740)	—	(1,425)	—
Other income (expense), net	41	(31)	25	(22)
Net loss	$ (9,932)	$ (22,670)	$ (19,720)	$ (44,224)
Net loss applicable to common stockholders	$ (9,932)	$ (22,670)	$ (19,720)	$ (44,224)
Basic and diluted net loss per share	$ (0.05)	$ (0.11)	$ (0.09)	$ (0.21)
Weighted average common shares outstanding, basic and diluted	214,998,893	214,426,406	214,972,876	214,191,839

The accompanying notes are an integral part of these financial statements.

Alaunos Therapeutics, Inc.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(unaudited)

(in thousands, except share and per share data)

For the Three Months Ended June 30, 2022

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at March 31, 2022	215,950,561	$ 216	$ 901,546	$ (852,640)	$ 49,122
Stock-based compensation	—	—	990	—	990
Restricted stock awards	280,000	—	—	—	—
Cancelled restricted common stock	(56,019)	—	—	—	—
Net loss	—	—	—	(9,932)	(9,932)
Balance at June 30, 2022	216,174,542	$ 216	$ 902,536	$ (862,572)	$ 40,180

The accompanying notes are an integral part of these financial statements.

For the Six Months Ended June 30, 2022

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	216,127,443	$ 216	$ 900,693	$ (842,852)	$ 58,057
Stock-based compensation	—	—	1,843	—	1,843
Restricted stock awards	280,000	—	—	—	—
Cancelled restricted common stock	(232,901)	—	—	—	—
Net loss	—	—	—	(19,720)	(19,720)
Balance at June 30, 2022	216,174,542	$ 216	$ 902,536	$ (862,572)	$ 40,180

The accompanying notes are an integral part of these financial statements.

For the Three Months Ended June 30, 2021

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at March 31, 2021	215,257,674	$ 215	$ 891,081	$ (785,655)	$ 105,641
Stock-based compensation	—	—	5,290	—	5,290
Exercise of employee stock options	10,667	—	20	—	20
Restricted stock awards	412,898	1	(1)	—	—
Cancelled restricted common stock	(122,091)	—	—	—	—
Net loss	—	—	—	(22,670)	(22,670)
Balance at June 30, 2021	215,559,148	$ 216	$ 896,390	$ (808,325)	$ 88,281

The accompanying notes are an integral part of these financial statements.

For the Six Months Ended June 30, 2021

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	214,591,906	$ 215	$ 887,868	$ (764,101)	$ 123,982
Stock-based compensation	—	—	7,486	—	7,486
Exercise of employee stock options	363,109	—	1,036	—	1,036
Restricted stock awards	726,224	1	—	—	1
Cancelled restricted common stock	(122,091)	—	—	—	—
Net loss	—	—	—	(44,224)	(44,224)
Balance at June 30, 2021	215,559,148	$ 216	$ 896,390	$ (808,325)	$ 88,281

The accompanying notes are an integral part of these financial statements.

Alaunos Therapeutics, Inc.

STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (19,720)	$ (44,224)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,374	1,219
Amortization of financing costs	405	—
Stock-based compensation	1,843	7,486
Reduction in the carrying amount of right-of-use assets	2,196	(721)
Gain on lease modification	(133)	—
(Increase) decrease in:		
Receivables	1,111	(2,961)
Prepaid expenses and other current assets	316	5,820
Other non-current assets	131	493
Increase (decrease) in:		
Accounts payable	(894)	22
Accrued expenses	(368)	(4,742)
Lease liabilities	(2,246)	843
Other non-current liabilities	28	—
Net cash used in operating activities	(15,957)	(36,765)
Cash flows from investing activities:		
Purchases of property and equipment	(86)	(2,594)
Net cash used in investing activities	(86)	(2,594)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	—	1,036
Net cash provided by financing activities	—	1,036
Net decrease in cash and cash equivalents	(16,043)	(38,323)
Cash and cash equivalents, beginning of period	76,054	115,069
Cash and cash equivalents, end of period	$ 60,011	$ 76,746
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 1,002	$ —
Amounts included in accrued expenses and accounts payable related to property and equipment	$ 17	$ 258

The accompanying notes are an integral part of these financial statements.

1. Organization

Overview

Alaunos Therapeutics, Inc., which is referred to herein as "Alaunos," or the "Company," is a clinical-stage oncology-focused cell therapy company developing adoptive TCR-T cell therapies, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. On January 25, 2022, the Company changed its corporate name from ZIOPHARM Oncology, Inc. to Alaunos Therapeutics, Inc. The Company is leveraging its proprietary, non-viral *Sleeping Beauty* gene transfer platform and its cancer hotspot mutation TCR library to design and manufacture personalized cell therapies that target neoantigens arising from shared tumor-specific mutations in key oncogenic genes, including *KRAS, TP53* and *EGFR.*

The Company's operations to date have consisted primarily of conducting research and development and raising capital to fund those efforts. In May 2021, the Company announced that it will be winding down its existing Controlled IL-12 clinical program. The Company continues to seek a partner for this program.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company follows the guidance of Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern, in order to determine whether there is substantial doubt about its ability to continue as a going concern for one year after the date its financial statements are issued.

The Company has operated at a loss since its inception in 2003 and has no recurring revenue from operations. The Company anticipates that losses will continue for the foreseeable future. As of June 30, 2022, the Company had approximately $60.0 million of cash and cash equivalents. The Company's accumulated deficit at June 30, 2022 was approximately $862.6 million. Given its current development plans and cash management efforts, the Company anticipates cash resources will be sufficient to fund operations into the second quarter of 2023. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, management may need to curtail its development efforts and planned operations to conserve cash.

Based on the current cash forecast, management has determined that the Company's present capital resources will not be sufficient to fund its planned operations for at least one year from the issuance date of the financial statements, which raises substantial doubt as to the Company's ability to continue as a going concern. This forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of expenses could vary materially and adversely as a result of a number of factors.

As of June 30, 2022, there were 216,174,542 shares of common stock outstanding and an additional 33,008,978 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in accordance with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. Certain information and note disclosures required by generally accepted accounting principles in the United States, or GAAP, have been condensed or omitted pursuant to such rules and regulations.

It is management's opinion that the accompanying unaudited interim financial statements reflect all adjustments (which are normal and recurring) that are necessary for a fair presentation of the financial position of the Company and its results of operations and cash flows for the periods presented. The unaudited interim financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 30, 2022, or the Annual Report.

The results disclosed in the statements of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the full fiscal year 2022.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although the Company regularly assesses

these estimates, actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

Impact of COVID-19 Pandemic

With the ongoing COVID-19 pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business and operations. The Company continues to evaluate the impact of the COVID-19 global pandemic on patients, healthcare providers and its employees, as well as its operations and the operations of its business partners and healthcare communities. In response to the COVID-19 pandemic, the Company has implemented policies at its locations to mitigate the risk of exposure to COVID-19 by its personnel. The extent to which the COVID-19 pandemic impacts the Company's business, clinical development and regulatory efforts and the value of its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements, the result of vaccination efforts and the effectiveness of any other actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the COVID-19 pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

2. Financings

2021 Loan and Security Agreement

On August 6, 2021, the Company entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Silicon Valley Bank and affiliates of Silicon Valley Bank (collectively, "SVB"). The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing (the "Term A Tranche"), with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022 (the "Term B Tranche").

Effective December 28, 2021, the Company, entered into a First Amendment (the "Amendment") to the Loan and Security Agreement (as so amended, the "Amended Loan and Security Agreement").

The Amended Loan and Security Agreement extends the interest-only period through August 31, 2022 and provides for an automatic extension of the interest-only period through August 31, 2023, if the Amended Milestones (as defined below) are met by August 31, 2022. The Amendment eliminated the Term B Tranche, which remained unfunded, leaving only the Term A Tranche (the "SVB Facility"). Under the Amended Loan and Security Agreement, the SVB Facility will mature on August 1, 2023; however, if the Company achieves the Amended Milestones on or prior to August 31, 2022, then the maturity will automatically extend to August 1, 2024.

Please refer to Note 4 - *Debt,* for further discussion of the Loan and Security Agreement and the Amended Loan and Security Agreement.

3. Summary of Significant Accounting Policies

The Company's significant accounting policies were identified in the Company's Annual Report. There have been no material changes in those policies since the filing of its Annual Report.

4. Debt

The carrying values of the Company's debt obligation were as follows:

($ in thousands)	June 30, 2022
Loan and Security Agreement	$ 25,423
Unamortized discount on Loan and Security Agreement	(900)
Total debt	24,523
Less: current portion of long-term debt	(20,051)
Long-term debt	$ 4,472

As of June 30, 2022, the SVB Facility was fully drawn in the amount of $25.0 million. The SVB Facility bears interest at a floating rate per annum on outstanding loans, payable monthly, at the greater of (a) 7.75% and (b) the current published U.S. prime rate, plus a margin of 4.5%. As of June 30, 2022, interest on the outstanding loans was 9.25%. The Amended Loan and Security Agreement

provides for an interest-only period which extends through August 31, 2022 and may be automatically extended through August 31, 2023 if, on or prior to August 31, 2022, SVB receives evidence satisfactory to it, confirming that the Company has (i) received at least $50.0 million in net cash proceeds from the sale of the Company's equity securities after the date of the Amended Loan and Security Agreement, on terms acceptable to SVB, and (ii) achieved positive data in the first cohort of the Library TCR-T Trial endorsed by an independent safety monitoring committee as a safe dose to proceed (together, the "Amended Milestones"). After the interest-only payment period, aggregate outstanding borrowings are payable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding principal and accrued and unpaid interest under the SVB Facility and all other outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023; however, if the Company achieves the Amended Milestones on or prior to August 31, 2022, then the maturity will be automatically extended to August 1, 2024. In addition to the payment of the outstanding principal plus accrued interest due, the Company will also owe SVB 5.75% of the original principal amounts borrowed as a final payment (the "Final Payment"). The Company is permitted to make up to two prepayments, subject to a prepayment premium, of the SVB Facility, each such payment to be at least $5.0 million. Such prepayment premium would be 3.00% of the principal amount of the SVB Facility if prepaid prior to the first anniversary of the effective date, 2.00% of the principal amount of the SVB Facility if prepaid on or after the first anniversary of the effective date but prior to the second anniversary of the effective date and 1.00% of the principal amount of the SVB Facility if prepaid on or after the second anniversary of the effective date but prior to the maturity date. No amount that has been repaid may be reborrowed.

The Amended Loan and Security Agreement requires the Company to cash collateralize half of the sum of the then-outstanding principal amount of the SVB Facility, plus an amount equal to 5.75% of the original principal amount of the SVB Facility if the Company does not achieve the Amended Milestones on or prior to August 31, 2022. In the event a cash collateralization were to occur, so long as no event of default has occurred, $2.5 million will be released from the collateral account following the eighth scheduled payment of principal and interest, and a further $4.0 million will be released following the tenth scheduled payment of principal and interest, in each case, so long as (i) after subtracting such scheduled payment, the sum of (a) the aggregate outstanding principal, (b) accrued and unpaid interest and (c) the Final Payment is less than $9,770,933 and $5,604,167, respectively and (ii) the balance in the collateral account after the release would equal or exceed $10.0 million and $6.0 million, respectively. The SVB Facility and related obligations under the Amended Loan and Security Agreement are secured by substantially all of the Company's properties, rights and assets, except for its intellectual property (which is subject to a negative pledge under the Amended Loan and Security Agreement). In addition, the Amended Loan and Security Agreement contains customary representations, warranties, events of default and covenants.

In connection with its entry into the Loan and Security Agreement, the Company issued to SVB warrants to purchase (i) up to 432,844 shares of the Company's common stock, in the aggregate, and (ii) up to an additional 432,842 shares of common stock, in the aggregate, in the event the Company achieves certain clinical milestones, in each case at an exercise price per share of $2.22.

In connection with its entry into the Amendment, the Company amended and restated the warrants issued to SVB. As amended and restated, the warrants are for up to 649,615 shares of the Company's common stock, in the aggregate, at an exercise price per share of $1.16, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

The issuance costs for the Loan and Security Agreement, including the Amended Loan and Security Agreement, were approximately $1.2 million and primarily related to the SVB Warrants, which will be amortized into interest expense over the period to August 1, 2023. Interest expense was $0.7 million for the three months ended June 30, 2022 and was $1.4 million for the six months ended June 30, 2022.

The fair value of the Amended Loan and Security Agreement as of June 30, 2022 approximates its face value due to proximity to the transaction.

5. Fair Value Measurements

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value on a recurring and nonrecurring basis as of June 30, 2022 and December 31, 2021 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of June 30, 2022**	**Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash equivalents	$ 59,011	$ 59,011	$ —	$ —

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of December 31, 2021**	**Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash equivalents	$ 75,222	$ 75,222	$ —	$ —

The cash equivalents represent demand deposit accounts and deposits in a short-term United States treasury money market mutual fund quoted in an active market and classified as a Level 1 asset.

6. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period. The Company's potentially dilutive shares, which include outstanding common stock options, inducement stock options, unvested restricted stock and warrants, have not been included in the computation of diluted net loss per share for any of the periods presented as the result would be anti-dilutive. Such potentially dilutive shares of common stock consisted of the following as of June 30, 2022 and 2021, respectively:

	June 30,	
	2022	**2021**
Common stock options	10,086,635	10,186,829
Inducement stock options	-	463,333
Unvested restricted stock	1,159,688	1,065,175
Warrants	22,922,342	22,272,727
	34,168,665	33,988,064

7. Related Party Transactions

Collaboration with Vineti Inc.

On July 9, 2020, the Company entered into a master service agreement and statement of work with Vineti, Inc. ("Vineti"). Pursuant to the agreement, Vineti has been developing a software platform to coordinate and orchestrate the order, cell collection and manufacturing process for the Company's T-cell therapy, or TCR-T, clinical programs. Heidi Hagen, who became a director of the Company in June 2019 and resigned November 2, 2021 and the Company's Interim Chief Executive Officer on February 25, 2021 and resigned on August 30, 2021, is a co-founder and former officer of Vineti. During the three and six months ended June 30, 2022, the Company recorded no expenses for Vineti, compared to $0.1 million of expenses for the three and six months ended June 30, 2021.

WaterMill Settlement Agreement

On February 4, 2021, the Company entered into an agreement, or the Settlement Agreement, with WaterMill Asset Management Corp. and Robert W. Postma (collectively, the "WaterMill Parties"). Pursuant to the Settlement Agreement, the Company increased the size of its board of directors from eight to nine directors and appointed Mr. Postma to fill the newly created directorship.

In accordance with the Settlement Agreement, the Company agreed to reimburse the WaterMill Parties for up to $0.4 million of their reasonable out-of-pocket expenses out of a total of approximately $0.7 million in fees and expenses actually incurred by the WaterMill Parties in connection with (i) the WaterMill Parties' solicitation of written consents from the Company's stockholders to vote in favor of certain proposals, as set forth in the definitive consent statement filed by the WaterMill Parties on October 30, 2020, and (ii) the negotiation, execution, and effectuation of the Settlement Agreement. As of February 19, 2021, the Company has fully reimbursed the WaterMill Parties an aggregate amount of $0.4 million.

Joint Venture with TriArm Therapeutics/Eden BioCell

On December 18, 2018, the Company and TriArm Therapeutics, Ltd. (“TriArm”) launched Eden BioCell, Ltd. (“Eden BioCell”) as a joint venture to lead commercialization of the Company’s *Sleeping Beauty*-generated CAR-T therapies in the People’s Republic of China (including Macau and Hong Kong), Taiwan and Korea. The Company licensed to Eden BioCell the rights in Greater China for its third-generation *Sleeping Beauty*-generated CAR-T therapies targeting the CD19 antigen. Eden BioCell is owned equally by the Company and TriArm and the parties share decision-making authority. TriArm has contributed $10.0 million to Eden BioCell and has committed up to an additional $25.0 million to this joint venture. TriArm also manages all clinical development in the territory pursuant to a master services agreement between TriArm and Eden BioCell. James Huang was the founder and serves as managing partner of Panacea Venture, which is an investor in TriArm. Mr. Huang is the Chair of the Company's board of directors and has been a director since July 2020. He also serves as a member of Eden BioCell’s board of directors.

For the three and six months ended June 30, 2022, Eden BioCell incurred a net loss and the Company continues to have no commitment to fund its operations. In September 2021, TriArm and Alaunos mutually agreed to dissolve the Eden BioCell joint venture. Refer to Note 12 - *Joint Venture*, for further details.

8. Leases

In the second quarter of 2022, the Company modified its real estate lease agreement executed on December 15, 2020 with MD Anderson, which reduced the Company's leased space for 18,111 square feet to 3,228 square feet. As a result, the associated lease liability and right-of-use asset were remeasured to $0.4 million based on revised lease payments. A gain of $0.1 million was recorded on the lease modification during the three months ended June 30, 2022.

9. Commitments and Contingencies

License Agreements

Exclusive License Agreement with PGEN Therapeutics

On October 5, 2018, the Company entered into an exclusive license agreement, or License Agreement, with PGEN Therapeutics, or PGEN, a wholly owned subsidiary of Precigen Inc., or Precigen, which was formerly known as Intrexon Corporation. Pursuant to the terms of the License Agreement, the Company has exclusive, worldwide rights to research, develop and commercialize (i) TCR products designed for neoantigens for the treatment of cancer, (ii) products utilizing Precigen’s RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products and (iii) CAR products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) BCMA for the treatment of cancer, subject to certain obligations to pursue such target under the Ares Trading Agreement. Under the License Agreement, the Company also has exclusive, worldwide rights for certain patents relating to the *Sleeping Beauty* technology to research, develop and commercialize TCR products for both neoantigens and shared antigens for the treatment of cancer, referred to as TCR Products.

The Company is solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. The Company is required to use commercially reasonable efforts, as defined in the License Agreement, to develop and commercialize IL-12 products, CD19 products, BCMA products and TCR Products.

In consideration of the licenses and other rights granted by PGEN, the Company will pay PGEN an annual license fee of $0.1 million and the Company has agreed to reimburse PGEN for certain historical costs of the licensed programs up to $1.0 million, which was fully paid during the year ended December 31, 2019.

The Company will make milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, the Company will pay PGEN tiered royalties ranging from low-single digits to high-single digits on the net sales derived from the sale of any approved IL-12 products and CAR products. The Company will also pay PGEN royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of any approved TCR products, up to a maximum royalty amount of $100.0 million in the aggregate. The Company will also pay PGEN twenty percent of any sublicensing income received by us relating to the licensed products. The Company is responsible for all development costs associated with each of the licensed products.

PGEN will pay the Company royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of PGEN's CAR products, up to a maximum royalty amount of $100.0 million.

In October 2020, the Company entered into an amendment to the License Agreement relating to the transfer of certain materials and PGEN's obligations to provide transition assistance relating to the IL-12 products.

License Agreement and 2015 Research and Development Agreement —The University of Texas MD Anderson Cancer Center

On January 13, 2015, the Company, together with Precigen, entered into the MD Anderson License with MD Anderson (which Precigen subsequently assigned to PGEN). Pursuant to the MD Anderson License, the Company, together with PGEN, holds an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR T-cell therapies, non-viral gene transfer systems, genetic modification and/or propagation of immune cells and other cellular therapy approaches, Natural Killer, or NK Cells, and TCRs, arising from the laboratory of Laurence Cooper, M.D., Ph.D., who served as the Company's Chief Executive Officer from May 2015 until February 2021 and was formerly a tenured professor of pediatrics at MD Anderson.

On August 17, 2015, the Company, Precigen and MD Anderson entered into the 2015 R&D Agreement to formalize the scope and process for the transfer by MD Anderson, pursuant to the terms of the MD Anderson License, of certain existing research programs and related technology rights, as well as the terms and conditions for future collaborative research and development of new and ongoing research programs. The rights and obligations of Precigen under the 2015 R&D Agreement were assigned to the Company pursuant to the Fourth Amendment to 2015 R&D Agreement which was entered into on September 19, 2019 (the "Fourth Amendment") with an effective date of October 5, 2018. The activities under the 2015 R&D Agreement are directed by a joint steering committee comprised of two members from the Company and one member from MD Anderson.

As provided under the MD Anderson License, the Company provided funding for research and development activities in support of the research programs under the 2015 R&D Agreement for a period of three years and in an amount of no less than $15.0 million and no greater than $20.0 million per year. On November 14, 2017, the Company entered into an amendment to the 2015 R&D Agreement, extending its term until April 15, 2021. In connection with the execution of the 2019 R&D Agreement described below, on October 22, 2019, the Company amended the 2015 R&D Agreement to extend the term of the 2015 R&D Agreement until December 31, 2026 and to allow cash resources on hand at MD Anderson under the 2015 R&D Agreement to be used for development costs under the 2019 R&D Agreement.

The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder, or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term of the MD Anderson License, the Company, together with Precigen, shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder. After ten years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if the Company and Precigen are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if the Company and Precigen are not meeting the diligence requirements in such funding agreement or contract, as applicable. MD Anderson may also terminate the agreement with written notice upon material breach by the Company and Precigen, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both the Company and Precigen and may be terminated by the mutual written agreement of the Company, PGEN, and MD Anderson.

2019 Research and Development Agreement—The University of Texas MD Anderson Cancer Center

On October 22, 2019, the Company entered into the 2019 Research and Development Agreement, or the 2019 R&D Agreement, with MD Anderson, pursuant to which the parties agreed to collaborate with respect to the TCR program. Under the 2019 R&D Agreement, the parties will, among other things, collaborate on programs to expand the Company's TCR library and conduct clinical trials. The

activities under the 2019 R&D Agreement are directed by a joint steering committee comprised of two members from the Company and one member from MD Anderson.

The Company will own all inventions and intellectual property developed under the 2019 R&D Agreement and the Company will retain all rights to intellectual property for oncology products manufactured using non-viral gene transfer technologies under the 2019 R&D Agreement, including the Company's *Sleeping Beauty* technology. The Company has granted MD Anderson an exclusive license for such intellectual property outside the field of oncology and to develop and commercialize TCR products manufactured using viral gene transfer technologies limited to autologous products if used for cancer treatment or prevention, and a non-exclusive license for allogenic anti-tumor TCR products manufactured using viral-based technologies.

Under the 2019 R&D Agreement, the Company agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of $20.0 million for development costs under the 2019 R&D Agreement, after the funds from the 2015 R&D Agreement are exhausted. In addition, the Company will pay MD Anderson royalties on net sales of its TCR products. The Company is required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to its TCR products. The aggregate potential benchmark payments are $36.5 million, of which only $3.0 million will be due prior to the first marketing approval of the Company's TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. The Company also agreed to sell its TCR products to MD Anderson at preferential prices and will sell the Company's TCR products in Texas exclusively to MD Anderson for a limited period of time following the first commercial sale of the Company's TCR products. For the three months ended June 30, 2022, the Company incurred expenses of $0.6 million from MD Anderson related to this agreement compared to $0 for the three months ended June 30, 2021. For the six months ended June 30, 2022, the Company incurred expenses of $1.0 million from MD Anderson related to this agreement compared to $0 for the six months ended June 30, 2021.

The 2019 R&D Agreement will terminate on December 31, 2026 and either party may terminate the 2019 R&D Agreement following written notice of a material breach. The 2019 R&D Agreement also contains customary provisions related to indemnification obligations, confidentiality and other matters.

In connection with the execution of the 2019 R&D Agreement, on October 22, 2019, the Company issued MD Anderson a warrant to purchase 3,333,333 shares of the Company's common stock, which is referred to as the MD Anderson Warrant. Please refer to Note 11 - *Warrants*, for further discussion of the MD Anderson Warrant. The MD Anderson Warrant has an initial exercise price of $0.001 per share, expires on December 31, 2026, and vests upon the occurrence of certain clinical milestones. As of June 30, 2022, the milestones have not been met.

License Agreement with the NCI

On May 28, 2019, the Company entered into a patent license agreement, or the Patent License, with the National Cancer Institute, or the NCI. Pursuant to the Patent License, the Company holds an exclusive, worldwide license to certain intellectual property to develop and commercialize patient-derived (autologous), peripheral blood T-cell therapy products engineered by transposon-mediated gene transfer to express TCRs reactive to mutated *KRAS, TP53* and *EGFR* neoantigens. In addition, pursuant to the Patent License, the Company holds an exclusive, worldwide license to certain intellectual property for manufacturing technologies to develop and commercialize autologous, peripheral blood T-cell therapy products engineered by non-viral gene transfer to express TCRs, as well as a non-exclusive, worldwide license to certain additional manufacturing technologies. On May 29, 2019, January 8, 2020, September 28, 2020, April 16, 2021, May 4, 2021, and August 13, 2021 the Company amended the Patent License to expand its TCR library to include additional TCRs reactive to mutated *KRAS* and *TP53* neoantigens licensed from the NCI.

The terms of the Patent License require the Company to pay the NCI minimum annual royalties in the amount of $0.3 million, which amount will be reduced to $0.1 million once the aggregate minimum annual royalties paid by the Company equals $1.5 million.

The Company is also required to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. Of such payments, the aggregate potential benchmark payments are $4.3 million, of which aggregate payments of $3.0 million are due only after marketing approval in the United States or in Europe, Japan, Australia, China or India. The first benchmark payment of $0.1 million will be due upon the initiation of the Company's first sponsored Phase 1 clinical trial of a licensed product or licensed process in the field of use licensed under the Patent License. The Company paid the first benchmark payment during the three months ended June 30, 2022.

In addition, the Company is required to pay the NCI one-time benchmark payments following aggregate net sales of licensed products at certain aggregate net sales ranging from $250.0 million to $1.0 billion. The aggregate potential amount of these benchmark payments is $12.0 million. The Company must also pay the NCI royalties on net sales of products covered by the Patent License at rates in the low to mid-single digits depending upon the technology included in a licensed product. To the extent the Company enters

into a sublicensing agreement relating to a licensed product, the Company is required to pay the NCI a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense.

The Patent License will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. The NCI may terminate or modify the Patent License in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the Patent License, or any portion thereof, in the Company's sole discretion at any time upon 60 days' written notice to the NCI. In addition, the NCI has the right to: (i) require the Company to sublicense the rights to the product candidates covered by the Patent License upon certain conditions, including if the Company is not reasonably satisfying required health and safety needs and (ii) terminate or modify the Patent License, including if the Company is not satisfying requirements for public use as specified by federal regulations.

For the three months ended June 30, 2022, the Company recognized $0.2 million in license payments to the NCI under this agreement, compared to $0.1 million for the three months ended June 30, 2021. For the six months ended June 30, 2022, the Company recognized $0.5 million in license payments to the NCI under this agreement, compared to $0.5 million for the six months ended June 30, 2021.

Cooperative Research and Development Agreement (CRADA) with the NCI

On January 9, 2017, the Company entered into a Cooperative Research and Development Agreement (the "CRADA") with the NCI. The purpose of this collaboration was to advance a personalized TCR-T approach for the treatment of solid tumors. Using the Company's *Sleeping Beauty* technology, the NCI would analyze a patient's own cancer cells, identify their unique neoantigens and TCRs reactive against those neoantigens and then use the Company's *Sleeping Beauty* technology to transpose one or more TCRs into T cells for re-infusion. Research conducted under the CRADA will be at the direction of Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI, in collaboration with the Company's researchers.

The Company is responsible for providing the NCI with the test materials necessary for them to conduct their studies, and eventually, clinical trials pursuant to the CRADA. Inventions, data and materials discovered or produced in connection with performance of the research plan under the CRADA will remain the sole property of the party who produced the discovery. The parties will jointly own all inventions jointly discovered under the research plan. The owner of any invention under the CRADA will make the decision to file a patent covering the invention, or in the case of a jointly owned invention, the Company will have the first opportunity to file a patent covering the invention. If the Company fails to provide timely notice of its decision to the NCI or decide not to file a patent covering the joint invention, the NCI has the right to make the filing. For any invention solely owned by the NCI or jointly made by the NCI and the Company for which a patent application was filed, the U.S. Public Health service grants the Company an exclusive option to elect an exclusive or non-exclusive commercialization license. For inventions owned solely by the NCI or jointly owned by the NCI and the Company, which are licensed according to the terms described above, the Company agreed to grant to the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world. The Company is also required to grant the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world for any of the Company's solely owned inventions. The agreement may be terminated by any of the parties upon 60 days prior written consent.

The NCI has a cleared Investigational New Drug Application, or IND, that would permit them to begin this trial. To the Company's knowledge, the trial has not yet enrolled due to matters internal to the NCI and unrelated to the Company's technology. The progress and timeline for this trial, including the timeline for dosing patients, are under control of the NCI.

In February 2019, the Company extended the CRADA with the NCI until January 9, 2022, committing an additional $5.0 million to this program. In March 2022, the Company entered into an amendment to the CRADA that is retroactive, effective January 9, 2022 to extend the term of the CRADA until January 9, 2023. In June 2022, the Company entered into the Fourth Amendment to the CRADA (the "CRADA Fourth Amendment") which, among other things, extended the term of the CRADA until January 9, 2025. In connection with the CRADA Fourth Amendment, the Company agreed to contribute $1.0 million per year, payable on a quarterly basis, beginning in the first quarter of 2023. The Company did not record expenses under the CRADA for the three and six months ended June 30, 2022, as compared to $0.6 million for the three months ended June 30, 2021 and $1.3 million for the six months ended June 30, 2021.

Patent and Technology License Agreement—The University of Texas MD Anderson Cancer Center and the Texas A&M University System

On August 24, 2004, the Company entered into a patent and technology license agreement with MD Anderson and the Texas A&M University System, which the Company refers to, collectively, as the Licensors. Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to U.S. and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals includes darinaparsin.

Under the terms of the agreement, the Company may be required to make additional payments to the Licensors upon achievement of certain other milestones in varying amounts which, on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. During the three and six months ended June 30, 2022 and June 30, 2021, no amounts were expensed or paid under the terms of the agreement.

Collaboration Agreement with Solasia Pharma K.K.

On March 7, 2011, the Company entered into a License and Collaboration Agreement with Solasia Pharma K. K. ("Solasia"), which was amended on July 31, 2014 to include an exclusive worldwide license and amended on October 14, 2021 to revise certain payment schedule details. Pursuant to the License and Collaboration Agreement, the Company granted Solasia an exclusive license to develop and commercialize darinaparsin in both intravenous and oral forms and related organic arsenic molecules, in all indications for human use.

As consideration for the license, the Company is eligible to receive from Solasia development- and sales-based milestones, a royalty on net sales of darinaparsin, once commercialized, and a percentage of any sublicense revenue generated by Solasia. Solasia will be responsible for all costs related to the development, manufacturing and commercialization of darinaparsin. The Company's licensors, as defined in the agreement, will receive a portion of all milestone and royalty payments made by Solasia to the Company in accordance with the terms of the license agreement with the licensors. During the three and six months ended June 30, 2022 and June 30, 2021, the Company did not record collaboration revenue under the collaboration agreement with Solasia.

10. Stock-Based Compensation

The Company recognized stock-based compensation expense on all employee and non-employee awards as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(in thousands)	2022	2021	2022	2021
Research and development	214	847	528	1,580
General and administrative	776	4,443	1,315	5,906
Stock-based compensation expense	$ 990	$ 5,290	$ 1,844	$ 7,486

The Company granted an aggregate of 692,500 stock options during the three months ended June 30, 2022, with a weighted-average grant date fair value of $0.55 per share, and granted an aggregate of 3,382,500 stock options during the six months ended June 30, 2022, with a weighted-average grant date fair value of $0.48 per share. The Company granted an aggregate of 41,500 stock options during the three months ended June 30, 2021, with a weighted-average grant date fair value of $2.27 per share, and granted an aggregate of 4,395,438 stock options during the six months ended June 30, 2021, with a weighted-average grant date fair value of $2.44 per share.

For the three and six months ended June 30, 2022 and 2021, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.83 – 3.54%	1.15 %	1.63 – 3.54%	0.09 – 1.15%
Expected life in years	5.27 - 6.25	6.25	5.27 - 6.25	5.50 - 6.25
Expected volatility	78.58 - 82.97%	74.08 %	74.49 - 82.97%	72.92 - 74.80%
Expected dividend yield	—%	—%	—%	—%

Stock option activity under the Company's stock option plans for the six months ended June 30, 2022 is as follows:

(in thousands, except share and per share data)	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2021	10,665,869	$ 2.87		
Granted	3,382,500	0.71		
Cancelled	(3,961,735)	3.33		
Outstanding, June 30, 2022	10,086,635	$ 1.97	8.95	$ 1,611
Options exercisable, June 30, 2022	2,955,111	$ 3.28	7.87	$ 89
Options exercisable, December 31, 2021	4,410,312	$ 3.85	7.53	$ —
Options available for future grant	15,780,200			

At June 30, 2022, total unrecognized compensation costs related to unvested stock options outstanding amounted to $6.1 million. The cost is expected to be recognized over a weighted-average period of 1.95 years.

A summary of the status of unvested restricted stock for the six months ended June 30, 2022 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2021	1,198,580	$ 2.10
Granted	280,000	0.82
Vested	(85,991)	3.87
Cancelled	(232,901)	3.15
Unvested, June 30, 2022	1,159,688	$ 1.45

At June 30, 2022, total unrecognized compensation costs related to unvested restricted stock outstanding amounted to $1.4 million. The cost is expected to be recognized over a weighted-average period of 1.92 years.

11. Warrants

In connection with the Company's November 2018 private placement that provided net proceeds of approximately $47.1 million, the Company issued warrants to purchase an aggregate of 18,939,394 shares of common stock, which became exercisable six months after the closing of the private placement (the "November 2018 Warrants"). The November 2018 Warrants had an exercise price of $3.01 per share and have a five-year term. The fair value of the November 2018 Warrants was estimated at $18.4 million using a Black-Scholes model with the following assumptions: expected volatility of 71%, risk free interest rate of 2.99%, expected life of five years and no dividends.

On July 26, 2019 and September 12, 2019, the Company entered into agreements with existing investors whereby the investors exercised the November 2018 Warrants for an aggregate of 17,803,031 shares of common stock, at an exercise price of $3.01 per share. Proceeds from the warrant exercise after deducting placement agent fees and other related expenses of $1.1 million were approximately $52.5 million.

The Company issued participating investors new warrants to purchase up to 17,803,031 additional shares of common stock (the "2019 Warrants") as consideration for the warrant holders to exercise their November 2018 Warrants. The 2019 Warrants will expire on the fifth anniversary of the initial exercise date and have an exercise price of $7.00. The 2019 Warrants were valued using a Black-Scholes valuation model and resulted in a $60.8 million non-cash charge in the Company's statement of operations in 2019.

On October 22, 2019, the Company entered into the 2019 R&D Agreement with MD Anderson. In connection with the execution of the 2019 R&D Agreement, the Company issued the MD Anderson Warrant to purchase 3,333,333 shares of common stock. The MD Anderson Warrant has an initial exercise price of $0.001 per share and grant date fair value of $14.5 million. The MD Anderson Warrant expires on December 31, 2026 and vests upon the occurrence of certain clinical milestones. The Company will recognize expense on the MD Anderson Warrant in the same manner as if the Company paid cash for services to be rendered. For the three and six months ended June 30, 2022 and June 30, 2021, the Company did not recognize any expense related to the MD Anderson Warrant as the clinical milestones had not been achieved.

On August 6, 2021, the Company entered into the Loan and Security Agreement with SVB. Refer to Note 4 - *Debt*. In connection with the Loan and Security Agreement, the Company issued SVB warrants to purchase 432,844 shares of common stock with an exercise price of $2.22 per share. The warrants have a ten-year life and were fully vested upon issuance. The fair value of the warrants was estimated at $0.8 million using a Black-Scholes model with the following assumptions: expected volatility of 79%, risk free interest rate of 1.31%, expected life of ten years and no dividends. On December 28, 2021, the Company entered into the Amendment, as described in Note 4 - *Debt,* in connection with which, the original warrants issued to SVB were amended and restated. As amended and restated, the SVB Warrants are for up to 649,615 shares of common stock, in the aggregate, at an exercise price per share of $1.16. The SVB Warrants expire on August 6, 2031 and were fully vested upon issuance. Using a Black-Scholes model with an expected volatility of 81%, risk free interest rate of 1.49%, expected life of 10 years and no dividends, the Company recorded a $0.2 million increase in the fair value of the SVB Warrants due to the modification of the SVB Warrants.

The Company assessed whether the SVB Warrants require accounting as derivatives. The Company determined that the SVB Warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the SVB Warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders' equity.

12. Joint Venture

On December 18, 2018, the Company entered into a Framework Agreement with TriArm whereby the parties agreed to launch Eden BioCell, to lead clinical development and commercialization of certain *Sleeping Beauty*-generated CAR-T therapies as set forth in a separate license agreement.

On January 3, 2019, Eden BioCell was incorporated in Hong Kong as a private company. Eden BioCell, the Company and TriArm entered into a Share Subscription Agreement on January 23, 2019, where the Company and TriArm agreed to contribute certain intellectual property, services and cash (only with respect to TriArm) to Eden BioCell to subscribe for a certain number of newly issued ordinary shares in the share capital of Eden BioCell.

The closing of the transaction occurred on July 5, 2019. The Framework Agreement and Share Subscription Agreements were each respectively amended to be effective as of this date. Upon consummation of the joint venture, Eden BioCell and the Company also entered into a license agreement, pursuant to which the Company licensed the rights to Eden BioCell for third generation *Sleeping Beauty*-generated CAR-T therapies targeting the CD19 antigen for the territory of China (including Macau and Hong Kong), Taiwan and Korea. TriArm and the Company each received a 50% equity interest in the joint venture in exchange for their contributions to Eden BioCell.

The Company determined that Eden BioCell was considered a variable interest entity, or VIE, and concluded that it is not the primary beneficiary of the VIE as it did not have the power to direct the activities of the VIE. As a result, the Company accounts for the equity interest in Eden BioCell under the equity method of accounting as it has the ability to exercise significant influence.

In March 2021, Eden BioCell began treating patients in a clinical trial with the Company's investigational CD19 RPM CAR-T cell therapy, under the IND cleared by the Taiwan FDA in December 2020. In the first half of 2021, two patients were treated in this trial. The lead investigator at National Taiwan University in Taipei, has reported no serious adverse safety events in either of these patients. Laboratory results continue to support, as previously published, that non-viral *Sleeping Beauty* gene transfer is effective in genetically modifying autologous T-cells. Patients were infused two days after gene transfer, thus shortening the turnaround time and demonstrating an advantage over viral methods.

Based on laboratory data from the first two patients generated between March and May 2021, the TriArm/Eden team concluded, in concert with the investigator and the Company, that further process development work is required.

In September 2021, TriArm and the Company mutually agreed to dissolve the joint venture.

For the three and six months ended June 30, 2022 and June 30, 2021, Eden BioCell incurred a net loss. The Company continues to have no commitment to fund its operations.

13. Subsequent Events

On August 12, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Piper Sandler & Co. ("Piper Sandler"), pursuant to which the Company can offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $50 million through Piper Sandler as its sales agent in an "at the market offering." Piper Sandler will receive a commission of 3.0% of the gross proceeds of any common stock sold under the Equity

Distribution Agreement. As of the date of this Quarterly Report on Form 10-Q, there have been no offers or sales of the Company's common stock under the Equity Distribution Agreement. In connection with entering into the Equity Distribution Agreement, the Company concurrently terminated, effective August 12, 2022, the Open Market Sale Agreement with Jefferies LLC, dated June 21, 2019, governing its former "at the market offering" program.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with our unaudited condensed financial statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC, on March 30, 2022, or the Annual Report.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "may," "expect," "anticipate," "estimate," "intend," "plan" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage oncology-focused cell therapy company developing adoptive TCR-T cell therapy, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. We are leveraging our cancer hotspot mutation TCR library and our proprietary, non-viral *Sleeping Beauty* gene transfer platform to design and manufacture patient-specific cell therapies that target neoantigens arising from shared tumor-specific mutations in key oncogenic genes, including *KRAS*, *TP53* and *EGFR*. In collaboration with the MD Anderson Cancer Center, or MD Anderson, we are currently enrolling patients for a Phase 1/2 clinical trial evaluating ten TCRs reactive to mutated *KRAS, TP53* and *EGFR* from our TCR library for the investigational treatment of non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers, which we refer to as our TCR-T Library Phase 1/2 Trial. On May 2, 2022, we announced that we treated our first patient in this trial; we anticipate reporting early data in the third quarter of 2022.

We have not generated any product revenue and have incurred significant net losses in each year since our inception. For the six months ended June 30, 2022, we had a net loss of $19.7 million, and as of June 30, 2022, we have incurred approximately $862.6 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses. Further development of our product candidates will likely require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- work with regulatory authorities to identify and address program-related inquiries;
- implement additional internal systems and infrastructure;
- hire additional personnel; and
- scale-up the formulation and manufacturing of our product candidates.

We continue to seek additional financial resources to fund the further development of our product candidates. If we are unable to obtain sufficient additional capital, one or more of these programs could be delayed, and we may be unable to continue our operations at planned levels and be forced to reduce our operations. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Recent Developments

On May 2, 2022, we announced dosing of the first patient in our TCR-T Library Phase 1/2 trial being conducted at MD Anderson at dose level 1, or $5x10^9$. The patient has non-small cell lung cancer and was treated with TCR-T cells targeting a *KRAS* G12D mutation. Following a safety review by the safety review committee at MD Anderson, we are moving ahead at the second dose level of $4x10^{10}$ TCR-T cells. We continue to enroll patients in the trial at dose levels according to the clinical protocol. We expect to present early data at an appropriate scientific or medical conference in the third quarter of 2022.

The TCR-T cell product was successfully manufactured in Alaunos' state-of-the-art good manufacturing practice ("cGMP") facility in Houston, Texas. We are executing a multi-prong strategy to expand our manufacturing capabilities, including implementing standard operating procedures that allow for simultaneous production of multiple products, hiring additional staff to support multiple shifts and evaluating physical expansion of the cGMP footprint.

On May 16, 2022, we presented preclinical data in poster M-234 on Stem-cell memory TCR-T cells targeting hotspot *EGFR*, *KRAS* and *TP53* neoantigens generated through co-expression of membrane-bound Interleukin-15, or mbIL-15, at the 25th Annual Meeting of the American Society of Gene and Cell Therapy. Our mbIL-15 program is designed to augment the function of TCR-T cells by co-expression of a proprietary potentially more potent mbIL-15. In this preclinical study, we observed that mbIL-15 TCR-T cells specifically targeted and killed tumors expressing matching neoantigen and HLAs with negligible off-target effects. Importantly, mbIL-15 seems to enhance the survival and persistence of TCR-T cells cultured in the absence of exogenous cytokine support. The persisting mbIL-15 TCR-T cells were observed to exhibit a preponderance of long-lived T stem-cell memory cells that were capable to giving rise to effector T cell subsets upon in vitro restimulation. These preclinical observations suggest that our proprietary mbIL-15 technology has the potential to establish long-lived tumor-specific TCR-T cells that may have the potential to survive in circulation and in the suppressive tumor microenvironment.

In June 2022, Solasia Pharma K. K. ("Solasia") announced that darinaparsin has been approved for relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. As a part of our license agreement with Solasia, we are eligible for sales-based milestones and a percentage of any sublicense revenue generated by Solasia. Solasia will continue to be responsible for all costs related manufacturing and commercialization.

On June 24, 2022, we entered into the Fourth Amendment (the "CRADA Fourth Amendment") to a Cooperative Research and Development Agreement, dated January 9, 2017, by and among the National Cancer Institute and the Company, as amended (the "CRADA"). Under the CRADA, the National Cancer Institute will work to generate proof of concept utilizing our *Sleeping Beauty* platform for personalized TCR-T therapies. The CRADA Fourth Amendment, among other things, extended the term of the CRADA until January 9, 2025. In connection with the CRADA Fourth Amendment, we agreed to contribute $1.0 million per year, payable on a quarterly basis, beginning in the first quarter of 2023.

We have continued advancing our hunTR discovery engine to discover new TCRs which may potentially be added to our TCR library. We are working to increase output and reduce screening costs and currently anticipate sharing data from the hunTR discovery engine in the fourth quarter of 2022.

Financial Overview

Collaboration Revenue

We recognize research and development funding revenue over the estimated period of performance. To date we have not generated product revenue. Unless and until we receive approval from the FDA and/or other regulatory authorities for our product candidates, we cannot sell our products and will not have product revenue.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities, reagents, and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to contract research organizations in conjunction with clinical trials, fees paid to contract research organizations in conjunction with costs of materials used in research and development, consulting, license and milestone payments and sponsored research fees paid to third parties.

Our future research and development expenses in support of our current and future programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous preclinical studies for safety, toxicology and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products or indications. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and

intended use of a product. It is not unusual for preclinical and clinical development of each of these types of products to require the expenditure of substantial resources.

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- The number of clinical sites included in the trials;
- The length of time required to enroll suitable patients;
- The number of patients that ultimately participate in the trials;
- The length of time and cost to develop and optimize manufacturing processes;
- The cost to manufacture the clinical products for patients;
- The duration of patient follow-up to ensure the absence of long-term product-related adverse events; and
- The efficacy and safety profile of the product.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to reduce or eliminate our activities in one or more of our programs or seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation, consulting and professional fees, including patent related costs, general corporate costs and facility costs not otherwise included in research and development expenses or cost of product revenue.

Other Income (Expense)

Other income (expense) consists primarily of interest expense associated with our Amended Loan and Security Agreement, as defined below.

Overview of Results of Operations

Three and Six Months Ended June 30, 2022 Compared to Three and Six Months Ended June 30, 2021

Research and Development Expenses

Research and development expenses during the three and six months ended June 30, 2022 and 2021 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
Research and development expenses	$ 5,937	$ 13,570	$ (7,633)	(56)%	$ 11,518	$ 26,906	$ (15,388)	(57)%

Research and development expenses for the three months ended June 30, 2022 decreased by $7.6 million when compared to the three months ended June 30, 2021 primarily due to a decrease in program-related costs of $2.0 million as a result of the winding down of our IL-12 and CAR-T programs, a $5.2 million decrease in employee related expenses due to our reduced headcount following our restructuring in the third quarter of 2021, and a $0.3 million decrease in consulting expenses due to reduced use of consultants.

Research and development expenses for the six months ended June 30, 2022 decreased by $15.4 million when compared to the six months ended June 30, 2021 primarily due to a decrease in program-related costs of $4.9 million as a result of the winding down of our IL-12 and CAR-T programs, a $9.8 million decrease in employee related expenses due to our reduced headcount following our restructuring in the third quarter of 2021, and a $0.6 million decrease in consulting expenses due to reduced use of consultants.

For the three and six months ended June 30, 2022, our clinical stage projects included our TCR-T Library Phase 1/2 trial evaluating TCRs from our library for the investigational treatment of non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers.

General and administrative expenses

General and administrative expenses during the three and six months ended June 30, 2022 and 2021 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
General and administrative expenses	$ 3,429	$ 9,069	$ (5,640)	(62)%	$ 6,935	$ 17,296	$ (10,361)	(60)%

General and administrative expenses for the three months ended June 30, 2022 decreased by $5.6 million as compared to the three months ended June 30, 2021, primarily due to a $5.4 million decrease in employee related expenses due to our reduced headcount following our restructuring in the third quarter of 2021 and a $0.2 million decrease in consulting and professional services expenses due to lower legal costs and a decreased use of consultants.

General and administrative expenses for the six months ended June 30, 2022 decreased by $10.4 million as compared to the six months ended June 30, 2021, primarily due to a $9.2 million decrease in employee related expenses due to our reduced headcount following our restructuring in the third quarter of 2021, a $1.0 million decrease in consulting and professional services expenses due to lower legal costs and a decreased use of consultants, and a $0.1 million decrease in facilities-related costs.

Gain on lease modification

Gains on lease modifications during the three and six months ended June 30, 2022 and 2021 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
Gain on lease modification	$ (133)	$ —	$ (133)	100%	$ (133)	$ —	$ (133)	100%

Gain on lease modification during the three and six months ended June 30, 2022 was $0.1 million compared to $0 during the three and six months ended June 30, 2021. As a result of a real estate lease modification during the second quarter of 2022, the associated lease liability and right-of-use asset were remeasured based on the revised lease payments, resulting in a gain of $0.1 million.

Other income (expense), net

Other income (expense), net during the three and six months ended June 30, 2022 and 2021 was as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
Interest expense	$ (740)	$ —	$ (740)	100%	$ (1,425)	$ —	$ (1,425)	100%
Other income (expense), net	41	(31)	72	(232)%	25	(22)	47	(214)%
Total	$ (699)	$ (31)	$ (668)	2155%	$ (1,400)	$ (22)	$ (1,378)	6264%

Other expense, net for the three months ended June 30, 2022 increased by $0.7 million as compared to the three months ended June 30, 2021, primarily due to $0.7 million of interest expense associated with our Amended Loan and Security Agreement, as defined below.

Other expense, net for the six months ended June 30, 2022 increased by $1.4 million as compared to the six months ended June 30, 2021, primarily due to $1.4 million of interest expense associated with our Amended Loan and Security Agreement.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations.

To date, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible equity securities, term debt and collaborations. Through June 30, 2022, we have received an aggregate of $714.1 million from issuances of equity and $25.0 million from our Amended Loan and Security Agreement, as defined below.

We follow the guidance of Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern*, in order to determine whether there is substantial doubt about our ability to continue as a going concern for one year after the date our financial statements are issued. Given our current development plans and cash management efforts, we anticipate that our cash resources will be sufficient to fund operations into the second quarter of 2023. Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in our focus and direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, management may need to curtail its development efforts and planned operations to conserve cash.

Based on the current cash forecast, management has determined that our present capital resources will not be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements, which raises substantial doubt as to our ability to continue as a going concern. This forecast of cash resources and planned operations is forward-looking information that involves risks and uncertainties, and the actual amount of expenses could vary materially and adversely as a result of a number of factors.

2022 Equity Distribution Agreement

On August 12, 2022, we entered into an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Piper Sandler & Co. (“Piper Sandler”), pursuant to which we can offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50 million through Piper Sandler as our sales agent in an “at the market offering.” Piper Sandler will receive a commission of 3.0% of the gross proceeds of any common stock sold under the Equity Distribution Agreement. As of the date of this Quarterly Report on Form 10-Q, there have been no offers or sales of our common stock under the Equity Distribution Agreement. In connection with entering into the Equity Distribution Agreement, we concurrently terminated, effective August 12, 2022, the Open Market Sale Agreement with Jefferies LLC, dated June 21, 2019, governing our former “at the market offering” program.

2021 Loan and Security Agreement

On August 6, 2021, we entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Silicon Valley Bank and affiliates of Silicon Valley Bank (collectively, "SVB"). The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing (the "Term A Tranche"), with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022 (the "Term B Tranche").

Effective December 28, 2021, we entered into a First Amendment (the "Amendment") to the Loan and Security Agreement (as so amended, the "Amended Loan and Security Agreement").

The Amended Loan and Security Agreement extends the interest-only period through August 31, 2022, and provides for an automatic extension of the interest-only period through August 31, 2023, if the Amended Milestones (as defined below) are met by August 31, 2022. The Amendment eliminated the Term B Tranche, which remained unfunded, leaving only the Term A Tranche (the "SVB Facility"). Under the Amended Loan and Security Agreement, the SVB Facility will mature on August 1, 2023; however, if we achieve the Amended Milestones on or prior to August 31, 2022, then the maturity will automatically extend to August 1, 2024. As of June 30, 2022, the SVB Facility was fully drawn in the amount of $25.0 million. The SVB Facility bears interest at a floating rate per annum on the outstanding loans, payable monthly, at the greater of (a) 7.75% and (b) the current published U.S. prime rate, plus a margin of 4.5%. The Amended Loan and Security Agreement provides for an interest-only period which extends through August 31, 2022, as compared to March 31, 2022 in the Loan and Security Agreement, and may be automatically extended through August 31, 2023, if, on or prior to August 31, 2022, SVB receives evidence, satisfactory to it, confirming that we have (i) received at least $50.0 million in net cash proceeds from the sale of our equity securities after the date of the Amended Loan and Security Agreement, on terms acceptable to SVB, and (ii) achieved positive data in the first cohort of the TCR-T Library Phase 1/2 Trial endorsed by an independent safety monitoring committee as a safe dose to proceed (together, the “Amended Milestones”). After the interest-only payment period, aggregate outstanding borrowings are repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding principal and accrued and unpaid interest under the SVB Facility and all other outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023; however, if we achieve the Amended Milestones on or prior to August 31, 2022, then the maturity will be automatically extended to August 1, 2024. In addition to the payment of the outstanding principal plus accrued interest due, we will also owe SVB 5.75% of the original principal amounts borrowed as a final payment (the "Final Payment"). We are permitted to make up to two prepayments, each such payment to be at least $5.0 million, subject to a prepayment premium of the SVB Facility. Such prepayment premium would be 3.00% of the principal amount of the SVB Facility if prepaid prior to the first anniversary of the effective date, 2.00% of the principal amount of the SVB Facility if prepaid on or after the first anniversary of the effective date but prior to the second anniversary of the effective date and 1.00% of the principal

amount of the SVB Facility if prepaid on or after the second anniversary of the effective date but prior to maturity date. No amount that has been repaid may be reborrowed.

The Amended Loan and Security Agreement requires us to cash collateralize half of the sum of the then-outstanding principal amount of the SVB Facility, plus an amount equal to 5.75% of the original principal amount of the SVB Facility if we do not achieve the Amended Milestones on or prior to August 31, 2022. In the event a cash collateralization were to occur, so long as no event of default has occurred, $2.5 million will be released from the collateral account following the eighth scheduled payment of principal and interest, and a further $4.0 million will be released following the tenth scheduled payment of principal and interest, in each case, so long as (i) after subtracting such scheduled payment, the sum of (a) the aggregate outstanding principal, (b) accrued and unpaid interest and (c) the Final Payment is less than $9,770,933 and $5,604,167, respectively and (ii) the balance in the collateral account after the release would equal or exceed $10.0 million and $6.0 million, respectively. The SVB Facility and related obligations under the Amended Loan and Security Agreement are secured by substantially all of our properties, rights and assets, except for its intellectual property (which is subject to a negative pledge under the Amended Loan and Security Agreement). In addition, the Amended Loan and Security Agreement contains customary representations, warranties, events of default and covenants.

In connection with our entry into the Loan and Security Agreement, we issued to SVB warrants to purchase (i) up to 432,844 shares of our common stock, in the aggregate, and (ii) up to an additional 432,842 shares of Common Stock, in the aggregate, in the event we achieve certain clinical milestones, in each case at an exercise price per share of $2.22. In connection with our entry into the Amendment, we amended and restated the warrants issued to SVB. As amended and restated, the warrants are for up to 649,615 shares of our common stock, in the aggregate, at an exercise price per share of $1.16, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

The issuance costs for the Loan and Security Agreement, including the Amended Loan and Security Agreement, were approximately $1.2 million and primarily related to the SVB Warrants, which will be amortized into interest expense over the period to August 1, 2023. Interest expense was $0.7 million for the three months ended June 30, 2022 and was $1.4 million for the six months ended June 30, 2022.

The fair value of the Amended Loan and Security Agreement as of June 30, 2022 approximates its face value due to proximity to the transaction.

Cash Flows

The following table summarizes our net decrease in cash and cash equivalents for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,	
	2022	2021
($ in thousands)		
Net cash provided by (used in):		
Operating activities	$ (15,957)	$ (36,765)
Investing activities	(86)	(2,594)
Financing activities	—	1,036
Net decrease in cash and cash equivalents	$ (16,043)	$ (38,323)

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating activities is derived by adjusting our net loss for:

- Non-cash operating items such as depreciation and stock-based compensation; and
- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations.

Net cash used in operating activities for the six months ended June 30, 2022 was $16.0 million, as compared to net cash used in operating activities of $36.8 million for the six months ended June 30, 2021. The net cash used in operating activities for the six months ended June 30, 2022 was primarily due to our net loss of $19.7 million, adjusted for $5.7 million of non-cash items such as depreciation and stock-based compensation, a $2.2 million decrease in lease liabilities, a decrease in accounts payable of $0.9 million and a $0.4 million decrease in accrued expenses, offset by a decrease in receivables of $1.1 million and a decrease to prepaid expenses and other assets of $0.4 million.

Net cash used in investing activities was $0.1 million for the six months ended June 30, 2022, compared to $2.6 million for the six months ended June 30, 2021. The decrease was primarily a result of the decision to use available cash to expand our internal cell therapy capabilities in our Houston, Texas facilities during the first half of 2021.

There were no financing activities for the six months ended June 30, 2022. Net cash provided by financing activities during the six months ended June 30, 2021 was $1.0 million, related primarily to proceeds from the exercise of stock options.

Operating Capital and Capital Expenditure Requirements

We anticipate that losses will continue for the foreseeable future. As of June 30, 2022, our accumulated deficit was approximately $862.6 million. Our actual cash requirements may vary materially from those planned because of a number of factors, including:

- changes in the focus, direction and pace of our development programs;
- the effect of competing technologies and market developments;
- the scope, progress, timing, costs and results of our TCR-T Library Phase 1/2 Trial for the treatment of certain solid tumors and costs associated with the development of our product candidates;
- our headcount growth focused on our TCR program and scaling our manufacturing capabilities;
- our ability to secure partnering arrangements; and
- costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments.

As of June 30, 2022, we had approximately $60.0 million of cash and cash equivalents. Given our current development plans, we anticipate our cash resources will be sufficient to fund our operations into the second quarter of 2023. In order to continue our operations beyond our forecasted runway, we will need to raise additional capital, and we have no committed sources of additional capital at this time. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate. Management does not know whether additional financing will be on terms favorable or acceptable to us when needed, if at all. If adequate additional funds are not available when required, management may need to curtail its development efforts and planned operations.

Working capital as of June 30, 2022 was $34.6 million, consisting of $61.4 million in current assets and $26.8 million in current liabilities. Working capital as of December 31, 2021 was $62.8 million, consisting of $78.8 million in current assets and $16.0 million in current liabilities.

Operating Leases

Our commitments for operating leases relate to laboratory and office space in Houston, Texas and office space in Boston, Massachusetts. On December 21, 2015 and April 15, 2016, we renewed the sublease for our office space in Boston through August 31, 2021. On April 22, 2021, we extended our lease for a portion of office space currently held at our office in Boston. The renewal of the portion of our office space was originally set to expire on August 31, 2021 but was extended through August 31, 2026.

On March 12, 2019, we entered into a lease agreement for office space in Houston at MD Anderson through April 2021. On October 15, 2019, we entered into another lease agreement for additional office and laboratory space in Houston through February 2027. On April 7, 2020, we entered into amendments to our existing lease to lease additional office and laboratory space in Houston through February 2027. In June and September 2020, we entered into short-term leases in Houston for additional office and laboratory space. On December 15, 2020, we entered into a second lease in Houston with MD Anderson which provided us additional office and laboratory space through April 2028.

In the second quarter of 2022, the Company modified its real estate lease agreement executed on December 15, 2020 with MD Anderson. The modification reduced the Company's leased space from 18,111 square feet to 3,228 square feet. As a result, the associated lease liability and right-of-use asset were remeasured to $0.4 million based on revised lease payments. A gain of $0.1 million was also recorded on the lease modification.

Royalty and License Fees

On May 28, 2019, we entered into a patent license agreement, or the Patent License, with the National Cancer Institute, or the NCI. The terms of the Patent License require us to pay the NCI minimum annual royalties in the amount of $0.3 million, which will be reduced to $0.1 million once the aggregate minimum annual royalties paid by us equals $1.5 million. For the three and six months ended June 30, 2022 and 2021, we recognized $0.3 million related to royalty payments under this agreement. As of June 30, 2022, we have paid a total of $0.8 million in minimum annual royalty payments under this agreement.

Pursuant to the Patent License, we are also required to make performance-based payments contingent upon the successful completion of clinical and regulatory benchmarks relating to the licensed products. Of such payments, the aggregate potential benchmark payments are $4.3 million, of which aggregate payments of $3.0 million are due only after marketing approval in the United States or in Europe, Japan, Australia, China or India. The first benchmark payment of $0.1 million will be due upon the initiation of our first sponsored Phase 1 clinical trial of a licensed product or licensed process in the field of use licensed under the Patent License. In

addition, we are required to pay the NCI one-time benchmark payments following aggregate net sales of licensed products at certain aggregate net sales ranging from $250.0 million to $1.0 billion. The aggregate potential amount of these benchmark payments is $12.0 million. A payment totaling $0.1 million was made during the three and six months ended June 30, 2022 related to the first benchmark payment, as compared to $0 during the three and six months ended June 30, 2021.

On October 5, 2018, we entered into an exclusive license agreement, or the License Agreement, with PGEN Therapeutics, Inc., or PGEN, a wholly owned subsidiary of Precigen Inc., or Precigen. Under the License Agreement, we are obligated to pay PGEN an annual licensing fee of $0.1 million expected to be paid through the term of the agreement and we have also agreed to reimburse certain historical costs of PGEN up to $1.0 million. For the three and six months ended June 30, 2022 and June 30, 2021, we have made licensing fee payments in accordance with the terms of the agreement.

Pursuant to the terms of the License Agreement, we are responsible for contingent milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, we will pay PGEN tiered royalties ranging from low-single digits to high-single digits on the net sales derived from the sale of any approved IL-12 products and CAR products. We will also pay PGEN royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of any approved TCR products, up to a maximum royalty amount of $100.0 million in the aggregate. We will also pay PGEN twenty percent of any sublicensing income received by us relating to the licensed products. We are responsible for all development costs associated with each of the licensed products. PGEN will pay us royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of PGEN's CAR products, up to a maximum royalty amount of $100.0 million.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2021, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to clinical trial expenses and other research and development expenses; collaboration agreements; fair value measurements for stock-based compensation; and income taxes. We reviewed our policies and determined that those policies remain our most critical accounting policies for the three and six months ended June 30, 2022.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal accounting officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) as of June 30, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our principal executive officer and principal accounting officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13(a)-15(f) of the Exchange Act) that occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities from time to time. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management attention and resources and other factors.

As of June 30, 2022, based on information readily available, there are no material matters that, in the opinion of management, are likely to result in a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

The following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. The risk factors in this Quarterly Report have been revised to incorporate changes to our risk factors from those included in our Annual Report. The risk factors set forth below with an asterisk (*) before the title are new risk factors or ones containing substantive changes from the risk factors previously disclosed in Item 1A of our Annual Report, as filed with the SEC. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of your investment. The impact of COVID-19 may also exacerbate other risks discussed in this filing, any of which could have a material effect on us. This situation is changing rapidly and additional impacts may arise. Additional risks that we currently do not know about, or that we currently believe to be immaterial, may also impair our business. Certain statements below are forward-looking statements. See “Special Note Regarding Forward-Looking Statements” in this Quarterly Report.

RISKS RELATED TO OUR BUSINESS

We will require substantial additional financial resources to continue as a going concern and to continue ongoing development of our product candidates and pursue our business objectives; if we are unable to obtain these additional resources when needed, we may be forced to delay or discontinue our planned operations, including clinical testing of our product candidates.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the six months ended June 30, 2022, we had a net loss of $19.7 million, and, as of June 30, 2022, our accumulated deficit since inception in 2003 was $862.6 million. We expect our operating expenditures and net losses to increase significantly in connection with our ongoing clinical trial and our internal research and development capabilities. Further development of our product candidates will require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- scale-up and scale-out the manufacturing of our TCR-T product candidates;
- seek regulatory approvals for product candidates;
- work with regulatory authorities to identify and address program-related inquiries;
- implement additional internal systems and infrastructure; and
- hire additional personnel, including highly-skilled and experienced scientific staff.

As of June 30, 2022, we have approximately $60.0 million of cash and cash equivalents. Given our current development plans and cash management efforts, we anticipate cash resources will be sufficient to fund operations into the second quarter of 2023, and we have no committed sources of additional capital at this time. We follow the guidance of Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern, in order to determine whether there is substantial doubt about our ability to continue as a going concern for one year after the date our financial statements are issued. Based on the current cash forecast, management has determined that our present capital resources will not be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements, which raises substantial doubt as to our ability to continue as a going concern.

The forecast of cash resources is forward-looking information that involves risks and uncertainties, and our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, slower and/or faster than expected progress of our research and development

efforts, changes in governmental regulation, competitive and technical advances, rising costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights. The COVID-19 pandemic continues to evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We need to raise additional capital to fund our operations. The manner in which we raise any additional funds may affect the value of your investment in our common stock.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. We do not have any committed external source of funds. The unpredictability of the capital markets may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. In particular, a decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. Moreover, if we fail to advance one or more of our current product candidates into early or later-stage clinical trials, successfully commercialize one or more of our product candidates, or acquire new product candidates for development, we may have difficulty attracting investors that might otherwise be a source of additional financing.

On August 6, 2021, we entered into the Loan and Security Agreement with SVB. The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing, with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022. In connection with the initial borrowing, we also issued warrants to SVB and certain of its affiliates for the purchase of up to 432,844 shares of our common stock, in the aggregate, at an exercise price of $2.22 per share. The Loan and Security Agreement was subsequently amended, effective December 28, 2021, to, among other things, eliminate the additional tranche so that the $25.0 million we have drawn down is the full amount available under the SVB Facility. As a result, we do not have any other borrowings available under the SVB Facility. In connection with entering into the Amendment we also amended and restated the warrants. These amended and restated warrants provide for the purchase of up to 649,615 shares of our common stock, in the aggregate, at an exercise price of $1.16 per share.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, creating liens, making capital expenditures or declaring dividends. Furthermore, the ongoing impact of COVID-19 and geopolitical instability, including the military conflict between Russia and Ukraine, on global financial markets could make the terms of any available financing less attractive to use and more dilutive to our existing shareholders. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

We have incurred indebtedness that could adversely affect our business and place restrictions on our operating and financial flexibility.

The Amended Loan and Security Agreement contains customary affirmative and negative covenants and events of default applicable to us and any subsidiaries. The affirmative covenants require us (and us to cause our subsidiaries, if any) to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage, and protect material intellectual property, among other things. The negative covenants restrict our and our subsidiaries' ability to, among other things, transfer collateral, change our business, engage in mergers or acquisitions, incur additional indebtedness, pay cash dividends or make other distributions, make investments, create liens, sell assets and make any payment on subordinated debt. The restrictive covenants of the Amended Loan and Security Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial, including entering into certain licensing arrangements, maintaining flexible cash management arrangements and engaging in certain change in control transactions, among others.

Our debt combined with our other financial obligations and contractual commitments could have significant adverse consequences for our business, including:

- Requiring us to dedicate a substantial portion of cash flows to payment on our debt, which would reduce available funds for further research and development;
- Increasing the amount of interest that we must pay on debt with variable interest rates, if market rates of interest increase;
- Subjecting us to restrictive covenants that reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing; and
- Requiring us to pledge our non-intellectual property assets as collateral, which could limit our ability to obtain additional debt financing.

We intend to satisfy our debt service obligations with our existing cash and cash equivalents and any additional amounts we may raise through future debt and equity financings. Our ability to make payments due under the SVB Facility depends on our future performance, which is subject to economic, financial, competitive conditions and other factors beyond our control. We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. In addition, a failure to comply with certain equity raise and clinical milestone requirements in the Amended Loan and Security Agreement could result in us having to deposit unrestricted and unencumbered cash equal to 50% of the principal amount of the SVB Facility then outstanding and an amount equal to 5.75% of the original principal amount in a cash collateral account with SVB. Failure to pay any amount due under the SVB Facility, to comply with covenants under the Amended Loan and Security Agreement, or the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, or condition (financial or otherwise), would result in an event of default. The occurrence and continuation of an event of default could cause interest to be charged at the rate that is otherwise applicable plus 3.00% (unless SVB elects to impose a smaller increase) and would provide SVB with the right to accelerate all obligations under the SVB Facility and exercise remedies against us and the collateral securing the SVB Facility and other obligations under the Amended Loan and Security Agreement, including foreclosure against assets securing the SVB Facility. In addition, the covenants under the Amended Loan and Security Agreement and the pledge of substantially all of our assets, excluding our intellectual property (which is subject to a negative pledge under the Amended Loan and Security Agreement), as collateral on the loan may limit our ability to obtain additional debt financing.

We have previously identified material weaknesses in our internal control, all of which have been remediated. We may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or could have a material adverse effect on our business and trading price of our securities.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the Nasdaq Global Select Market. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting. We may also be required to have our independent registered public accounting firm issue an opinion on the effectiveness of our internal control over financial reporting on an annual basis.

We have identified material weaknesses in our internal control over financial reporting in the past. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

Although the material weaknesses identified in the past have been remediated, we cannot assure you that any measures we have taken or may take in the future will be sufficient to avoid potential future material weaknesses. If we are unable to successfully remediate any future material weakness and maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results in future periods, or report them within the timeframes required by the requirements of the SEC, Nasdaq or the Sarbanes-Oxley Act. Failure to comply with the Sarbanes-Oxley Act, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in the identification of additional material weaknesses or significant deficiencies, cause us to fail to meet our reporting obligations or result

in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

Our plans to develop and commercialize non-viral adoptive TCR-T cell therapies can be considered a new approach to cancer treatment, the successful development of which is subject to significant challenges.

We intend to employ technologies such as the technology licensed from MD Anderson pursuant to that certain license agreement between us, Precigen, and MD Anderson, with an effective date of January 13, 2015, or the MD Anderson License, which was subsequently assigned by Precigen and assumed by PGEN effective as of January 1, 2018, from PGEN, pursuant to the License Agreement, and from NCI, pursuant to the Patent License described above, to pursue the development and commercialization of non-viral cellular therapies based on T-cells and TCRs, targeting solid tumor malignancy. Because this is a new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities that have very limited experience with the commercial development of genetically modified T-cell therapies for cancer;
- designing and conducting our clinical trials using this new approach or selecting the appropriate TCRs in a way that may lead to optimal results;
- identifying and manufacturing appropriate TCRs from either the patient or third parties that can be administered to a patient;
- developing and deploying consistent and reliable processes for engineering a patient's and/or donor's T-cells ex vivo and infusing the T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivering each of the potential products, which may increase the risk of adverse side effects of the potential products;
- educating medical personnel regarding the potential side effect profile of each of the potential products, such as the potential adverse side effects related to cytokine release;
- addressing any competing technological and market developments;
- developing processes for the safe administration of these potential products, including long-term follow-up for all patients who receive the potential products;
- sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process the potential products;
- developing a manufacturing process with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance;
- developing therapies for types of cancers beyond those addressed by the current potential products;
- maintaining and defending the intellectual property rights relating to any products we develop; and
- not infringing the intellectual property rights, in particular, the patent rights, of third parties, including competitors, such as those developing T-cell therapies.

We cannot assure you that we will be able to successfully address these challenges, which could prevent us from achieving our research, development and commercialization goals.

Our current product candidates are based on novel technologies and are supported by limited clinical data and we cannot assure you that our current and planned clinical trials will produce data that supports regulatory approval of one or more of these product candidates.

Our genetically modified TCR-T cell product candidates are supported by limited clinical data, all of which has been generated through trials conducted by MD Anderson and the NCI, not by us. We have assumed control of the overall clinical and regulatory development of our TCR-T cell product candidates, and any failure to obtain, or delays in obtaining, sponsorship of new INDs, or in

filing INDs sponsored by us for these or any other product candidates we determine to advance could negatively affect the timing of our potential future clinical trials. Such an impact on timing could increase research and development costs and could delay or prevent obtaining regulatory approval for our product candidates, either of which could have a material adverse effect on our business. We began enrolling patients in our TCR-T Library Phase 1/2 Trial in January 2022.

Further, we did not control the design or conduct of the previous trials. It is possible that the FDA will not accept these previous trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any of one or more reasons, including the safety, purity and potency of the product candidate, the degree of product characterization, elements of the design or execution of the previous trials or safety concerns or other trial results. We may also be subject to liabilities arising from any treatment-related injuries or adverse effects in patients enrolled in these previous trials. As a result, we may be subject to unforeseen third-party claims and delays in our potential future clinical trials. We may also be required to repeat in whole or in part clinical trials previously conducted by MD Anderson or other entities, which will be expensive and delay the submission and licensure or other regulatory approvals with respect to any of our product candidates.

Moreover, there are a number of regulatory requirements that we must continue to satisfy as we conduct our clinical trials of TCR-T cell product candidates in the United States. The criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products and change frequently. Satisfaction of these requirements will entail substantial time, effort and financial resources. To date, the FDA has approved only a few adoptive cell therapies for commercialization. Because adoptive cell therapies are relatively new and our product candidates employ novel gene expression and cell technologies, regulatory agencies may lack experience in evaluating product candidates like our Library TCR-T product candidates. This novelty may heighten regulatory scrutiny of our therapies or lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent commercialization of our product candidates. These factors make it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates. Any time, effort and financial resources we expend on our clinical product candidates and other early-stage product development programs, which are ultimately not successful may adversely affect our business.

We report interim data on certain of our clinical trials and we cannot assure you that interim data will be predictive of either future interim results or final study results. In addition, the results ultimately obtained from our preclinical studies or other earlier clinical trials for our product candidates may not be predictive of future results.

As part of our business, we provide updates related to the development of our product candidates, which may include updates related to interim clinical trial data. We anticipate that our clinical trials will involve small patient populations and because of the small sample size, the interim results of these, and all, clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results.

We commenced enrollment in our TCR-T Library Phase 1/2 Trial in January 2022 and announced the treatment of the first patient in May 2022. We do not know at this stage whether patient response data from this trial will be favorable, and initial success in clinical trials may not be indicative of results obtained when such trials are completed. Our product candidates may fail to show the desired safety and efficacy in clinical development, and we cannot assure you that the results of any future trials will demonstrate the value and efficacy of our product candidates. Even if our clinical trials are completed as planned, we cannot be certain that their results will support approval of our product candidates.

There are no approved engineered TCR-T cell immunotherapies for solid tumors. We believe our product candidates may be effective against solid tumors and plan to develop product candidates for use in solid tumors. We cannot guarantee that our product candidates will be able to access the solid tumor or show any functionality in the solid tumor microenvironment. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. In addition, the safety profile of our product candidates may differ in a solid tumor setting. If we are unable to make our product candidates function in solid tumors, our development plans and business will be significantly harmed.

Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. Negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

In addition, the results of any preclinical studies for our product candidates may not be predictive of the results of clinical trials. For example, preclinical models as applied to cell therapy in oncology do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks.

We will need to attract, recruit and retain qualified personnel and we will continue to rely on key scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

In 2021, we experienced transitions in our senior management culminating in the appointment of Kevin S. Boyle, Sr. as Chief Executive Officer and a member of the board of directors in August 2021 and the hiring of Michael Wong as our Vice President, Finance in September 2021 and his appointment as principal accounting officer in November 2021. In November 2021, we hired Melinda Lackey as our Senior Vice President, Legal. Management transition is often difficult and inherently causes some loss of institutional knowledge and creates potential uncertainty in strategy execution.

In addition, we may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on our principal scientific, regulatory and medical advisors. The loss of any of our key personnel, could result in delays in product development, loss of key personnel or partnerships and diversion of management resources, which could adversely affect our operating results. We do not carry "key person" life insurance policies on any of our officers or key employees.

****We face substantial competition from other biopharmaceutical companies, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.***

Our TCR-T cell therapies targeting solid tumors face significant competition from multiple companies, and their collaborators, in the TCR and CAR technology space. We face competition from several companies, including Achilles Therapeutics, Annoca, Adaptimmune Therapeutics in collaboration with GlaxoSmithKline, Affini-T Therapeutics, ArsenalBio, BioNTech, bluebird bio, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Lion TCR, Lyell Immunopharma, Medigene, Nurix Therapeutics, Neogene Therapeutics, NexImmune, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, TCR^2 Therapeutics, T-Cure BioScience, T-knife Therapeutics, Tmunity Therapeutics, Triumvira Immunologics, TScan Therapeutics, Turnstone Biologics, Zelluna Immunotherapy and others. Many of these companies are either investigating TCR-T cells against germline antigens or are utilizing tumor infiltrating lymphocytes. Some are pursuing CAR-T cells for solid tumors. In contrast, we are focused on developing TCR-T cell products against neoantigens arising from somatic mutations in solid tumors.

Companies in the T-cell therapy segment that have target discovery platforms like ours include Adaptive Therapeutics, Affini-T Therapeutics, Immatics, Enara Bio, T-knife Therapeutics, TScan Therapeutics and 3T Biosciences. Several companies, including Advaxis, Amgen, BioNTech, Geneos Therapeutics, and Gritstone, are pursuing vaccine platforms to target neoantigens for solid tumors. Other companies are developing non-viral gene therapies, including Poseida Therapeutics and several companies developing CRISPR technology, including Crispr Therapeutics.

Several companies are pursuing the development of allogeneic CAR-T therapies, including Allogene Therapeutics, Atara Biotherapeutics, Precision Biosciences, and Servier Laboratories (in collaboration with Cellectis), which may compete with our product candidates. We also face competition from companies developing therapies using cells other than T cells such as Athenex, Fate Therapeutics, ImmunityBio, IN8bio, Nkarta Therapeutics, and Takeda Pharmaceutical. Other competitors are developing T cells with cytokines such as Fate Therapeutics and Obsidian Therapeutics. Finally, we also face competition from non- cell-based treatments offered by other companies such as Amgen, AstraZeneca, Bristol-Myers Squibb, Incyte, Merck, and Roche. Additionally, our ability to pursue partnerships relating to our IL-12 and CAR-T programs may be impacted by substantial competition from these and other biopharmaceutical companies.

Even if we obtain regulatory approval of potential TCR products, we may not be the first to market and that may affect the price or demand for our potential products. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication, or fewer side effects, than our potential products or may offer comparable performance at a lower cost. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our potential products thereby reducing or eliminating our commercial opportunity. We may not be able to implement our business plan if the acceptance of our potential products is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our potential products, or if physicians switch to other new drug or biologic products or choose to reserve our potential products. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our potential products, that may

prevent us from obtaining approval from the FDA for such potential products for the same indication for seven years, except in limited circumstances. If our potential products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and biopharmaceuticals;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs and biopharmaceuticals;
- formulating and manufacturing drugs and biopharmaceuticals; and
- launching, marketing and selling drugs and biopharmaceuticals.

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Any termination of our licenses with PGEN, MD Anderson or the National Cancer Institute or our research and development agreements with MD Anderson and the National Cancer Institute could result in the loss of significant rights and could harm our ability to develop and commercialize our product candidates.

We are dependent on patents, know-how, and proprietary technology that are licensed from others, particularly MD Anderson, PGEN, and the NCI, as well as the contributions by MD Anderson under our research and development agreements. Any termination of these licenses or research and development agreements could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and these licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the applicable license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes, and the technology and processes of PGEN, MD Anderson, the NCI and our other licensors, infringe intellectual property of the licensor that is not subject to the applicable license agreement;
- our right to sublicense patent and other rights to third parties pursuant to our relationships with our licensors and partners;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our potential products under the MD Anderson License, the License Agreement with PGEN and our patent license agreement with the NCI;
- whether or not our partners are complying with all of their obligations to support our programs under licenses and research and development agreements; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements, particularly with MD Anderson, PGEN and the NCI, on acceptable terms, we may be unable to successfully develop and commercialize the affected potential products. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize potential products under our applicable licenses could suffer. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the United States Patent and Trademark Office, or USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review

and post-grant review have been implemented, which adds uncertainty to the possibility of challenge to our or our licensors' patents in the future.

We may not be able to retain the rights licensed to us and PGEN by MD Anderson or the rights licensed to us by the National Cancer Institute to technologies relating to TCR-T cell therapies and other related technologies.

Under the MD Anderson License, we, together with PGEN, received an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR-T cell and TCR-T cell therapies as well as either co-exclusive or non-exclusive licenses under certain related technologies. These proprietary methods and technologies, along with others within PGEN's technology suite and licensed to us by PGEN, may help realize the promise of genetically modified TCR-T cell therapies by controlling cell expansion and activation in the body, minimizing off-target and unwanted on-target effects and toxicity while maximizing therapeutic efficacy. The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term, we and PGEN shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder.

After 10 years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if we and PGEN are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if we and PGEN are not meeting the diligence requirements in such funding agreement or contract, as applicable. MD Anderson may also terminate the agreement with written notice upon material breach by us or PGEN, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both us or PGEN and may be terminated by the mutual written agreement of us, PGEN and MD Anderson.

Under the Patent License, we received an exclusive, worldwide license to certain intellectual property and patents from NCI for TCRs we can introduce into T cells using transposon-based genetic engineering. These T cells may be used in our TCR-T Library Phase 1/2 Clinical Trial or in subsequent clinical trials, if initiated. The term of the Patent License shall expire with the last of the licensed patents. The NCI could terminate or modify the Patent License if it believes we have materially breached, by failing to meet the defined milestones by the required dates, or upon certain insolvency events that are not cured within the 90-day time limit once we are notified of such alleged breach. The Patent License is also subject to certain public use requirements wherein the NCI could require us to sublicense certain product candidates or terminate or modify the Patent License if we do not meet these public use requirements. The Patent License could also be terminated by the NCI if we are unable to pay the required benchmark payments or the annual minimum royalty payments.

There can be no assurance that we will be able to successfully perform under the MD Anderson License or the Patent License and if the MD Anderson License or the Patent License is terminated it may prevent us from achieving our business objectives.

****We are partly reliant on the National Cancer Institute for research and development and early clinical testing of certain of our product candidates.***

A portion of our research and development is being conducted by the NCI under the CRADA entered into in January 2017 and which was amended in March 2018, February 2019, March 2022 and June 2022. Under the CRADA, the NCI, with Dr. Steven A. Rosenberg as the principal investigator, is responsible for conducting a clinical trial using the *Sleeping Beauty* system to express TCRs for the treatment of solid tumors. We have limited control over the nature or timing of the NCI's clinical trial and limited visibility into their day-to-day activities, including with respect to how they are providing and administering T-cell therapy. For example, the research we are funding constitutes only a small portion of the NCI's overall research. Additionally, other research being conducted by Dr. Rosenberg may at times receive higher priority than research on our program. Further, in response to the COVID-19 pandemic, the NCI has taken precautionary measures that have delayed the enrollment of the personalized TCR-T clinical trial using the *Sleeping Beauty* system to express TCRs for the treatment of solid tumors. The progress and timeline, including the timeline for dosing patients, for this trial are under the control of the NCI.

The CRADA expired by its terms on January 9, 2022. In March 2022, we entered into an amendment to the CRADA that is retroactive, effective January 9, 2022 to extend the term of the CRADA until January 9, 2023. In June 2022, we entered into the Fourth Amendment to the CRADA (the "CRADA Fourth Amendment") which, among other things, extended the term of the CRADA

until January 9, 2025. In connection with the CRADA Fourth Amendment, the Company agreed to contribute $1.0 million per year, payable on a quarterly basis, beginning in the first quarter of 2023.

We may not be able to commercialize any products, generate significant revenues, or attain profitability.

To date, none of our product candidates have been approved for commercial sale in any country. The process to develop, obtain regulatory approval for, and commercialize potential product candidates is long, complex and costly. Unless and until we receive approval from the FDA and/or other foreign regulatory authorities for our product candidates, we cannot sell our products and will not have product revenues. Even if we obtain regulatory approval for one or more of our product candidates, if we are unable to successfully commercialize our products, we may not be able to generate sufficient revenues to achieve or maintain profitability or to continue our business without raising significant additional capital, which may not be available. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

Our operating history makes it difficult to evaluate our business and prospects.

We have not previously completed any pivotal clinical trials, submitted a BLA or demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- Continuing to undertake preclinical development and clinical trials;
- Participating in regulatory approval processes;
- Formulating and manufacturing products; and
- Conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary product candidates and undertaking preclinical and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We may not be successful in establishing development and commercialization collaborations, which failure could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Developing biopharmaceutical products and complementary technologies, conducting clinical trials, obtaining marketing approval, establishing manufacturing capabilities and marketing approved products is expensive, and therefore, we anticipate exploring collaborations with third parties that have alternative technologies, more resources and more experience than we do. In situations where we enter into a development and commercial collaboration arrangement for a product candidate or complementary technology, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate or technology. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on reasonable and acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in some or all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be able to successfully manage our growth as we expand our development and regulatory capabilities, which could disrupt our operations.

As we advance our product candidates to the point of, and through, clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide for these capabilities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel with expertise in preclinical and clinical research and testing, manufacturing, government regulation and eventually sales and marketing. Competition for qualified individuals is intense among numerous biopharmaceutical companies, universities, and other research institutions and we cannot be certain that our search will be successful. If we are unable to manage our growth effectively, including attracting and retaining qualified personnel, our business may be harmed.

Restructuring activities could disrupt our business and effect our results of operations. In addition, we may not achieve anticipated benefits and saving from such restructuring activities.

In September 2021, we announced a restructuring enabling us to focus on and enhance our TCR program. We eliminated approximately 60 positions, representing more than 50% of our workforce. The restructuring resulted in the loss of institutional knowledge and expertise and the reallocation of and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Further, the restructuring and possible additional cost-containment measures may yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. In addition, we may not achieve anticipated benefits from the restructuring. Due to our limited resources, we may not be able to effectively manage our operations or retain qualified personnel, which may result in weaknesses to our infrastructure and operations, risks that we may be unable to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, manufacturing and regulatory functions, which would have a negative impact on our ability to successfully develop and, ultimately, commercialize our product candidates. If our management is unable to successfully manage this transition and restructuring activities, our expenses may be more than expected and we may be unable to implement our business strategy. As a result, our future financial performance and our ability to commercialize our product candidates successfully would be negatively affected.

Our business will subject us to the risk of liability claims associated with the use of hazardous materials and chemicals.

Our contract research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could have a materially adverse effect on our business, financial condition, and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require our contractors to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability, and we will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- Decreased demand for our product candidates;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Initiation of investigations by regulators;
- Withdrawal of prior governmental approvals;
- Costs of related litigation;
- Substantial monetary awards to patients;
- Product recalls;
- Loss of revenue;
- The inability to commercialize our product candidates; and
- A decline in our share price.

Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, it may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

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

Our operations, and those of our clinical investigators, contractors and consultants, are based primarily in Houston, Texas. These operations could be subject to power shortages, telecommunications failures, water shortages, hurricanes, floods, earthquakes, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we maintain customary insurance policies that we believe are appropriate. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to manufacture clinical supplies of our product candidates could be disrupted if our own operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. We may have limited recourse against third parties if the non-compliance is due to factors outside of the manufacturer's control.

We may be unable to find appropriate partners to continue the development of the product candidates we de-prioritized in 2021 which may prevent us from ever deriving meaningful revenue from them.

In 2021, we elected to prioritize our Library TCR-T program and significantly reduced our activities in connection with our Controlled IL-12 and CAR-T programs to preserve our capital resources. The decision to significantly reduce activities for our Controlled IL-12 and CAR-T programs may negatively impact the potential for these programs, which could have a material adverse effect on our business. We are actively exploring partnership opportunities for our Controlled IL-12 and CAR-T programs to support their continued development. If we are unable to identify an appropriate strategic partner or to negotiate and consummate a license or sale agreement with such a partner, it will be difficult to advance the development of these two programs, increasing the likelihood that we may be unable to derive any meaningful revenue from these assets.

We have also mutually agreed with TriArm Therapeutics Ltd., or TriArm, to dissolve the Eden BioCell joint venture.

Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in our manufacturing operations or the operations of third-party manufacturers, CROs and other third parties upon whom we rely or may rely on in the future.

We depend on a worldwide supply chain to manufacture products used in our preclinical studies and clinical trials. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at our own manufacturing facilities or third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and our ongoing TCR-T Library Phase 1/2 Trial at MD Anderson have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, have been and may continue to be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, if we are unable to successfully recruit and retain patients, principal investigators, and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city, or state, our clinical trial operations could be adversely impacted.

The global COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar epidemic is highly uncertain and subject to change. We may experience a material impact on our operations, and we continue to monitor the COVID-19 situation closely.

RISKS RELATED TO THE CLINICAL TESTING, GOVERNMENT REGULATION AND MANUFACTURING OF OUR PRODUCT CANDIDATES

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials, including our ongoing TCR-T Library Phase 1/2 Trial, for a variety of reasons, including impacts that have resulted or may result from the COVID-19 pandemic. The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- The patient eligibility criteria defined in the clinical trial protocol;
- The size of the patient population required for analysis of the clinical trial's primary endpoints;
- The proximity of patients to clinical trial sites;
- The design of the clinical trial;
- Our ability to recruit and retain clinical trial investigators with the appropriate competencies and experience;
- Our ability to obtain and maintain patient consents;
- Reporting of the preliminary results of any of our clinical trials; and
- The risk that patients enrolled in clinical trials will drop out of the clinical trials before the manufacturing and infusion of our product candidates or clinical trial completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some of our potential patients may instead opt to enroll in a clinical trial being conducted by one of our competitors. In addition, patients may be unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology industry or for other reasons. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because some of our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

Delays in completing patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective, or with respect to a biological product candidate, safe, pure and potent, for their intended uses.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- Such authorities may disagree with the design or implementation of our or our current or future collaborators' clinical trials;
- Negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- Serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs or biologics similar to our therapeutic product candidates;
- Such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- We, or any of our current or future collaborators, may be unable to demonstrate that a product candidate is safe and effective, and that the therapeutic product candidate's clinical and other benefits outweigh its safety risks;
- We may be unable to demonstrate to the satisfaction of such authorities that our companion diagnostics are suitable to identify appropriate patient populations;
- Such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- Such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA, NDA, premarket approval, or PMA, or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- Such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- Approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- Such authorities may find deficiencies in the manufacturing processes, test procedures and specifications or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies;
- Regulations and approval policies of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- Such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS.

Events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs or biologics based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

We are very early in our development efforts. Our most advanced product candidates are only in an early-stage clinical trial, which is very expensive and time-consuming. We cannot be certain when we will be able to submit a BLA to the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.

Our product candidates are in various stages of development and require extensive clinical testing. Our most advanced product candidates are in our TCR-T Library Phase 1/2 Trial, which is currently enrolling patients. Human clinical trials are very expensive and difficult to design, initiate and implement, in part because they are subject to rigorous regulatory requirements. Notwithstanding our current clinical trial plans for each of our existing product candidates, which we estimate will take several years to complete, we may not be able to commence additional trials or see results from these trials within our anticipated timelines. Failure can occur at any stage of a clinical trial, and we can encounter problems that cause us to delay the start of, abandon or repeat clinical trials. Some factors which may lead to a delay in the commencement or completion of our clinical trials include: requests for additional nonclinical data from regulators, unforeseen safety issues, dosing issues, lack of effectiveness during clinical trials, difficulty recruiting or monitoring patients, difficulty manufacturing clinical products, among other factors.

As they enter later stages of development, our product candidates generally will become subject to more stringent regulatory requirements, including the FDA's requirements for chemistry, manufacturing and controls for product candidates entering Phase 3 clinical trials. There is no guarantee the FDA will allow us to commence Phase 3 clinical trials for product candidates studied in earlier clinical trials.

If the FDA does not allow our product candidates to enter later stage clinical trials or requires changes to the formulation or manufacture of our product candidates before commencing Phase 3 clinical trials, our ability to further develop, or seek approval for, such product candidates may be materially impacted. As such, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval of our product candidates or whether such a BLA will be accepted. Because we do not anticipate generating revenues unless and until we submit one or more BLAs and thereafter obtain requisite FDA approvals, the timing of our BLA submissions and FDA determinations regarding approval thereof will directly affect if and when we are able to generate revenues.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any potential marketing approval.

As with many pharmaceutical and biological products, treatment with our product candidates may produce undesirable side effects or adverse reactions or events, including potential adverse side effects related to cytokine release. If our product candidates or similar products or product candidates under development by third parties demonstrate unacceptable adverse events, we may be required to halt or delay further clinical development of our product candidates. The FDA or other foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. If a serious adverse event was to occur in our TCR-T Library Phase 1/2 Trial, the FDA may place a hold on the clinical trial.

The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the institutions that collaborate with us, as toxicities resulting from our novel technologies may not be normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand their side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our

product candidates could result in adverse effects to patients, including death. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the product's label;
- we may be required to create a risk evaluation and mitigation strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved. Furthermore, any of these occurrences may harm our business, financial condition and prospects significantly.

Our cell-based therapy immuno-oncology product candidates rely on the availability of reagents, specialized equipment and other specialty materials and infrastructure, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates, including the DNA plasmids used, which are used as the vector to insert our TCRs into human T cells. Some of these suppliers may not have the capacity to support commercial products manufactured under current good manufacturing practices by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, infrastructure, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

In addition, some of the reagents and products used by us, including in our clinical trials, may be stored at a single vendor. The loss of materials located at a single vendor, or the failure of such a vendor to manufacture clinical product in accordance with our specifications, would impact our ability to conduct ongoing or planned clinical trials and continue the development of our products. Further, manufacturing replacement material may be expensive and require a significant amount of time, which may further impact our clinical programs.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain additional rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to maintain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical trials, the change may require us to perform both ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Because we are dependent, at least in part, upon clinical research institutions and other CROs for clinical testing and/or for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

We materially rely upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. In addition, we hire CROs to help us manage clinical trials, collect data and analyze clinical samples. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our product development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new products, if any, will be delayed. These institutions may also have, or implement in the future, policies and procedures that limit their ability to advance our programs. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors to our detriment, our competitive position would be harmed.

We have limited experience producing and supplying our product candidates. We may be unable to consistently manufacture our product candidates to the necessary specifications or in quantities necessary to treat patients in our clinical trials.

We have limited experience in biopharmaceutical manufacturing. We recently began manufacturing our product candidates at our in-house cGMP manufacturing facility at our leased headquarters in Houston, Texas. Our ability to manufacture our product candidates depends on our finding and retaining personnel with the appropriate background and training to staff and operate the facility on a daily basis. Should we be unable to find or retain these individuals, we may need to train additional personnel to fill the needed roles or engage with external contractors. There are a small number of individuals with experience in cell therapy and the competition for these individuals is high.

Specifically, the operation of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals who have successful previous experience in cleanroom environments. Cell therapy facilities, like other biological agent manufacturing facilities, require appropriate commissioning and validation activities to demonstrate that they operate as designed. Additionally, each manufacturing process must be proven through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. While we have developed our own manufacturing processes using an in-house team, there is timing risk associated with increased in-house product manufacture.

The manufacture of our product candidates is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of product candidates or in our manufacturing facilities, the manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. It is possible that stability or other issues relating to the manufacture of our product candidates could occur in the future.

Our product candidates currently are and will continue to be manufactured on a patient-by-patient basis. Delays in manufacturing could adversely impact the treatment of each patient and may discourage participation in our current or future clinical trials. We have not yet manufactured our clinical trial product candidates on a large scale and may not be able to achieve large scale clinical trial or commercial manufacturing and processing on our own to satisfy expected clinical trial or commercial demands for any of our product candidates. While we believe that our current manufacturing and processing approaches are appropriate to support our early-stage clinical product development, we have limited experience in managing the T cell engineering process, and our processes may be more difficult or more expensive than anticipated. The manufacturing processes employed by us may not result in product candidates that will be safe and effective. If we are unable to manufacture sufficient number of TCR-T cells for our product candidates, our development efforts would be delayed, which would adversely affect our business and prospects.

Our manufacturing operations will be subject to review and oversight by the FDA upon commencement of the manufacturing of our product candidates for our TCR-T Library Phase 1/2 Trial. We will be subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

We do not yet have sufficient information to reliably estimate the cost of commercial manufacturing and processing of our product candidates. The actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

We also may fail to manage the logistics of collecting and shipping patient material to our manufacturing site and shipping the product candidate back to the patient. Logistical and shipment delays and problems, whether or not caused by us or our vendors, could prevent or delay the delivery of product candidates to patients.

In addition, it is possible that we could experience manufacturing difficulties in the future due to resource constraints or because of labor disputes. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients could be materially adversely affected.

We may have difficulty validating our manufacturing process as we manufacture our product candidates from an increasingly diverse patient population for our clinical trials.

During our development of the manufacturing process, our TCR-T cell product candidates have demonstrated consistency from lot to lot and from donor to donor. However, our sample size is small and the starting material used during our development work came from healthy donors. Once we have experience with working with white blood cells taken from our patient population, we may encounter unforeseen difficulties due to starting with material from donors who are not healthy, including challenges inherent in harvesting white blood cells from unhealthy patients.

Although we believe our current manufacturing process is scalable for our clinical trials, and if our any of our product candidates are approved or commercialized, we may encounter challenges in validating our process due to the heterogeneity of the product starting material. However, we anticipate that during the early phases of our clinical trials we will be able to adapt our process to account for these differences resulting in a more robust process. We cannot guarantee that any other issues relating to the heterogeneity of the starting material will not impact our ability to commercially manufacturing our product candidates.

The gene transfer vectors from our Sleeping Beauty system used to manufacture our product candidates may incorrectly modify the genetic material of a patient's T cells, potentially triggering the development of a new cancer or other adverse events.

Our TCR-T cells are manufactured using our *Sleeping Beauty* system, a non-viral vector to insert genetic information encoding the TCR construct into the patient's T cells. The TCR construct is then primarily integrated at thymine-adenine, or TA, dinucleotide sites throughout the patient's genome and, once expressed as protein, is transported to the surface of the patient's T cells. Because the gene transfer vector modifies the genetic information of the T cell, there is a theoretical risk that modification will occur in the wrong place in the T cell's genetic code, leading to vector-related insertional oncogenesis, and causing the T cell to become cancerous. If the cancerous T cell is then administered to the patient, the cancerous T cell could trigger the development of a new cancer in the patient. We use non-viral vectors to insert genetic information into T cells, which we believe have a lower risk of insertional oncogenesis as opposed to viral vectors. However, the risk of insertional oncogenesis remains a concern for gene therapy, and we cannot assure that it will not occur in any of our ongoing or planned clinical trials. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of the vectors used to carry the genetic material. Although we use non-viral vectors, the FDA has stated that lentiviral vectors possess characteristics that may pose high risks of delayed adverse events. If any such adverse events occur from our non-viral vector, further advancement of our preclinical studies or clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a

REMS, which could include requirements for a restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved uses, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA closely regulates the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- Litigation involving patients taking our product;
- Restrictions on such products, manufacturers or manufacturing processes;
- Restrictions on the labeling or marketing of a product;
- Restrictions on product distribution or use;
- Requirements to conduct post-marketing studies or clinical trials;
- Warning letters;
- Withdrawal of the products from the market;
- Refusal to approve pending applications or supplements to approved applications that we submit;
- Recall of products;
- Fines, restitution or disgorgement of profits or revenues;
- Suspension or withdrawal of marketing approvals;
- Damage to relationships with existing and potential collaborators;
- Unfavorable press coverage and damage to our reputation;
- Refusal to permit the import or export of our products;
- Product seizure; and
- Injunctions or the imposition of civil or criminal penalties.

Noncompliance with requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

If we are unable to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.

We may not be able to obtain the approvals necessary to commercialize our product candidates, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the United States and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a BLA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the

product candidate, and will require substantial resources for research, development and testing. We cannot predict whether our research, development, and clinical approaches will result in products that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- Delay commercialization of, and our ability to derive product revenues from, our product candidates;
- Impose costly procedures on us; and
- Diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our BLAs. We cannot be sure that we will ever obtain regulatory approval for any of our product candidates. Failure to obtain FDA approval for our product candidates will severely undermine our business by leaving us without a marketable product, and therefore without any potential revenue source, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will obtain FDA approval if we are able to do so.

In foreign jurisdictions, we similarly must receive approval from applicable regulatory authorities before we can commercialize any of our product candidates. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.

We currently have no marketing, sales, or distribution capabilities. If, and when we become reasonably certain that we will be able to commercialize our current or future product candidates, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America and in certain other countries; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of certain of our product candidates, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product candidates in the United States or overseas.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would harm our business. If we rely on pharmaceutical or biotechnology companies with established distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties that may not be successful and that will be only partially in our control.

If physicians and patients do not accept and use our product candidates, once approved, our ability to generate revenue from sales of our products will be materially impaired.

Even if the FDA and/or foreign equivalents thereof approve our product candidates, physicians and patients may not accept and use them. The use of engineered T cells as potential cancer treatments is a relatively recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. Acceptance and use of our products will depend upon a number of factors including:

- The clinical indications for which our product candidates are approved;

- Perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- The prevalence and severity of any side effects;
- Pharmacological benefit and cost-effectiveness of our products relative to competing products;
- Relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- Availability of coverage and adequate reimbursement for our products from government or other third-party payors;
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- The price at which we sell our products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of a product to find market acceptance would harm our business and could require us to seek additional financing in order to fund the development of future product candidates. 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.

Our ability to generate product revenues will be diminished if our products do not obtain coverage and adequate reimbursement from payors.

Our ability to commercialize our product candidates, if approved, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement will be available from third-party payors, including government and health administration authorities, private health maintenance organizations and health insurers and other payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Sufficient coverage and adequate reimbursement from third-party payors are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. It is difficult to predict the coverage and reimbursement decisions that will be made by third-party payors for novel gene and cell therapy products such as ours. Even if we obtain coverage for our product candidates, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In addition, the market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement, which might not include all of the FDA-approved drugs for a particular indication. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that approval will be obtained. If we are unable to obtain coverage of and adequate payment levels for our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer our products and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

In addition, in many foreign countries, particularly the countries of the European Union, or EU, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the

medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments.

Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Our market opportunities may also be limited by competitor treatments that may enter the market.

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

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory enactments in recent years that change the healthcare system in ways that could impact our future ability to sell our product candidates profitably.

Furthermore, there have been and continue to be a number of initiatives at the federal and state level that seek to reduce healthcare costs. Most significantly, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, which included measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- Created an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- Increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- Created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- Created new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;

- Expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- Expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- Created a new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians;
- Expanded healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- Created a licensure framework for follow-on biologic products;
- Created new requirements under the federal Physician Payments Sunshine Act for certain drug manufacturers to annually report information related to payments and other transfers of value made to physicians, as defined by such law, and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;
- Created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- Established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, legal and political challenges to certain aspects of the ACA. For example, President Trump signed several executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued that 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 care coverage through the ACA marketplace, which began on February 21, 2021 and remained open 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 ACA and our business. The ultimate content, timing or effect of any healthcare reform measures on the U.S. healthcare industry is unclear.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. As a result, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. 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, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's 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 U.S. 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 Medicare 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 until January 2023. On November 20, 2020, CMS issued an interim final rule implementing 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 model interim rule. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included 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 price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Individual states in the United States also have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or, if we receive regulatory approval, commercialize our products.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute, which regulates our business activities, including our clinical research and relationships with healthcare providers or other entities as well as our future marketing practices, educational programs and pricing policies, and by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws, including the False Claims Act, which permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal civil and criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- The Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities and individuals subject to the law including certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that perform services for them which involve the use, or disclosure of, individually identifiable health information, known as business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- Requirements under the Physician Payments Sunshine Act to report annually to CMS certain financial arrangements with physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as defined in the ACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching

hospitals, and physicians, as defined by such law and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which 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 applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities; state laws that require the reporting of information related to drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including our consulting agreements with physicians, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has further strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. 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 False Claims Act.

To the extent that any of our product candidates is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations.

Efforts to ensure that our business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in United States federal or state health care programs, such as Medicare and Medicaid, disgorgement, imprisonment, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations any of which could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. 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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our immuno-oncology product candidates may face competition in the future from biosimilars and/or new technologies.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, provides an abbreviated pathway for the approval of follow-on biological products. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period, potentially creating the opportunity for generic competition sooner than anticipated. Further, this data exclusivity does not prevent another company from developing a product that is highly similar to the original branded product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cyber security incidents, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could harm our ability to operate our business effectively and adversely affect our business and reputation.

In the ordinary course of our business, we, our contract research organizations and other third parties on which we rely collect and store sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. In addition, due to the COVID-19 pandemic, we have enabled many of our employees to work remotely, which may make us more vulnerable to cyberattacks. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Although we have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates, we cannot guarantee that those measures will be successful in preventing any such security incident. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct research, development and commercialization activities, process and prepare Company financial information, manage various general and administrative aspects of our business and damage our reputation, in addition to possibly requiring substantial expenditures of resources to remedy, any of which could adversely affect our business. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. If the technology supporting our hunTR discovery engine were to experience a cyber-incident resulting in the disclosure or theft of our proprietary screening software or library of TCRs, our business may be materially and negatively impacted. While we are not aware of any such material system failure, accident or security breach to date, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired.

Our success, competitive position, and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve confidential information, including trade secrets, to prevent third parties from infringing our proprietary rights, and to operate without infringing the proprietary rights of third parties.

To date, we have exclusive rights in the field of cancer treatment to certain U.S. and foreign intellectual property with respect to certain cell therapy and related technologies from MD Anderson and NCI, as well as with respect to the PGEN technology, including *Sleeping Beauty*. Under the MD Anderson License, future patent applications require the agreement of each of MD Anderson, PGEN and us, and MD Anderson has the right to control the preparation, filing, and prosecution of such patent applications unless the parties agree that we or PGEN instead may control such activities. Although under the agreement MD Anderson has agreed to review and incorporate any reasonable comments that we or PGEN may have regarding licensed patents and patent applications, we cannot guarantee that our comments will be solicited or followed. Under the Patent License with the NCI for certain TCRs, the NCI is responsible for the preparation, filing, prosecution, and maintenance of patent applications and patents licensed to us. Although under the Patent License, the NCI is required to consult with us in the preparation, filing, prosecution, and maintenance of all its patent applications and patents licensed to us, we cannot guarantee that our comments will be solicited or followed. Under our License Agreement with PGEN, PGEN has the right, but not the obligation, to prepare, file, prosecute, and maintain the patents and patent applications licensed to us and shall bear all related costs incurred by it in regard to those actions. PGEN is required to consult with us and keep us reasonably informed of the status of the patents and patent applications licensed to us, and to confer with us prior to submitting any related filings and correspondence. Although under the License Agreement PGEN has agreed to consider in good faith

and consult with us regarding any comments we may have regarding these patents and patent applications, we cannot guarantee that our comments will be solicited or followed. Without direct control of the in-licensed patents and patent applications, we are dependent on MD Anderson, the NCI or PGEN, as applicable, to keep us advised of prosecution, particularly in foreign jurisdictions where prosecution information may not be publicly available. We anticipate that we, MD Anderson, the NCI and PGEN will file additional patent applications both in the United States and in other jurisdictions. However, we cannot predict or guarantee for either our in-licensed patent portfolios or for Alaunos' patent portfolio:

- When, if at all, any patents will be granted on such applications;
- The scope of protection that any patents, if obtained, will afford us against competitors;
- That third parties will not find ways to invalidate and/or circumvent our patents, if obtained;
- That others will not obtain patents claiming subject matter related to or relevant to our product candidates; or
- That we will not need to initiate litigation and/or administrative proceedings that may be costly whether we win or lose.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of other jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, methods of therapeutic treatment, which are patent-eligible in the United States, may not be claimed in many other jurisdictions; some patent offices (such as the European Patent Office) may permit the redrafting of method of treatment claims into a "medical use" format that is patent-eligible, while other patent offices (such as the Indian Patent Office) may not accept any redrafted claiming format for such claims.

Changes in patent laws or in interpretations of patent laws in the United States and other jurisdictions may diminish the value of our intellectual property or narrow the scope of our patent protection. In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, resulting in a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In addition, the United States Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. As the USPTO continues to implement the Leahy-Smith Act, and as the federal courts have the opportunity to interpret the Leahy-Smith Act, the laws and regulations governing patents, and the rules regarding patent procurement could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Certain technologies utilized in our research and development programs are already in the public domain. Moreover, a number of our competitors have developed technologies, or filed patent applications or obtained patents on technologies, compositions and methods of use that are relevant to our business and may cover or conflict with our owned or licensed patent applications, technologies or product candidates. Such conflicts could limit the scope of the patents, if any, that we may be able to obtain. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases at all, and because publications of discoveries in the scientific literature lag behind actual discoveries per se, neither we nor our licensors can be certain that others have not filed patent applications for technology used by us or covered by our pending patent applications. We cannot know with certainty whether we were the first to make and file for the inventions claimed in our owned patent portfolio, or whether our licensors were the first to make and file for the inventions claimed in our in-licensed patent portfolio. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. In addition, our own earlier filed patents and applications or those of MD Anderson, NCI or PGEN may limit the scope of later patents we obtain, if any. If third parties file or have

filed patent applications or obtained patents on technologies, compositions and methods of use that are relevant to our business and that cover or conflict with our owned or licensed patent applications, technologies or product candidates, we may be required to challenge such protection, terminate or modify our programs impacted by such protection, or obtain licenses from such third parties, which might not be available on acceptable terms, or at all.

Even if our owned and licensed patent applications were to be issued as patents, they may not issue in a form that would provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity due to our patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or even after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to protect the confidentiality of our confidential information, our business and competitive position would be harmed.

Our success also depends upon the skills, knowledge, and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, and to maintain our competitive position, we rely on trade secret protection and confidentiality agreements. To this end, it is our general policy to require our employees, consultants, advisors, and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries, and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how, confidential information or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. Moreover, we may not be able to obtain adequate remedies for any breaches of these agreements. Our trade secrets or other confidential information may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or other confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets or other confidential information were to be lawfully obtained or independently developed by competitors, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Third-party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.

In order to protect or enforce patent rights, we may initiate patent infringement litigation against third parties. Similarly, we may be sued by others for patent infringement. We also may become subject to pre- and post-grant proceedings conducted in the USPTO, including interferences, derivations, post-grant review, *inter partes* review, or reexamination. In other jurisdictions, our patent estate may be subject to pre- and post-grant opposition, nullity, revocation proceedings, and the like. Asserting and defending against intellectual property actions are costly and divert technical and management personnel away from their normal responsibilities.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our products or use of our products do not infringe or will not be asserted to infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications, or that as-yet unpublished third-party patent applications will later result in the grant of patents relevant to our business. Another possibility is for a third-party patent or patent application to first contain claims not relevant to our business but then to be reissued or amended in such a way that it does become relevant.

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be asserted to infringe patents or patent applications under which we do not hold licenses or other rights. Owning a patent does not confer on the patentee the right to practice the claimed invention and does not protect the patentee from being sued for infringement of another owner's patent. Our patent position cannot and does not provide any assurance that we are not infringing or will not be asserted to infringe the patent rights of another.

The patent landscape in the field of immuno-oncology is particularly complex. We are aware of numerous United States and foreign patents and pending patent applications of third parties directed to compositions, methods of use and methods of manufacture of immuno-oncology products. In addition, there may be patents and patent applications in the field of which we are not aware. The technology we license from MD Anderson, NCI and PGEN is early-stage technology, and we are in the process of designing and developing products using this technology. Although we will seek to avoid pursuing the development of products that may infringe any third-party patent claims that we believe to be valid and enforceable, we may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of immuno-oncology and the complexities and uncertainties associated with them, third parties may allege that we are infringing patent claims even if we do not believe such claims have merit.

If a claim for patent infringement is asserted, there can be no assurance that the resolution of the claim would permit us to continue marketing the relevant product on commercially reasonable terms, if at all. We may not have sufficient resources to bring these actions to a successful conclusion. If we do not successfully defend any infringement actions to which we become a party or if we are unable to have any asserted third-party patents declared invalid or unenforceable, we may have to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, and/or we may be required to discontinue or significantly delay commercialization and development of the affected products.

Any legal action against us or our collaborators claiming damages and seeking to enjoin developmental or marketing activities relating to affected products could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain licenses to continue to develop, manufacture, or market the affected products. Such licenses may not be available to us on commercially reasonable terms, or at all.

An adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry in the market of substitutes, including biosimilar or generic substitutes, for our products.

Obtaining and maintaining our 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 noncompliance with these requirements.

Annuities and other similar fees must be paid to the respective patent authority to maintain patents (or patents and patent applications) in most jurisdictions worldwide. Further, patent authorities in jurisdictions worldwide require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to submit documents with the necessary formal requirements such as notarization and legalization. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have in-licensed patents and patent applications under our MD Anderson License, our license agreement with the NCI, and our license agreement with PGEN. Under these agreements, we are subject to a range of obligations pertaining to commercialization and development, sublicensing, royalty, patent prosecution and maintenance, and insurance.

Any failure by us to obtain a needed license, comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. On termination we may be required to license to the licensor any related intellectual property that we developed.

In addition, in certain cases, the rights licensed to us are rights of a third party licensed to our licensor. In such instances, if our licensors do not comply with their obligations under such licenses, our rights under our license agreements with our licensor may be adversely affected.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

OTHER RISKS RELATED TO OUR COMPANY

Our stock price has been, and may continue to be, volatile.

The market price for our common stock is volatile and may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- Price and volume fluctuations in the overall stock market;
- Changes in operating results and performance and stock market valuations of other biopharmaceutical companies generally, or those that develop and commercialize cancer drugs in particular;
- Market conditions or trends in our industry or the economy as a whole;
- Preclinical studies or clinical trial results;
- the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- Public concern as to the safety of drugs developed by us or others;
- The financial or operational projections we may provide to the public, any changes in these projections or our failure to meet these projections;

- Comments by securities analysts or changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- The public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, as well as announcements of the status of development of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements and other announcements relating to product development, litigation and intellectual property impacting us or our business;
- Government regulation;
- FDA determinations on the approval of a product candidate BLA submission;
- The sustainability of an active trading market for our common stock;
- Future sales of our common stock by us, our executive officers, directors and significant stockholders;
- Announcements of mergers or acquisition transactions;
- Our inclusion or deletion from certain stock indices;
- Developments in patent or other proprietary rights;
- Changes in reimbursement policies;
- Announcements of medical innovations or new products by our competitors;
- Announcements of changes in our senior management or directors;
- General economic, industry, political and market conditions, including, but not limited to, the ongoing impact of the COVID-19 pandemic;
- Other events or factors, including those resulting from war, incidents of terrorism, natural disasters, pandemics or responses to these events; and
- Changes in accounting principles.

In addition, the stock market in general and our stock in particular from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Public debt and equity markets, and in particular the Nasdaq Global Select Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies.

Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources, and the attention of management could be diverted from our business.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of 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, even if doing so would benefit our stockholders. These provisions authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of stockholders. In addition, Section 203 of the Delaware General Corporation Law, or Section 203, generally prohibits a publicly held Delaware corporation from engaging in a business combination with a party that owns at least 15% of its common stock unless the business combination is approved by our board of directors before the person acquires the 15% ownership stake or later by its board of directors and two-thirds of its stockholders. Section 203 could

have the effect of delaying, deferring or preventing a change in control that our stockholders might consider to be in their best interests.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the amended and restated certificate of incorporation or our bylaws; (v) any claim or cause of action as to which the General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at a profit.

We have never paid dividends on our common stock, and we do not anticipate that we will pay any dividends for the foreseeable future. Accordingly, any return on an investment in us will be realized, if at all, only when you sell shares of our common stock.

Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards, or NOLs, and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, respectively. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the U.S. Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 of the Code imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carry forwards and Section 383 of the Code imposes an annual limitation on the amount of tax a corporation may offset with business credit (including R&D credits) carryforwards.

We may have experienced an "ownership change" within the meaning of Section 382 of the Code in the past and there can be no assurance that we will not experience additional ownership changes in the future. As a result, our NOLs and business credits (including R&D credits) may be subject to limitations, and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs or R&D credits were freely usable.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Our business could be negatively affected as a result of the actions of activist stockholders.

In 2021, we were engaged in a consent solicitation led by WaterMill Asset Management Corp., or WaterMill, where three new directors were added to our board of directors. We could experience other stockholder activism in the future, including another consent solicitation or a proxy contest. Activist shareholders may advocate for certain governance and strategic changes at our company. In the event of stockholder activism, particularly with respect to matters which our board of directors, in exercising their fiduciary duties, disagree with or have determined not to pursue, our business could be adversely affected because responding to actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management, and perceived uncertainties as to our future direction may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel, business partners, and customers.

In addition, if faced with a consent solicitation or proxy contest, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. If individuals are elected to our board of directors with a differing agenda, our ability to effectively and timely implement our strategic plan and create additional value for our stockholders may be adversely affected.

****The exercise of outstanding warrants, and issuance of equity awards may have a dilutive effect on our stock, and negatively impact the price of our common stock.***

As of June 30, 2022, we had warrants for 22,922,342 shares of our common stock outstanding at a weighted average exercise price of $5.62 per share. We are able to grant stock options, restricted stock, restricted stock units, stock appreciation rights, bonus stocks, and performance awards under the 2020 Equity Incentive Plan. Under the 2020 Equity Incentive Plan and our 2012 Equity Incentive Plan, 10,086,635 shares were issuable upon the exercise of outstanding options at a weighted average exercise price of $1.97 per share.

****Our principal stockholders, executive officers and directors have substantial control over the Company, which may prevent you and other stockholders from influencing significant corporate decisions and may harm the market price of our common stock.***

As of June 30, 2022, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 44.1% of our outstanding common stock. These stockholders may have interests that conflict with our other stockholders and, if acting together, have the ability to influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- Delaying, deferring or preventing a change in control;
- Impeding a merger, consolidation, takeover or other business combination involving us; or
- Discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, this significant concentration of stock ownership may adversely affect the trading price of our common stock should investors perceive disadvantages in owning shares of common stock in a company that has such concentrated ownership.

Changes to corporate tax legislation, including the Tax Cuts and Jobs Act, signed into law in 2017, could adversely affect our business and financial condition.

The Tax Act contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time

taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, enacted in 2020, modified certain of these tax changes, and enacted other tax changes applicable to corporations. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act and the CARES Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. Currently, bills introduced in Congress, including the Build Back Better Act, contain additional changes to the taxation of corporations, which could adversely affect our business and financial condition. The impact of the Tax Act, the CARES Act and any other tax legislation on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million if our annual revenues are $100 million or more, or until our public float exceeds $700 million if our annual revenues are less than $100 million.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information
Amendments to the Registrant's Code of Ethics, or Waiver of a Provision of the Code of Ethics

Effective August 12, 2022, the Board adopted a revised Code of Ethics and Conduct (the "Revised Code"). The Revised Code applies to all employees, officers and directors of the Company. The Revised Code was adopted to reflect what the Company considers to be current best practices and policies for an operating company and to make certain technical, administrative and non-substantive amendments to the prior Code of Ethics and Conduct. The adoption of the Revised Code did not relate to or result in any waiver, explicit or implicit, of any provision of the prior Code of Ethics and Conduct.

The above description of the Revised Code does not purport to be complete and is qualified in its entirety by reference to the full text of the Revised Code, a copy of which is filed as Exhibit 14.1 hereto and incorporated herein by reference. The Revised Code is also available on the Company's investor relations website (ir.alaunos.com). The contents of the Company's website are not incorporated by reference in this Quarterly Report on Form 10-Q or made a part hereof for any purpose.

Item 6. Exhibits

Exhibit Number	Description
3.1+	Amended and Restated Certificate of Incorporation of the Registrant, and all amendments thereto.
3.2	Amended and Restated Bylaws of the Registrant, dated as of September 21, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed September 22, 2020).
10.1+	Fourth Amendment to the Cooperative Research and Development Agreement, dated June 24, 2022, by and between the National Cancer Institute and the Registrant.
10.2+	Equity Distribution Agreement, dated August 12, 2022, by and between Piper Sandler & Co. and the Registrant.
14.1+	Code of Ethics and Conduct, as amended August 12, 2022.
31.1+	Certification of Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a) or 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certifications of Principal Executive Officer and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH+	Inline XBRL Taxonomy Extension Schema Document
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104+	Cover Page Interactive Data File—the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments

\+ Filed herewith.

++ This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

ALAUNOS THERAPEUTICS, INC.

By:

/s/ Kevin S. Boyle, Sr.
Kevin S. Boyle, Sr.
Chief Executive Officer
(On Behalf of the Registrant and as Principal Executive Officer and Principal Financial Officer)
Dated: August 15, 2022

By:

/s/ Michael Wong
Michael Wong
Vice President, Finance
(Principal Accounting Officer)
Dated: August 15, 2022

Exhibit 3.1

CERTIFICATE OF AMENDMENT OF THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF ALAUNOS THERAPEUTICS, INC.

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Alaunos Therapeutics, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law proposing this Amendment of the Amended and Restated Certificate of Incorporation and declaring the advisability of this Amendment of the Amended and Restated Certificate of Incorporation, and authorizing the appropriate officers of the Corporation to solicit the approval of the stockholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED: that the first paragraph of section four of the Amended and Restated Certificate of Incorporation of the Corporation, as amended, be and it hereby is, deleted in its entirety and the following paragraph is inserted in lieu thereof:

"4. Number of Shares. The total number of shares of all classes of stock that the Corporation shall have authority to issue is Four Hundred Fifty Million (450,000,000) shares consisting of: Four Hundred Twenty Million (420,000,000) shares of common stock, $0.001 par value per share ("Common Stock"); and Thirty Million (30,000,000) shares of preferred stock, $0.001 par value per share ("Preferred Stock")."

2. This Certificate of Amendment of the Amended and Restated Certificate of Incorporation has been duly adopted by the stockholders of the Corporation in accordance with the provisions of Section 242 of the General Corporation Law.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Amended and Restated Certificate of Incorporation to be signed by its Chief Executive Officer this 16th day of June, 2022.

/s/ Kevin S. Boyle, Sr.

Name: Kevin S. Boyle, Sr.
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
ZIOPHARM ONCOLOGY, INC.

ZIOPHARM Oncology, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. The name of the Corporation is ZIOPHARM Oncology, Inc., formerly known as EasyWeb, Inc. The date of filing of its original Certificate of Incorporation with the Secretary of State was May 16, 2005.

2. This Certificate of Amendment amends the provisions of the Corporation's Amended and Restated Certificate of Incorporation filed with the Secretary of State on April 26, 2006, as amended (the "Certificate of Incorporation").

3. Article 1 of the Certificate of Incorporation is hereby amended and restated to read as follows:

"1. *Name.* The name of the corporation is Alaunos Therapeutics, Inc. (the "Corporation")."

4. This Certificate of Amendment has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law.

5. All other provisions of the Certificate of Incorporation shall remain in full force and effect.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 25th day of January, 2022.

/s/ Kevin S. Boyle, Sr.

Name: Kevin S. Boyle, Sr.
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT OF THE RESTATED
CERTIFICATE OF INCORPORATION OF ZIOPHARM ONCOLOGY, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Ziopharm Oncology, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law proposing this Amendment of the Restated Certificate of Incorporation and declaring the advisability of this Amendment of the Restated Certificate of Incorporation, and authorizing the appropriate officers of the Corporation to solicit the consent of the shareholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that the first paragraph of section four of the Restated Certificate of Incorporation of the Corporation, as amended, be and it hereby is, deleted in its entirety and the following paragraph is inserted in lieu thereof:

"4. *Number of Shares.* The total number of shares of all classes of stock that the Corporation shall have authority to issue is Three Hundred Eighty Million (380,000,000) shares consisting of: Three Hundred Fifty Million (350,000,000) shares of common stock, $.001 par value per share ("Common Stock"); and Thirty Million (30,000,000) shares of preferred stock, $.001 par value per share ("Preferred Stock").

shareholders of the Corporation in accordance with the provisions of Section 242 of the General Corporation Law.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Restated Certificate of Incorporation to be signed by its Chief Executive Officer this 19th day of May, 2021.

/s/ Heidi Hagen
Heidi Hagen
Interim Chief Executive Officer

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
of
ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc., a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

1. The name of the corporation is ZIOPHARM Oncology, Inc., formerly known as EasyWeb, Inc. The date of filing of its original Certificate of Incorporation with the Secretary of State was May 16, 2005.

2. That the Board of Directors of the corporation adopted resolutions, in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, setting forth a proposed Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate"), declaring the Amended and Restated Certificate to be advisable. The resolution setting forth the proposed Amended and Restated Certificate is as follows:

> "RESOLVED, that, subject to the approval of the holders of a majority of the outstanding shares of the Corporation's common stock, par value $.001 per share (the "Common Stock"), the Corporation's Amended Certificate of Incorporation shall be amended and restated in the manner set forth on the attached Exhibit A."

[Please see Exhibit A attached hereto.]

3. This Amended and Restated Certificate was duly adopted by vote of the stockholders of the Corporation in accordance with the provisions of Sections 222, 242 and 245 of the General Corporation Law of the State of Delaware.

4. That the Amended and Restated Certificate was duly adopted in accordance with the applicable provisions of Sections 222, 242 and 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this document to be executed in its corporate name as of this 26th day of April, 2006.

ZIOPHARM Oncology, Inc.

By: /s/ Jonathan Lewis
Jonathan Lewis, *Chief Executive Officer*

EXHIBIT A

1. *Name.* The name of the corporation is ZIOPHARM Oncology, Inc. (the "Corporation").

2. *Address; Registered Office and Agent.* The address of the Corporation's registered office is 2711 Centerville Road Suite 400, Wilmington, Delaware 19808. The Corporation may from time to time, in the manner provided by law, change the registered agent and the registered office within the State of Delaware. The Corporation may also maintain offices for the conduct of its business, either within or without the State of Delaware.

3. *Purposes.* The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law.

4. *Number of Shares.* The total number of shares of all classes of stock that the Corporation shall have authority to issue is Two Hundred Eighty Million (280,000,000) shares consisting of: Two Hundred Fifty Million (250,000,000) shares of common stock, $.001 par value per share ("Common Stock"); and Thirty Million (30,000,000) shares of preferred stock, $.001 par value per share ("Preferred Stock").

The Preferred Stock may be divided into, and may be issued from time to time in one or more series. The Board of Directors of the Corporation (the "Board") is authorized from time to time to establish and designate any such series of Preferred Stock, to fix and determine the variations in the relative rights, preferences, privileges and restrictions as between and among such series and any other class of capital stock of the Corporation and any series thereof, and to fix or alter the number of shares comprising any such series and the designation thereof. The authority of the Board from time to time with respect to each such series shall include, but not be limited to, determination of the following:

a. The designation of the series;

b. The number of shares of the series and (except where otherwise provided in the creation of the series) any subsequent increase or decrease therein;

c. The dividends, if any, for shares of the series and the rates, conditions, times and relative preferences thereof;

d. The redemption rights, if any, and price or prices for shares of the series;

e. The terms and amounts of any sinking fund provided for the purchase or redemption of the series;

f. The relative rights of shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation;

g. Whether the shares of the series shall be convertible into shares of any other class or series of shares of the Corporation, and, if so, the specification of such other class or series, the conversion prices or rate or rates, any adjustments thereof, the date or dates as of which such shares shall be convertible and all other terms and conditions upon which such conversion may be made;

h. The voting rights, if any, of the holders of such series; and

i. Such other designations, powers, preference and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof.

5. *Election of Directors.* Unless and except to the extent that the by-laws of the Corporation (the "By-laws") shall so require, the election of directors of the Corporation need not be by written ballot.

6. *Limitation of Liability.* To the fullest extent permitted under the General Corporation Law, as amended from time to time, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Any amendment, repeal or modification of the foregoing provision shall not adversely affect any right or protection of a director of the Corporation hereunder in respect of any act or omission occurring prior to the time of such amendment, repeal or modification.

7. *Indemnification.*

7.1. *Right to Indemnification.* The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "Covered Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity (an "Other Entity"), including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence, except as otherwise provided in Section 7.3, the Corporation shall be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person only if the commencement of such Proceeding (or part thereof) by the Covered Person was authorized by the Board.

7.2. *Prepayment of Expenses.* The Corporation shall pay the expenses (including attorneys' fees) incurred by a Covered Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by applicable law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Covered Person to repay all amounts advanced if it should be ultimately determined that the Covered Person is not entitled to be indemnified under this Article 7 or otherwise.

7.3. *Claims.* If a claim for indemnification or advancement of expenses under this Article 7 is not paid in full within 30 days after a written claim therefor by the Covered Person has been received by the Corporation, the Covered Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Covered Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

7.4. *Nonexclusivity of Rights.* The rights conferred on any Covered Person by this Article 7 shall not be exclusive of any other rights that such Covered Person may have or hereafter acquire under any statute, provision of this Certificate of Incorporation, the By-laws, agreement, vote of stockholders or disinterested directors or otherwise.

7.5. *Other Sources.* The Corporation's obligation, if any, to indemnify or to advance expenses to any Covered Person who was or is serving at its request as a director, officer, employee or agent of an Other Entity shall be reduced by any amount such Covered Person may collect as indemnification or advancement of expenses from such Other Entity.

7.6. *Amendment or Repeal.* Any repeal or modification of the foregoing provisions of this Article 7 shall not adversely affect any right or protection hereunder of any Covered Person in respect of any act or omission occurring prior to the time of such repeal or modification.

7.7. *Other Indemnification and Prepayment of Expenses.* This Article 7 shall not limit the right of the Corporation, to the extent and in the manner permitted by applicable law, to indemnify and to advance expenses to persons other than Covered Persons when and as authorized by appropriate corporate action.

8. *Adoption, Amendment and/or Repeal of By-Laws.* In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board is expressly authorized to make, alter and repeal the

By-laws, subject to the power of the stockholders of the Corporation to alter or repeal any By-law whether adopted by them or otherwise.

9. *Certificate Amendments.* The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by applicable law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Amended and Restated Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this article.

ZIOPHARM ONCOLOGY, INC.

**AMENDED AND RESTATED CERTIFICATE OF DESIGNATION,
PREFERENCES AND RIGHTS**

OF THE SERIES 1 PREFERRED STOCK

I, Caesar J. Belbel, Chief Operating Officer, Executive Vice President and Chief Legal Officer of ZIOPHARM Oncology, Inc. (the "***Corporation***"), organized and existing under the General Corporation Law of the State of Delaware, hereby certify that the following recitals and resolution were adopted by the Board of Directors of the Corporation as required by Section 151 of the General Corporation Law by unanimous written consent on July 1, 2016:

"**WHEREAS**, pursuant to the Certificate of Incorporation (which authorizes 30,000,000 shares of preferred stock, $.001 par value per share ("***Preferred Stock***")), the Board of Directors fixed the voting powers, preferences and relative, participating, optional and other special rights of the Corporation's Series 1 Preferred Stock; and

WHEREAS, no shares of Series 1 Preferred Stock have been issued.

RESOLVED, that, pursuant to the authority vested in the Board of Directors of this Corporation and in accordance with the provisions of the Certificate of Incorporation of this Corporation, the Certificate of Designations, Preferences and Rights of the Series 1 Preferred Stock filed with the office of the Secretary of State of Delaware on June 29, 2016, creating a class of authorized Preferred Stock of this Corporation designated as Series 1 Preferred Stock is hereby amended and restated in its entirety and that the designation and number of shares thereof and the relative rights, powers and preferences, and qualifications, limitations and restrictions thereof, as amended and restated, are as follows:

A) 250,000 of the authorized shares of the Corporation's preferred stock, par value $0.001 per share (the "***Preferred Stock***") are hereby designated "Series 1 Preferred Stock" (the "***Series 1 Preferred***"). Each share of Series 1 Preferred shall have a stated value equal to $1,200 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other recapitalization with respect to the Series 1 Preferred) (the "***Stated Value***").

B) The rights, preferences, privileges, restrictions and other matters relating to the Series 1 Preferred are as follows:

1) Dividend Rights.

a) From and after the date of the issuance of any shares of Series 1 Preferred, dividends at the rate per month of the Series 1 Dividend Rate (as defined below) shall accrue on such shares of Series 1 Preferred (the "***Series 1 PIK Dividends***"). The Series 1 PIK Dividends shall accrue on each share of Series 1 Preferred from day to day and shall be paid monthly in the form of a number of additional shares of Series 1 Preferred equal to the cash value of the Series 1 PIK Dividend on such share that accrued during the preceding month, divided by the Stated Value of such share of Series 1 Preferred, within 10 days following the end of the preceding calendar month; provided, however, that the Series 1 PIK Dividend on any shares of Series 1 Preferred issued on or about July 1, 2016 shall commence accruing on June 30, 2016 (but for the purposes of clarity, shall be due and paid on July 31, 2016). The payment of the Series 1 PIK Dividend each calendar month shall be mandatory for so long as the Corporation has funds legally available therefor. The "Series 1 Dividend Rate" for each share of Series 1 Preferred shall equal: (i) in the event that such share is not Unconverted Series 1 Preferred (as defined below), (A) $12.00 per month (subject to appropriate adjustment in the event of any stock dividend, stock split, combination, adjustment in the Stated Value or other recapitalization with respect to the Series 1 Preferred) or (ii) in the event that such share is Unconverted Series 1 Preferred, (A)

$24.00 per month (subject to appropriate adjustment in the event of any stock dividend, stock split, combination, adjustment in the Stated Value or other recapitalization with respect to the Series 1 Preferred). For the avoidance of doubt, Series 1 PIK Dividends shall be paid only in the form of shares of Series 1 Preferred and not in the form of cash. No fractional shares of Series 1 Preferred shall be issued as a Series 1 PIK Dividend. Whether or not fractional shares would be issuable as Series 1 PIK Dividends shall be determined on the basis of the total number of shares of Series 1 Preferred to be issued as a Series 1 PIK Dividend to any single holder of Series 1 Preferred based on the total shares of Series 1 Preferred held by such holder immediately prior to the payment of such Series 1 PIK Dividend. Any fractional shares not paid pursuant to this Section 1(a) shall be forfeited.

2) Voting Rights. The holders of Series 1 Preferred have no voting power whatsoever, other than as set forth in Section 2(a) below.

a) At any time when shares of Series 1 Preferred are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of at least a majority of the then outstanding shares of Series 1 Preferred (the "**Requisite Holders**"), given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of the Certificate of Incorporation in a manner that adversely affects the powers, preferences or rights of the Series 1 Preferred in a manner that is more adverse than the effect on any other class or series of the Corporation's capital stock;

(ii) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior or pari passu to the Series 1 Preferred with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or (B) reclassify, alter or amend any existing security of the Corporation that is junior or pari passu to the Series 1 Preferred with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series 1 Preferred in respect of any such right, preference or privilege; or

(iii) enter into any transaction (or series of related transactions) the effect of which would adversely affect the holders of the Series 1 Preferred in a manner that is more adverse than the effect on any other class or series of the Corporation's capital stock; *provided; however*, that any issuances of the Corporation's capital stock in connection with any transaction (or series of related transactions) would not require approval of the Requisite Holders, unless the special rights, preferences, privileges and obligations of the Series 1 Preferred are adversely affected.

3) Conversion Of Series 1 Preferred Shares Into Common Stock.

a) Subject to Section 3(f) and 3(g), upon the close of business on the second (2nd) business day following the Conversion Event Date (as defined below) (the "***Mandatory Conversion Time***"), each outstanding share of Series 1 Preferred shall automatically be converted into shares of Common Stock, without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Stated Value of such share of Series 1 Preferred by the Series 1 Conversion Price (as defined below). The "***Series 1 Conversion Price***" shall be equal to the greater of: (x) the volume weighted average closing price of the Corporation's Common Stock as reported by the Nasdaq Stock Market, LLC over the 20 trading days ending on the Conversion Event Date or (y) $1.00 per share. The "***Conversion Event Date***" shall be the date that the first approval in the United States of (i) a ZIOPHARM Product, as defined in and

developed under the Exclusive Channel Partner Agreement dated as of January 6, 2011 and as amended from time to time, by and between the Corporation and Intrexon Corporation, or (ii) a Product, as defined in and developed under the Exclusive Channel Collaboration Agreement dated September 28, 2015 and as amended from time to time, by and between the Corporation and Intrexon Corporation, or (iii) a Product, as defined in and developed under the License and Collaboration Agreement dated March 27, 2015 and as amended from time to time, by and among Intrexon Corporation, ARES TRADING Trading, S.A. and the Corporation, is publicly announced.

b) No fractional shares of Common Stock shall be issued upon conversion of the Series 1 Preferred. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Series 1 Preferred the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

c) All holders of record of shares of Series 1 Preferred shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Series 1 Preferred pursuant to this Section 3. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Series 1 Preferred in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Series 1 Preferred converted pursuant to Section 3(a), including the rights, if any, to receive the Series 1 PIK Dividends, notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Section 3(c) (though for the avoidance of doubt this sentence shall not apply to Unconverted Series 1 Preferred unless and until such Unconverted Series 1 Preferred is converted). As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Series 1 Preferred, the Corporation shall (i) deliver, or cause to be delivered, to the converting holder a certificate or book-entry statement representing the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (ii) pay cash as provided in Section 3(b) in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion. Such converted Series 1 Preferred shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series 1 Preferred accordingly.

d) The Corporation shall at all times when the Series 1 Preferred shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Series 1 Preferred, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Series 1 Preferred; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Series 1 Preferred, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation,

engaging in commercially reasonable efforts to obtain the requisite stockholder approval of any necessary amendment to the Certificate of Incorporation.

e) The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Series 1 Preferred pursuant to this Section 3. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Series 1 Preferred so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

f) The Corporation shall not effect any conversion of the Series 1 Preferred into Common Stock to the extent that the number of shares of Common Stock issued in such conversion would represent a number of shares in excess of the Conversion Limitation (as defined below), unless prior to such conversion, stockholder approval for such issuances have been obtained in accordance with and to the extent required by the NASDAQ Stock Market Listing Rules (such approval, the "***Conversion Approval***"). In the event that the limitation provided in the preceding sentence applies, then on the Mandatory Conversion Date, the Corporation shall convert the maximum number of shares of Series 1 Preferred into Common Stock as is possible without exceeding the Conversion Limitation. Any shares of Series 1 Preferred that are not converted on the Mandatory Conversion Date (such shares of Series 1 Preferred remaining outstanding after the Mandatory Conversion Time are referred to as "***Unconverted Series 1 Preferred***") shall remain outstanding until the Conversion Approval is obtained, at which point all Unconverted Series 1 Preferred shall be converted into Common Stock at the Series 1 Conversion Price as provided in this Section 3. The "***Conversion Limitation***" shall be 19.9% of the lesser of (i) the number of outstanding shares of the Corporation's Common Stock immediately prior to the closing of the transactions contemplated by that certain Share Issuance Agreement by and between the Corporation and Intrexon corporation dated on or about the date hereof or (ii) the number of outstanding shares of Corporation's Common Stock at the time of conversion. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 3(f) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Conversion Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation.

g) Notwithstanding any provision to the contrary in this Section 3, without stockholder approval in accordance with the NASDAQ Stock Market Listing Rules, the Corporation shall not effect any conversion of the Series 1 Preferred into Common Stock to the extent that the number of shares of Common Stock issued in such conversion should constitute a change of control under the NASDAQ Stock Market Listing Rules, taking into account for these purposes, the NASDAQ Stock Market's policy of calculating of beneficial ownership in accordance with Section 13 of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Any shares of Series 1 Preferred that are not converted into Common Stock on or after the Mandatory Conversion Date as a result of the limitation in this Section 3(g) shall be Unconverted Series 1 Preferred, and shall remain outstanding until such time as stockholder approval in accordance with the NASDAQ Stock Market Listing Rules is obtained such that such shares of Series 1 Preferred may be converted into Common Stock in accordance with the NASDAQ Stock Market Listing Rules, at which point such shares of Series 1 Preferred shall be converted into Common Stock at the Series 1 Conversion Price as provided in this Section 3. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 3(g) to correct this paragraph (or any portion hereof) to the extent necessary to ensure compliance with the NASDAQ Stock Market Listing Rules.

4) Liquidation.

a) Each of the following events shall be considered a "***Deemed Liquidation Event***":

(i) a merger or consolidation in which (A) the Corporation is a constituent party or (B) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting entity; or (2) if the surviving or resulting entity is a wholly owned subsidiary of another entity immediately following such merger or consolidation, the parent entity of such surviving or resulting entity; or

(ii) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation; or

(iii) the closing of the transfer of this Corporation's capital stock (whether by merger, consolidation or otherwise), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter of this Corporation's securities), if, after such closing, such person or group of affiliated persons would hold at least a majority, by voting power, of the capital stock of (1) the surviving or resulting entity; or (2) if the surviving or resulting entity is a wholly owned subsidiary of another entity immediately following such merger or consolidation, the parent entity of such surviving or resulting entity.

b) In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of the shares of Series 1 Preferred and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all shares of Series 1 Preferred as if they had been converted into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Stated Value of such share of Series 1 Preferred by the Series 1 Liquidation Assumed Conversion Price (as defined below), rounded down to the nearest whole share. The amount per share payable to the Series 1 Preferred pursuant to the preceding sentence is referred to as the "***Series 1 Liquidation Amount***." The "***Series 1 Liquidation Assumed Conversion Price***" shall be equal to either (i) if such shares of Series 1 Preferred are <u>not</u> Unconverted Series 1 Preferred, the volume weighted average closing price of the Corporation's Common Stock as reported by the Nasdaq Stock Market, LLC over the 20 trading days ending on the public announcement of such voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event or (ii) if such shares of Series 1 Preferred are Unconverted Series 1 Preferred, the Series 1 Conversion Price.

c) In connection with or following a Deemed Liquidation Event, the Corporation may, in lieu of distributing the proceeds of such Deemed Liquidation Event pro rata among the holders of Series 1 Preferred and Common Stock as contemplated by Section 4(b), elect to redeem all, but not less than all of the Series 1 Preferred then outstanding at a price per share of Series 1 Preferred equal to the Series 1 Liquidation Amount. A redemption of the Series 1 Preferred pursuant to this Section 4(c) shall occur upon the closing of such Deemed Liquidation Event or on such other date determined by the Corporation during the period commencing on the date of the closing of such Deemed Liquidation

Event and ending on the 20th day following such Deemed Liquidation Event (such date, the "***Redemption Date***") and shall be effected in accordance with Subsections 4(c)(i) through 4(c)(iii):

(i) The Corporation shall send written notice of the redemption (the "***Redemption Notice***") to each holder of record of Series 1 Preferred not less than 5 days prior to the Redemption Date. Each Redemption Notice shall state: (A) the number of shares of Series 1 Preferred held by such holder that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice; (B) the Redemption Date and the Series 1 Liquidation Amount payable for such holder's shares of Series 1 Preferred; and (C) that the holder is to surrender to the Corporation, in the manner and at the place designated in the Redemption Notice, his, her or its certificate or certificates, if any, representing the shares of Series 1 Preferred to be redeemed.

(ii) On or before the Redemption Date, each holder of shares of Series 1 Preferred to be redeemed on the Redemption Date shall surrender the certificate or certificates, if any, representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the Series 1 Liquidation Amount, for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof.

(iii) If the Redemption Notice shall have been duly given, and if on the Redemption Date the Series 1 Liquidation Amount, payable upon redemption of the shares of Series 1 Preferred to be redeemed on the Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that the certificates, if any, evidencing any of the shares of Series 1 Preferred so called for redemption shall not have been surrendered, all rights with respect to such shares of Series 1 Preferred shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Series 1 Liquidation Amount, without interest, upon surrender of their certificate or certificates therefor.

5) **Redeemed Or Otherwise Acquired Shares**. Any shares of Series 1 Preferred that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Series 1 Preferred following redemption.

6) **Waiver**. Any of the rights, powers, preferences and other terms of the Series 1 Preferred set forth herein may be waived on behalf of all holders of Series 1 Preferred by the affirmative written consent or vote of the Requisite Holders.

7) **Next Business Day**. Whenever any payment or other obligation hereunder shall be due on a day other than a business day, such payment shall be made on the next succeeding business day.

IN WITNESS WHEREOF, ZIOPHARM Oncology, Inc. has caused this Amended and Restated Certificate of Designation, Preferences and Rights of the Terms of the Series 1 Preferred Stock to be executed by its Chief Operating Officer, Executive Vice President and Chief Legal Officer this 1st day of July, 2016.

/ s/ Caesar J. Belbel

Caesar J. Belbel
Chief Operating Officer, Executive Vice President and Chief Legal Officer

ZIOPHARM ONCOLOGY, INC.
SIGNATURE PAGE TO CERTIFICATE OF DESIGNATION

Exhibit 10.1

Amendment #4

Cooperative Research and Development Agreement # 03111

"Development and Evaluation of Alaunos Therapeutics, Inc.'s Proprietary Non-viral *Sleeping Beauty* Vectors for Genetic Modification of Peripheral Blood Lymphocytes with Genes Encoding Mutated Tumor Neoantigen-specific T Cell Receptors (also referred to as Mutation Reactive T Cell Receptors) that Have Been Identified Using NCI Proprietary Methods"

IC Principal Investigator: Steven A. Rosenberg, M.D., Ph.D.

Collaborator: Alaunos Therapeutics, Inc. ("Alaunos")

The purpose of this amendment is to change certain terms of the above-referenced Cooperative Research and Development Agreement (CRADA). These changes are reflected below, and except for these changes, all other provisions of the original CRADA and Amendments #1, 2 and 3 remain in full force and effect. Upon execution, IC and Alaunos will each retain a copy of this amendment.

The Parties agree:

1. Upon final signature, the term of the CRADA will be extended from January 9, 2023 to January 9, 2025.

2. Appendix B to the CRADA is deleted in its entirety and replaced with the revised Appendix B attached to this Amendment.

3. Appendix A of the CRADA: Research Plan is deleted in its entirety and replaced with the revised Appendix A attached to this amendment. The Research Plan is modified to address the following: The Neo-Antigen (NeoAg) TCR studies will be conducted at NCI, contingent upon finding a GMP manufacturing source for plasmid. Studies using TCRs against KRAS and P-53 TCR will be conducted solely by Alaunos outside the scope of this CRADA. Alaunos will hold the IND for the KRAS/P-53 studies, and NCI will hold the IND for the NeoAg studies to be conducted at NCI.

   Additional changes are made to update the Research Plan and are reflected in Appendix A as follows: Appendix A: Section listing "Related Intellectual Property of the Parties" is amended to include additional patent applications from NCI. Also, Appendix A is amended to reflect the license executed by Alaunos to NCI inventions.

4. The paragraph in Article 2 of the CRADA that contains the definition of "Adverse Event" is deleted in its entirety and replaced with the following:

"**Adverse Event**" or "**AE**" means any untoward medical occurrence associated with the use of a Test Article in humans, whether or not considered related to the Test Article (21 C.F.R §§ 312.32, 308.3; see also E6(R2): Good Clinical Practice: Integrated Addendum to International Council for Harmonisation (ICH) E6(R1) Guidance for Industry, 83 Federal Register 8882 (2018).

5. Article 3.10 of the CRADA is deleted in its entirety and replaced with the following:

3.10 **Monitoring**. Subject to the restrictions in Article 8.1 (the Rights of Access and Publications section) and Article 8.9 (the Certificate of Confidentiality Obligations section), and with reasonable advance notice and at reasonable times, ICD will permit Collaborator or its designee(s) to audit the clinical monitoring performed by the ICD, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with the Protocol(s) and E6(R2) Good Clinical Practice: Integrated Addendum to International Council for Harmonisation (ICH) E6(R1) Guidance for Industry, 83 Federal Register 8882 (2018).

6. Article 3.11 of the CRADA is deleted in its entirety and replaced with the following:

3.11: **FDA Meetings/Communications**. All formal meetings with the FDA concerning any clinical trial within the scope of the Research Plan will be discussed by Collaborator and ICD in advance. Each Party reserves the right to take part in setting the agenda for, to attend, and participate in these meetings, as appropriate.

7. Article 4.1 of the CRADA is deleted in its entirety and replaced with the following:

4.1 **Interim Research and Development Reports**. The CRADA PIs shall exchange information in writing every three (3) months during the course of this CRADA. This exchange of information may be accomplished through meeting minutes, detailed correspondence, circulation of draft manuscripts, Steering Committee reports, copies of Annual Reports, and any other reports updating the progress of the CRADA research. However, the Parties must exchange updated Investigator's Brochure, formulation and preclinical data, and toxicology findings, as they become available. These data and documents will be provided in eCTD format. The Investigator's Brochure will be reviewed at least annually and updated if necessary. In addition, all CRADA research meetings between the Collaborator and consultants, and the ICD scientific and clinical employees will be organized in advance through the offices of ICD, Principal Investigator, and the Collaborator's Chief Executive Officer. All meetings, telephone and video conferences will be held at mutually agreeable times and dates to allow all relevant Collaborator and consultants, and ICD employees to participate.

8. Article 4.4.1 of the CRADA is deleted in its entirety and replaced with the following:

4.4.1 **Safety Reports**. In accordance with FDA requirements ICD, as the IND Sponsor, will establish and maintain records and submit safety reports to the FDA, as required by 21 C.F.R. § 312.32 and 21 C.F.R. 812.150(b)(1), or other applicable Federal regulations. In the conduct of research under this CRADA, the Parties will comply with specific ICD guidelines and policies for reporting ADEs and AEs. ICD must provide Collaborator with copies of all Safety Reports concurrently with their submission to the FDA, and with any other information affecting the safety of Human Subjects in research conducted under this CRADA.

9. The IC Clinical Contact as needed for Article 4.4.2 is deleted and replaced with the following:

Steven A. Rosenberg, M.D., Ph.D. Surgery Branch, NCI
10 Center Drive, MSC 1201 Bldg. I 0, CRC Room 3-3940 Bethesda, MDA 20892-120 I
Tel. [***]
Fax: [***]

and [***]

SIGNATURES ON THE FOLLOWING PAGE

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/ James H. Doroshow, M.D	06/22/2022
James H. Doroshow, M.D Deputy Director for Clinical and Translational Research, NCI	Date

For Alaunos:

/s/ Kevin S. Boyle, Sr	06/24/2022
Name: Kevin S. Boyle, Sr. Title: Chief Executive Officer	Date

Exhibit 10.2

ALAUNOS THERAPEUTICS, INC.

EQUITY DISTRIBUTION AGREEMENT

August 12, 2022

PIPER SANDLER & CO.
U.S. Bancorp Center
800 Nicollet Mall
Minneapolis, Minnesota 55402

Ladies and Gentlemen:

As further set forth in this agreement (this ***"Agreement"***), Alaunos Therapeutics, Inc., a Delaware corporation (the ***"Company"***), proposes to issue and sell from time to time through Piper Sandler & Co. (the ***"Agent"***), as sales agent, the Company's common stock, par value $0.001 per share (the ***"Common Stock"***) (such shares of Common Stock to be sold pursuant to this Agreement, the ***"Shares"***) on terms set forth herein. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in Section 2 of this Agreement on the number of Shares issued and sold under this Agreement shall be the sole responsibility of the Company, and the Agent shall have no obligation in connection with such compliance.

The Company hereby confirms its agreement with the Agent with respect to the sale of the Shares.

1. Representations and Warranties of the Company.

(a)The Company represents and warrants to, and agrees with, the Agent that, unless otherwise specified below, and except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto) on or before each date of delivery, as of the date of this Agreement, each Representation Date (as defined in Section 3(o) below), each date on which a Placement Notice (as defined in Section 2(a)(i) below) is given (each, a *"Notice Date"*), each date on which Shares are sold hereunder (each, an *"Applicable Time"*), and each Settlement Date (as defined in Section 2(a)(vii) below) as follows:

(i) *Registration Statement and Prospectus*. The Company will file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the ***"Securities Act"***), with the Securities and Exchange Commission (the ***"Commission"***) a registration statement on Form S-3, including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, as well as a prospectus relating to the Shares (the ***"EDA Prospectus"***), both of which incorporate by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the

"Exchange Act"). The Company will furnish to the Agent, for use by the Agent, copies of the EDA Prospectus. Except where the context otherwise requires, such registration statement, as amended when it becomes effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, is herein called the ***"Registration Statement."*** The EDA Prospectus, including all documents incorporated therein by reference, included in the Registration Statement, in the form in which the EDA Prospectus has most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any ***"issuer free writing prospectus,"*** as defined in Rule 433 of the Securities Act (***"Rule 433"***), relating to the Shares, if any, that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the ***"Prospectus."*** Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant the Electronic Data Gathering Analysis and Retrieval System (***"EDGAR"***).

(ii) *Continuing Effectiveness of Registration Statement*. As of each Representation Date, Notice Date, Applicable Time and Settlement Date: The Registration Statement and any Rule 462(b) Registration Statement will have been declared effective by the Commission under the Securities Act. The Company will have complied, to the Commission's satisfaction, with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement shall be in effect and, to the knowledge of the Company, no proceedings for such purpose shall have been instituted, be pending or be contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Shares hereunder meets the requirements of General Instruction I.B.1 of Form S-3.

(iii) *No Material Misstatements or Omissions*. The Prospectus when filed, and as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it becomes effective or its date, as applicable, and as of each Settlement Date, will comply in all material respects with the Securities Act, and as of each effective date and each Settlement Date, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein

not misleading. The Prospectus, as amended or supplemented, as of its date and as of each Settlement Date, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.

(iv) *Eligible Issuer*. The Company is not an "ineligible issuer" (as defined in Rule 405 under the Securities Act) as of the eligibility determination date for purposes of Rules 164 and 433 under the Securities Act with respect to the offering of the Shares contemplated by the Registration Statement; the parties hereto agree and understand that the content of any and all "road shows" (as defined in Rule 433 under the Securities Act) related to the offering of the Shares contemplated hereby is solely the property of the Company.

(v) *Financial Statements*. The historical financial statements (including the related notes and supporting schedules) to be included or incorporated by reference in the Registration Statement and the Prospectus comply as to form in all material respects with the requirements of Regulation S-X under the Securities Act (***"Regulation S-X"***) and present fairly in all material respects the financial condition, results of operations and cash flows of the entities purported to be shown thereby at the dates and for the periods indicated and have been prepared in conformity with generally accepted accounting principles in the United States applied on a consistent basis throughout the periods involved. There are no financial statements (historical or pro forma) that are required to be included in the Registration Statement or the Prospectus that are not so included as required. The interactive data in eXtensible Business Reporting Language (***"XBRL"***) included or incorporated by reference in the Registration Statement and the Prospectus fairly present the information called for in all material respects and have been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(vi) *No Off-Balance Sheet Transactions*. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structural finance, special purpose or limited purpose entity (each, an ***"Off-Balance Sheet Transaction"***) that could reasonably be expected to affect materially the Company's liquidity or the availability of or requirements for its capital resources, including those Off-Balance Sheet Transactions described in the Commission's Statement about Management's Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), and are required to be described in the Prospectus, which have not been described as required.

(vii) *Auditor Independence.* RSM US LLP, who have certified certain financial statements of the Company, whose report appears in the Registration Statement and the Prospectus, are independent public accountants as required by the Securities Act and the Public Accounting Oversight Board.

(viii) *Organization and Good Standing*. The Company has no "significant subsidiaries" as defined in Rule 405 under the Securities Act. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's most recent Annual Report on Form 10-K. The Company has been duly organized and is validly existing and in good standing under the laws of their respective jurisdictions of organization. The Company is, and will be, duly licensed or qualified as a foreign entity for transaction of business and in good standing under the laws of each other jurisdiction in which its ownership or lease of property or the conduct of its business requires such license or qualification, and has all corporate power and authority necessary to own or hold its properties and to conduct its business as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. ***"Material Adverse Effect"*** shall mean any material adverse effect, or any development involving a prospective material adverse change or effect, on (i) the business, earnings, assets, liabilities, prospects, condition (financial or otherwise), operations, general affairs, management, financial position, stockholders' equity or results of operations of the Company, or (ii) the ability of the Company to perform its obligations under this Agreement, including the issuance and sale of the Shares, or to consummate the transactions contemplated in the Prospectus.

(ix) *Capitalization*. The Company has an authorized capitalization as set forth in each of the Registration Statement and the Prospectus (other than for subsequent issuances, if any, pursuant to a Specified Equity Plan (as defined in Section 1(a)(xviii) below) or upon the exercise of outstanding options or warrants), and all of the issued shares of the Company have been duly authorized and validly issued, are fully paid and non-assessable, conform in all material respects to the description thereof contained in the Registration Statement and the Prospectus and were not issued in violation of any preemptive right, resale right, right of first refusal or similar right. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's capital stock have been duly authorized and validly issued, and conform in all material respects to the description thereof contained in the Registration Statement and the Prospectus.

(x) *Due Authorization, Valid Issuance and Non-Assessiblity of Shares*. The Shares to be issued and sold by the Company to the Agent hereunder have been duly authorized and, upon payment and delivery in accordance with this Agreement, will be validly issued, fully paid and non-assessable, will conform in all material respects to the description thereof contained in the Registration Statement and the Prospectus, will be

issued in compliance with federal and state securities laws and will be free of statutory and contractual preemptive rights, rights of first refusal and similar rights.

(xi) *Authority to Enter into this Agreement*. The Company has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement. This Agreement has been duly and validly authorized, executed and delivered by the Company.

(xii) *Non-Contravention*. The issue and sale of the Shares, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby and the application of the proceeds from the sale of the Shares as described under "Use of Proceeds" in the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, impose any lien, charge or encumbrance upon any property or assets of the Company, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which the Company is a party or by which the Company is bound or to which any of the property or assets of the Company is subject; (ii) result in any violation of the provisions of the certificate of incorporation or bylaws of the Company, as currently in effect; or (iii) result in any violation of any statute or any judgment, order, decree, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its properties or assets, except, with respect to clauses (i) and (iii), for such conflicts, breaches, violations, liens, charges, encumbrances or defaults that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xiii) *No Consent or Approval Required*. No consent, approval, authorization or order of, or filing, registration or qualification with, any court or governmental agency or body having jurisdiction over the Company or any of its properties or assets is required for the issue and sale of the Shares, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby or the application of the proceeds from the sale of the Shares as described under "Use of Proceeds" in the Prospectus, except for (i) the registration of the Shares under the Securities Act; (ii) such consents, approvals, authorizations, orders, filings, registrations or qualifications as may be required under the Exchange Act, and applicable state or foreign securities laws and/or the bylaws and rules of the Financial Industry Regulatory Authority (***"FINRA"***) in connection with the sale of the Shares by the Agent; and (iii) the inclusion of the Shares on the Exchange. ***"Exchange"*** shall mean the Nasdaq Global Select Market or, if then the principal market on which the Common Stock is listed or quoted, the Nasdaq Global Market or Nasdaq Capital Market.

(xiv) *Internal Controls*. The Company maintains a system of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are

executed in accordance with management's general or specific authorization, (ii) transactions are recorded as necessary to permit preparation of the Company's financial statements in conformity with generally accepted accounting principles in the United States and to maintain accountability for its assets, (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization, (iv) the recorded accountability for the Company's assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences, and (v) the interactive data in XBRL included or incorporated by reference in the Registration Statement and the Prospectus fairly present the information called for in all material respects and are prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as disclosed in the Registration Statement or the Prospectus, as of the date of the most recent balance sheet of the Company audited by RSM US LLP, there were no "significant deficiencies" or "material weaknesses" (each as defined by the Public Company Accounting Oversight Board) in the Company's internal controls over financial reporting, or any fraud, whether or not material, that involves management or other employees of the Company who have a significant role in the Company's internal controls; and since the end of the latest audited fiscal year, there has been no change in the Company's internal control over financial reporting (whether or not remediated) that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting. The Company's board of directors has, subject to the exceptions, cure periods and the phase in periods specified in the Nasdaq listing rules (***"Exchange Rules"***), validly appointed an audit committee to oversee internal accounting controls whose composition satisfies the applicable requirements of the Exchange Rules and the Company's board of directors and/or the audit committee has adopted a charter that satisfies the requirements of the Exchange Rules.

(xv) *Disclosure Controls*. The Company maintains an effective system of "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company has carried out evaluations of the effectiveness of its disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act.

(xvi) *Critical Accounting Policies*. The section entitled "Critical Accounting Policies and Significant Estimates" incorporated by reference in the Registration Statement and the Prospectus accurately describes in all material respects (i) the accounting policies that the Company believes are the most important in the portrayal of the Company's financial condition and results of operations and that require management's most difficult, subjective or complex judgments (***"Critical Accounting Policies"***); (ii) the judgments and uncertainties affecting the application of Critical Accounting Policies; and (iii) the likelihood that materially different amounts would be reported under different conditions or using different assumptions, and an explanation thereof.

(xvii) *Sarbanes-Oxley Compliance*. There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith that are applicable to the Company or its directors or officers in their capacities as directors or officers of the Company.

(xviii)*Exceptions*. Except as would not, in the aggregate, reasonably be expected to have a Material Adverse Effect, since the date of the latest audited financial statements included in the Registration Statement and the Prospectus, and, except as disclosed in the Registration Statement and the Prospectus, the Company has not (i) sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, (ii) issued or granted any securities (other than pursuant to inducement awards under the Exchange Rules or employee benefit plans, qualified stock option plans or other equity compensation plans or arrangements disclosed in the Registration Statement and the Prospectus (collectively, the ***"Specified Equity Plans"***)), (iii) incurred any material liability or obligation, direct or contingent, other than liabilities and obligations that were incurred in the ordinary course of business, (iv) entered into any material transaction not in the ordinary course of business, or (v) declared or paid any dividend on its share capital; and since such date, except as disclosed in the Registration Statement and the Prospectus, there has not been any change in the share capital, long-term debt, net current assets or short-term debt of the Company or any adverse change, or any development involving a prospective adverse change, in or affecting the condition (financial or otherwise), results of operations, stockholders' equity, properties, management, business or prospects of the Company.

(xix) *Valid Title*. The Company has good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by it, that is material to the business of the Company, in each case free and clear of all liens, encumbrances and defects, except such liens, encumbrances and defects as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company. All assets held under lease by the Company, that are material to the business of the Company, are held by it under valid, subsisting and enforceable leases, with such exceptions as do not materially interfere with the use made and proposed to be made of such assets by the Company.

(xx) *Intellectual Property*. The Company owns, possesses, has rights to or can acquire on reasonable terms, all Intellectual Property (as defined below) necessary for the conduct of the Company's business as now conducted or as proposed to be conducted, as described in the Registration Statement and the Prospectus, except where the failure to own, possess, have rights to or such ability to acquire would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Furthermore, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (A) to the knowledge of the Company, there

is no infringement, misappropriation or violation by third parties of any such Intellectual Property; (B) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (C) the Intellectual Property owned by the Company and, to the knowledge of the Company, the Intellectual Property licensed to the Company, has not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (D) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other fact which would form a reasonable basis for any such claim; (E) to the Company's knowledge, no employee of the Company is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or actions undertaken by the employee while employed with the Company; (F) there is no prior art or public or commercial activity of which the Company is aware that may render any patent included in the Intellectual Property invalid or that would preclude the issuance of any patent on any patent application included in the Intellectual Property, which has not been disclosed to the U.S. Patent and Trademark Office or the relevant foreign patent authority, as the case may be; and (G) to the Company's knowledge, the issued patents included in the Intellectual Property are valid and enforceable and the Company is unaware of any facts that would preclude the issuance of a valid and enforceable patent on any pending patent application included in the Intellectual Property; (H) the Company has taken steps reasonably designed to secure the interests of the Company in the Intellectual Property purported to be owned by the Company from all employees, consultants, agents or contractors that developed (in whole or in part) such Intellectual Property; (I) no government funding, facilities or resources of a university, college, other educational institution or research center was used in the development of any Intellectual Property that is owned or purported to be owned by the Company that would confer upon any governmental agency or body, university, college, other educational institution or research center any claim or right in or to any such Intellectual Property; and (J) to the Company's knowledge, none of the technology employed by the Company has been obtained or is being used by the Company in violation of the rights of any entity. ***"Intellectual Property"*** shall mean all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, domain names, technology, know-how and other intellectual property in the United States and foreign jurisdictions.

(xxi) *Health Care Authorizations*. The Company has submitted and possesses, or qualifies for applicable exemptions to, such valid and current registrations, listings, approvals, clearances, licenses, certificates, authorizations or permits and supplements or amendments thereto issued or required by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct its business as described in the Registration Statement and the Prospectus (***"Permits"***), including, without limitation, all such Permits required by the U.S. Food and Drug Administration (the ***"FDA"***), the U.S. Department of Health and Human Services (***"HHS"***), the U.S. Centers for Medicare & Medicaid Services (***"CMS"***), the European Medicines Agency (***"EMA"***), Health Canada or any other comparable state, federal or foreign agencies or bodies to which it is subject, except for such Permits, the lack of which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and the Company has not received any written notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Permit.

(xxii) *Compliance with Health Care Laws*. The Company is in material compliance with all health care laws applicable to the Company, or any of its products or activities, including, but not limited to, any state, federal or foreign law, rule or regulation which imposes requirements on manufacturing, development, testing, labeling, advertising, marketing, promotion, distribution, reporting, kickbacks, patient or program charges, recordkeeping, claims process, documentation requirements, medical necessity, referrals, the hiring of employees or acquisition of services or supplies from those who have been excluded from government health care programs, quality, safety, privacy, security, licensure, accreditation or any other aspect of providing health care, clinical laboratory or diagnostics products or services (collectively, ***"Health Care Laws"***). Since January 1, 2019, the Company has not received any notification, including notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority, including, without limitation, the FDA, the EMA, Health Canada, the U.S. Federal Trade Commission, the U.S. Drug Enforcement Administration (***"DEA"***), CMS, HHS's Office of Inspector General, the U.S. Department of Justice and state Attorneys General or similar agencies of non-compliance by, or liability of, the Company under any Health Care Laws, except, with respect to any of the foregoing, such as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The statements with respect to Health Care Laws and the Company's compliance therewith included in the Registration Statement and in the Prospectus fairly summarize in all material respects the matters therein described.

(xxiii)*Clinical Trials*. The studies, tests and preclinical and clinical trials conducted by or on behalf of, or sponsored by, the Company, or in which the Company has participated, that are described in the Registration Statement or the Prospectus, or the results of which are referred to in the Registration Statement or the Prospectus, were and, if still pending, are, to the Company's knowledge, being conducted in all material respects in accordance with protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company and all applicable

statutes, rules and regulations of the FDA, the EMA, Health Canada and other comparable regulatory agencies outside of the U.S. to which they are subject; the descriptions of the results of such studies, tests and trials contained in the Registration Statement or the Prospectus do not contain any misstatement of a material fact or omit a material fact necessary to make such statements not misleading, except where the failure to be in such accordance would not reasonably be expected to have a Material Adverse Effect; the Company has no knowledge of any studies, tests or trials not described in the Registration Statement or the Prospectus the results of which the Company believes reasonably call into question in any material respect the results of the studies, tests and trials described in the Registration Statement or Prospectus, when viewed in the context in which such results are described and the clinical state of development; and the Company has not received any notices or other correspondence from the FDA, EMA, Health Canada or any other foreign, state or local governmental body exercising comparable authority or any Institutional Review Board or comparable authority requiring or threatening the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of, or sponsored by, the Company or in which the Company has participated, and, to the Company's knowledge, there are no reasonable grounds for the same. Except as disclosed in the Registration Statement and the Prospectus, there has not been any violation of law or regulation by the Company in its respective product development efforts, submissions or reports to any regulatory authority that could reasonably be expected to require investigation, corrective action or enforcement action.

(xxiv)*Absence of Settlement Agreements or Undertakings*. Except as disclosed in the Registration Statement and the Prospectus, the Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental authority.

(xxv) *Absence of Legal or Governmental Proceedings*. Except as disclosed in the Registration Statement and the Prospectus, there are no legal or governmental proceedings pending to which the Company is a party or of which any property or assets of the Company is the subject that, if determined adversely to the Company, would, in the aggregate, reasonably be expected to have a Material Adverse Effect; and to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or others.

(xxvi)*Material Contracts*. There are no contracts or other documents required to be described in the Registration Statement or filed as exhibits to the Registration Statement that are not described and filed as required. The statements made in the Registration Statement and Prospectus, insofar as they purport to constitute summaries of the terms of the contracts and other documents described and filed, constitute accurate summaries of the terms of such contracts and documents in all material respects. Except as disclosed in the Registration Statement and the Prospectus, the Company has no knowledge that any other party to any such contract or other document has any intention not to render full performance as contemplated by the terms thereof.

(xxvii)*Insurance*. The Company maintains insurance from nationally recognized insurers in such amounts and covering such risks as is commercially reasonable in accordance with customary practices for companies engaged in similar businesses and similar industries for the conduct of its business and the value of its properties. All policies of insurance of the Company are in full force and effect; the Company is in compliance with the terms of such policies in all material respects; and the Company has not received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance; there are no material claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; and the Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

(xxviii)*Related Party Disclosure*. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company, on the other hand, that is required to be described in the Registration Statement or the Prospectus which is not so described.

(xxix)*No Labor Dispute*. No labor disturbance by or dispute with the employees of the Company exists or, to the knowledge of the Company, is imminent that would reasonably be expected to have a Material Adverse Effect.

(xxx) *No Violation or Default*. Except as disclosed in the Registration Statement and the Prospectus, the Company is not (i) in violation of its certificate of incorporation or bylaws, as currently in effect, (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant, condition or other obligation contained in any indenture, mortgage, deed of trust, loan agreement, license or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, or (iii) in violation of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over it or its property or assets or has failed to obtain any license, permit, certificate, franchise or other governmental authorization or permit necessary to the ownership of its property or to the conduct of its business, except in the case of clauses (ii) and (iii), to the extent any such conflict, breach, violation or default would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xxxi)*Environmental Laws*. Except as disclosed in the Registration Statement and the Prospectus, the Company (i) is, and at all times prior hereto was, in compliance with all applicable laws, regulations, ordinances, rules, orders, judgments, decrees, permits or other legal requirements of any governmental authority, including without limitation any international, foreign, national, state, provincial, regional, or local authority, relating to pollution, the protection of human health or safety, the environment, or natural resources, or to use, handling, storage, manufacturing, transportation, treatment, discharge, disposal

or release of hazardous or toxic substances or wastes, pollutants or contaminants (***"Environmental Laws"***), which compliance includes, without limitation, obtaining, maintaining and complying with all permits and authorizations and approvals required by Environmental Laws to conduct its business, except for such non-compliance as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and (ii) has not received notice of any actual or alleged violation of Environmental Laws, or of any actual or potential liability for or other obligation concerning the presence, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants and has no knowledge of any event or condition that would reasonably be expected to result in any such notice. Except as described in the Registration Statement and the Prospectus, (x) there are no proceedings that are pending or, to the Company's knowledge, threatened, against the Company under Environmental Laws in which a governmental authority is also a party, other than such proceedings regarding which it is reasonably believed no monetary sanctions of $100,000 or more will be imposed, (y) the Company is not aware of any issues regarding compliance with Environmental Laws or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would reasonably be expected to have a Material Adverse Effect, and (z) the Company does not anticipate material capital expenditures relating to Environmental Laws.

(xxxii)*Taxes*. The Company has filed all federal, state, local and foreign tax returns required to be filed through the date hereof, subject to permitted extensions, and have paid all taxes due (except where the failure to so file or pay would not, in the aggregate, reasonably be expected to have a Material Adverse Effect, and except as currently being contested in good faith and for which reserves have been created), and no tax deficiency has been determined adversely to the Company, nor does the Company have any knowledge of any tax deficiencies that have been, or would reasonably be expected to be, asserted against the Company that would, in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xxxiii)*ERISA Compliance*. Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (i) each "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Security Act of 1974, as amended (***"ERISA"***)) for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the ***"Code"***)) would have any liability (each a ***"Plan"***) has been maintained in compliance in all material respects with its terms and with the requirements of all applicable statutes, rules and regulations including ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) with respect to each Plan subject to Title IV of ERISA (A) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur that would result in a material loss to the Company, (B) no "accumulated funding deficiency" (within the meaning of Section 302 of ERISA or Section 412 of the Code), whether or not waived, has occurred

or is reasonably expected to occur, (C) the fair market value of the assets under each Plan that is required to be funded exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan), and (D) neither the Company or any member of its Controlled Group has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(c)(3) of ERISA); and (iv) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, to the Company's knowledge, whether by action or by failure to act, which would cause the loss of such qualification.

(xxxiv)*Accuracy of Statistical and Market Data*. The statistical and market-related data included in the Registration Statement and the Prospectus are based on or derived from sources that the Company believes to be reliable in all material respects.

(xxxv)*Not an Investment Company*. The Company is not, nor, after giving effect to the offer and sale of the Shares and the application of the proceeds therefrom as described under "Use of Proceeds" in the Prospectus, will be, (i) an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the ***"Investment Company Act"***), and the rules and regulations of the Commission thereunder, or (ii) a "business development company" (as defined in Section 2(a)(48) of the Investment Company Act).

(xxxvi)*Accuracy of Certain Summaries and Statements*. The statements set forth or incorporated by reference, as applicable, in each of the Registration Statement and the Prospectus under the captions "Description of Capital Stock," and in the Company's most recent Annual Report on Form 10-K under the captions "Legal Proceedings" and "Certain Relationships and Related Transactions, and Director Independence", insofar as they purport to summarize the provisions of the laws and documents referred to therein, are accurate summaries in all material respects.

(xxxvii)*Registration Rights*. Except as disclosed in the Registration Statement and the Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person. There are no contracts, agreements or understandings to require the Company to include any such securities in the securities proposed to be offered pursuant to this Agreement.

(xxxviii)*No Other Brokers*. The Company is not a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against it or the Agent for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares, except for such contracts, agreements or understandings as have been waived.

(xxxix)*No Integration*. The Company has not sold or issued any securities that would be integrated with the offering of the Shares contemplated by this Agreement pursuant to the Securities Act or the interpretations thereof by the Commission.

(xl) *Absence of Stabilization or Manipulation*. The Company has not taken, directly or indirectly, any action designed to or that has constituted or that could reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company in connection with the offering of the Shares.

(xli) *Exchange Act Registration and Listing of the Common Stock*. The shares of Common Stock are registered pursuant to Section 12(b) of the Exchange Act and listed on the Exchange; the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing, except as disclosed in the Registration Statement and the Prospectus.

(xlii) *Offering Material*. The Company has not distributed and prior to any Settlement Date, will not distribute any offering material in connection with any Placement (as defined in Section 2(a)(i) below), other than any preliminary prospectus, the Prospectus, and any Permitted Free Writing Prospectus (as defined in Section 3(n) below) to which the Agent has consented.

(xliii) *Compliance with Labor Laws*. The Company is not in violation of and has not received notice of any violation with respect to any federal or state law relating to discrimination in the hiring, promotion or pay of employees, nor any applicable federal or state wage and hour laws, nor any state law precluding the denial of credit due to the neighborhood in which a property is situated, the violation of any of which would reasonably be expected to have a Material Adverse Effect.

(xliv) *No Unlawful Payments*. The Company has not, nor, to the knowledge of the Company, has any director, officer, agent, employee or other person acting on behalf of the Company (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, the Organization for Economic Co-operation and Development Convention on Bribery of Foreign Public Officials in International Business Transactions, and the rules and regulations thereunder and any other similar foreign or domestic law or regulation applicable to the Company; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment. The Company has instituted and maintains policies and procedures reasonably designed to ensure continued compliance with the laws and regulations referenced in clause (iii) of this paragraph.

(xlv) *Anti-Money Laundering Compliance*. The operations of the Company are, and have been conducted at all times, in compliance with applicable financial

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

(xlvi) *OFAC*.

(A) Neither the Company nor any of its directors, officers or employees, nor, to the Company's knowledge, any agent, affiliate or representative of the Company, is an individual or entity that is, or is owned or controlled by an individual or entity that is:

(1) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, ***"Sanctions"***), nor

(2) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea and Syria).

(B) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other individual or entity:

(1) to fund or facilitate any activities or business of or with any individual or entity or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(2) in any other manner that will result in a violation of Sanctions by any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(C) For the past five years, the Company has not knowingly engaged in, and is not now knowingly engaged in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(xlvii)*[Reserved]*.

(xlviii)*No Taxes or Fees Due Upon Issuance*. No stamp, issue, registration, documentary, transfer or other similar taxes and duties, including interest and penalties, are payable by the Agent on or in connection with the issuance and sale of the Shares by the Company or the execution and delivery of this Agreement.

(xlix) *No Immunity*. Neither the Company, nor any of its owned properties or assets, has any immunity from the jurisdiction of any court or from any legal process (whether through service or notice, attachment to prior judgment, attachment in aid of execution or otherwise) under the laws of any jurisdiction in which it is organized, headquartered or doing business.

(l) *No Legal, Accounting or Tax Advice*. The Company has not relied upon the Agent or legal counsel for the Agent for any legal, tax or accounting advice in connection with the offering and sale of the Shares.

(li) *Certificate as Representation and Warranty*. Any certificate signed by any officer of the Company and delivered to the Agent or the Agent's counsel in connection with the offering of the Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby.

(lii) *Cybersecurity.* The Company's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, ***"IT Systems"***) are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company as currently conducted, free and clear, to the knowledge of the Company, of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company has implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. ***"Personal Data"*** means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR (as defined in Section 1(a)(liii) below); (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, ***"HIPAA"***); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no material breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company is presently in material compliance with all applicable laws or statutes and all judgments,

orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(liii) *Compliance with Data Privacy Laws.* The Company is, and at all prior times was, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company has, since May 25, 2018, been and currently is in material compliance with, the European Union General Data Protection Regulation (***"GDPR"***) (EU 2016/679) (collectively, the ***"Privacy Laws"***). To promote compliance with the Privacy Laws, the Company has taken appropriate steps reasonably designed to ensure compliance in all material respects with such Privacy Laws. The Company has at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company (i) has not received notice of any actual or potential material liability under or relating to, or actual or potential material violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is not currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; and (iii) is not a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(liv) *No Shutdowns or Prohibitions*. The Company has not had any product, clinical laboratory or manufacturing site (whether Company-owned or that of a third party manufacturer for the Company's products) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of adverse finding, "warning letters," "untitled letters," requests to make changes to the Company's products, processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action.

2. Purchase, Sale and Delivery of Shares.

(a) *At-the-Market Sales.* On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell through the Agent as sales agent, and the Agent agrees to use its commercially reasonable efforts to sell for and on behalf of the Company, the Shares on the following terms and conditions; *provided*, *however*, that any obligation of the Agent to use such commercially reasonable efforts shall be subject to the continuing accuracy of the representations and warranties of the Company herein, the performance by the Company of its covenants and obligations hereunder and the continuing satisfaction of the additional conditions specified in Section 4 of this Agreement. The Company acknowledges and agrees that (i) there can be no

assurance that the Agent will be successful in selling Shares, and (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Shares as required under this Section 2.

(i) Each time that the Company wishes to issue and sell the Shares hereunder (each, a ***"Placement"***), it will notify the Agent by email notice (or other method mutually agreed to in writing by the parties) (a ***"Placement Notice"***) containing the parameters in accordance with which it desires the Shares to be sold, which shall at a minimum include the number of Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Shares that may be sold in any one Trading Day (as defined below) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 2 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 2. Schedule 2 may be amended from time to time upon notice by the amending party to the other. The Placement Notice shall be effective upon receipt by the Agent unless and until (i) in accordance with the notice requirements set forth in Section 2(a)(iii) of this Agreement, the Agent declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Shares have been sold, (iii) the Company suspends or terminates the Placement Notice in accordance with the notice requirements set forth in Section 2(a)(iii) below, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of Section 7. The amount of any commission or other compensation to be paid by the Company to the Agent in connection with the sale of the Shares shall be calculated in accordance with the terms set forth in Section 2(a)(v) below. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Shares unless and until the Company delivers a Placement Notice to the Agent, and then only upon the terms specified therein and herein and unless and until such time as the Agent declines such Placement Notice pursuant to the terms set forth above. It is expressly acknowledged and agreed that the Agent may delay sales following delivery of a Placement Notice to the extent necessary to avoid a violation of the provisions of Rule 101(a) of Regulation M applicable to the Shares to be sold pursuant to such Placement Notice. In the event of a conflict between the terms of this Agreement and the terms of the Placement Notice, the terms of the Placement Notice will control. For the purposes hereof, ***"Trading Day"*** means any day on which the Company's Common Stock is purchased and sold on the Exchange.

(ii) The Shares are to be sold by the Agent on a daily basis or otherwise as shall be agreed to by the Company and the Agent on any day that is a Trading Day (other than a day on which the Exchange is scheduled to close prior to its regular weekday closing time). The gross sales price of the Shares sold under this Section 2(a) shall be the market price for the Company's Common Stock sold by the Agent under this Section 2(a) at the time of such sale.

(iii) Notwithstanding the foregoing, the Company may instruct the Agent by telephone (confirmed promptly by email) not to sell the Shares if such sales cannot be effected at or above the price designated by the Company in any such instruction. Furthermore, the Company shall not authorize the issuance and sale of, and the Agent shall not be obligated to use its commercially reasonable efforts to sell, any Share at a price lower than the minimum price therefor designated from time to time by the Company's Board of Directors and notified to the Agent in writing. In addition, the Company or the Agent may, upon notice to the other party hereto by telephone (confirmed promptly by email), suspend the offering of the Shares, whereupon the Agent shall so suspend the offering of Shares until further notice is provided to the other party to the contrary; *provided*, *however*, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice. Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and the Agent agree that (i) no sale of Shares will take place, (ii) the Company shall not request the sale of any Shares, and (iii) the Agent shall not be obligated to sell or offer to sell any Shares.

(iv) Subject to the terms of the Placement Notice, the Agent may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including sales made directly on or through the Exchange. Subject to the terms of any Placement Notice, the Agent may also sell Shares in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law, subject to the prior written consent of the Company.

(v) The compensation to the Agent for sales of the Shares, as an agent of the Company, shall be 3.0% of the gross sales price of the Shares sold pursuant to this Section 2(a), payable in cash (the ***"Sales Commission"***); *provided that* the combined Sales Commission and reimbursement of the Agent for its out-of-pocket expenses pursuant to Section 3(g), including reasonable fees and disbursements of the Agent's counsel, shall not exceed 8.0% of the gross sales price of the Shares. The remaining proceeds, after further deduction for any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales, and reimbursement of expenses that the Agent may be entitled to pursuant to Section 3(g), shall constitute the net proceeds to the Company for such Shares (the ***"Net Proceeds"***).

(vi) The Agent will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on Schedule 2), no later than the opening of the Trading Day immediately following the Trading Day on which it has made sales of Shares hereunder, setting forth the number of Shares sold on such day, the volume-weighted average price of the Shares sold, and the Net Proceeds payable to the Company.

(vii) All Shares sold pursuant to this Section 2(a) will be delivered by the Company to the Agent for the account of the Agent, against payment of the Net Proceeds therefor, by wire transfer of same-day funds payable to the order of the Company at the offices of Piper Sandler & Co., U.S. Bancorp Center, 800 Nicollet Mall, Minneapolis, Minnesota, or such other location as may be mutually acceptable, at 9:00 a.m. Central Time on the second full business day following the date on which such Shares are sold, or at such other time and date as the Agent and the Company determine pursuant to Rule 15c6-1(a) under the Exchange Act, each such time and date of delivery being herein referred to as a ***"Settlement Date."*** If the Agent so elects, delivery of the Shares may be made by credit through full fast transfer to an account or accounts at The Depository Trust Company designated by the Agent. On each Settlement Date, the Agent will deliver the Net Proceeds in same day funds to an account designated by the Company on, or prior to, such Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to timely deliver duly authorized Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 5 hereof, it will (i) hold the Agent harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company, (ii) reimburse the Agent for any losses incurred by the Agent attributable, directly or indirectly, to such default and (iii) pay to the Agent any commission or other compensation to which the Agent would otherwise have been entitled absent such default.

(b) *Maximum Amount*. Under no circumstances shall the aggregate number or aggregate value of the Shares sold pursuant to this Agreement exceed: (i) the aggregate number and aggregate dollar amount of shares of Common Stock available for issuance and sale under the currently effective Registration Statement (including any limit set forth in General Instruction I.B.6 thereof, if applicable), (ii) the aggregate number of authorized but unissued shares of Common Stock that are available for issuance under the Company's certificate of incorporation or (iii) the aggregate number or aggregate dollar amount of shares of Common Stock for which the Company has filed the Prospectus in connection with the Shares (the lesser of (i), (ii) and (iii), the *"Maximum Amount"*).

(c) *No Association or Partnership*. Nothing herein contained shall constitute the Agent as an unincorporated association or partner with the Company.

(d) *Duration*. Under no circumstances shall any Shares be sold pursuant to this Agreement after the date which is three years after the Registration Statement is first declared effective by the Commission.

(e) *Market Transactions by Agent*. The Company acknowledges and agrees that the Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act, the Exchange Act and this Agreement, purchase and sell shares of Common Stock for its own account while this Agreement is in effect, *provided, that* (i) no sale for its own account shall take place while a Placement Notice is in effect (except to the extent the Agent may engage in sales of Shares purchased or deemed purchased from the Company as a "riskless principal" or

in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent. The Company consents to the Agent trading in the Common Stock for the account of any of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

3. Covenants of the Company. The Company covenants and agrees with the Agent as follows:

(a) *Amendments to Registration Statement and Prospectus*. After the date of this Agreement and during any period in which a prospectus relating to any Shares is required to be delivered by the Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company agrees that it will: (i) notify the Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference or amendments not related to the Shares, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus related to the Shares has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement (insofar as it relates to the transactions contemplated hereby) or Prospectus or for additional information; (ii) prepare and file with the Commission, promptly upon the Agent's written request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agent's reasonable opinion, may be necessary or advisable in connection with the sale of the Shares by the Agent (*provided, however*, that the failure of the Agent to make such written request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement); (iii) not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Shares unless a copy thereof has been submitted to the Agent within a reasonable period of time before the filing and the Agent has not reasonably objected thereto (*provided, however*, that (A) the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide the Agent any advance copy of such filing or to provide the Agent an opportunity to object to such filing if the filing does not name the Agent or does not relate to a Placement or other transaction contemplated hereunder, and (C) the only remedy that the Agent shall have with respect to the failure by the Company to provide the Agent with such copy or the filing of such amendment or supplement despite the Agent's objection shall be to cease making sales under this Agreement); (iv) furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (v) cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act.

(b) *Stop Order*. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose, and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) *Continuing Amendments*. During any period in which a prospectus relating to the Shares is required to be delivered by the Agent under the Securities Act with respect to any Placement or pending sale of the Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and file on or before their respective due dates all reports (taking into account any extensions available under the Exchange Act) and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(d) *Qualification of the Shares*. The Company shall take or cause to be taken all necessary action to qualify the Shares for sale under the securities laws of such jurisdictions as the Agent reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Shares, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or to execute a general consent to service of process in any jurisdiction. The Company shall promptly advise the Agent of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for offer or sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose.

(e) *Copies of Registration Statement and Prospectus*. The Company will furnish to the Agent and counsel for the Agent copies of the Registration Statement (which will include three complete manually signed copies of the Registration Statement and all consents and exhibits filed therewith), the Prospectus and all amendments and supplements to such documents, in each case as soon as available and in such quantities as the Agent may from time to time reasonably request; *provided, however*, that the Company shall not be required to furnish any document to the extent such document is available on EDGAR.

(f) *Section 11(a)*. The Company will make generally available to its security holders as soon as practicable an earnings statement (which need not be audited) covering a 12-month period that shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 promulgated thereunder.

(g) *Expenses*. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid (i) all expenses (including stock or transfer taxes and stamp or similar duties allocated to the respective transferees) incurred in connection with the registration, issue, sale and delivery of the Shares, (ii) all expenses and fees (including, without limitation, fees and expenses of the Company's accountants and counsel) in connection with the preparation, printing, filing, delivery, and shipping of the Registration Statement (including the financial statements therein and all amendments, schedules, and exhibits thereto), the Shares, the Prospectus and any amendment thereof or supplement thereto, and the producing, word-processing, printing, delivery, and shipping of this Agreement and other transaction documents or closing documents, including Blue Sky Memoranda (covering the states and other applicable jurisdictions) and including the cost to furnish copies of each thereof to the Agent, (iii) all filing fees, (iv) all reasonable fees and disbursements of the Agent's counsel incurred in connection with the qualification of the Shares for offering and sale by the Agent or by dealers under the securities or blue sky laws of the states and other jurisdictions which the Agent shall designate, (v) the fees and expenses of any transfer agent or registrar, (vi) the filing fees and reasonable fees and disbursements of the Agent's counsel incident to any required review and approval by FINRA of the terms of the sale of the Shares, (vii) listing fees, if any, (viii) the cost and expenses of the Company relating to investor presentations or any "roadshow" undertaken in connection with marketing of the Shares, and (ix) all other reasonable costs and expenses incident to the performance of its obligations hereunder that are not otherwise specifically provided for herein. In addition to (iv) and (vi) above, the Company shall reimburse the Agent for its out-of-pocket expenses, including reasonable fees and disbursements of the Agent's counsel in connection with this Agreement, the Registration Statement and the Prospectus; provided that such fees and disbursements shall not exceed: (A) $75,000 in connection with the execution of this Agreement and the filing of the Registration Statement and Prospectus (which shall include any fees and disbursements of Agent's counsel pursuant to Sections 3(g)(iv) and 3(g)(vi) hereof), and (B) $15,000 in connection with each Representation Date on which a Representation Certificate is delivered pursuant to Section 3(q) below.

(h) *Use of Proceeds*. The Company will apply the net proceeds from the sale of the Shares in the manner described in the Prospectus.

(i) *Restrictions on Future Sales*. Without the written consent of the Agent, the Company will not offer for sale, sell, contract to sell, pledge, grant any option for the sale of, enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of Common Stock (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any affiliate, or otherwise issue or dispose of, directly or indirectly (or publicly disclose the intention to make any such offer, sale, pledge, grant, issuance or other disposition), any Common Stock or any securities convertible into or exchangeable for, or any options or rights to purchase or acquire, Common Stock, or permit the registration under the Securities Act of any Common Stock, such securities, options or rights during the period beginning on the Trading Day immediately prior to the date on which any Placement Notice is delivered to the Agent hereunder and ending on the Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Placement Notice; *provided, however*, that such restrictions shall not apply to: (i) the registration of the Shares and

the sales through the Agent pursuant to this Agreement, (ii) any transaction in which the Agent is a participant or acting as an advisor to or agent of the Company or in some similar capacity, (iii) sales of Common Stock through any dividend reinvestment and stock purchase plan of the Company, (iv) restricted stock, restricted stock units, options and other awards granted pursuant to Specified Equity Plans, the Common Stock issuable upon the exercise of such options, the vesting of such restricted stock or restricted stock units or the exercise or vesting of any such other awards, (v) the filing of registration statements on Form S-8, (vi) the issuance or sale of Common Stock issuable upon exchange, conversion or redemption of securities or the exercise or vesting of warrants or options, in each case described in the Registration Statement and Prospectus; (vii) modification of any such securities, options or warrants, (viii) issuances or sales of Common Stock in connection with any research and development collaborations or similar transactions, provided that number of shares of Common Stock issued in such transactions is equal to or less than 5% of the Company's outstanding capital stock as of the date of such issuance, or (ix) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets.

(j) *No Stabilization or Manipulation*. The Company has not taken and will not take, directly or indirectly, any action designed to, or which might reasonably be expected to cause or result in, or which constitutes: (i) the stabilization or manipulation of the price of the Common Stock or any other security of the Company to facilitate the sale or resale of the Shares, (ii) a violation of Regulation M. The Company shall notify the Agent of any violation of Regulation M by the Company or any of its officers or directors promptly after the Company has received notice or obtained knowledge of any such violation. The Company shall not invest in futures contracts, options on futures contracts or options on commodities, unless the Company is exempt from the registration requirements of the Commodity Exchange Act, as amended (the *"Commodity Act"*), or otherwise complies with the Commodity Act. The Company will not engage in any activities bearing on the Commodity Act, unless such activities are exempt from the Commodity Act or otherwise comply with the Commodity Act.

(k) *No Other Broker*. Except as contemplated by this Agreement, the Company will not incur any liability for any finder's or broker's fee or agent's commission in connection with the execution and delivery of this Agreement, or the consummation of the transactions contemplated hereby.

(l) *Timely Securities Act and Exchange Act Reports*. During any prospectus delivery period with respect to the Shares, the Company will use its commercially reasonable efforts to file on a timely basis with the Commission such periodic and special reports as required by the Securities Act and the Exchange Act.

(m) *Internal Controls*. The Company will maintain controls and other procedures, including without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 and the applicable regulations thereunder, that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's

management, including its principal executive officer and its principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, to ensure that material information relating to the Company is made known to them by others within those entities.

(n) *Permitted Free Writing Prospectus*. The Company represents and agrees that it has not made and, unless it obtains the prior written consent of the Agent, will not make, and the Agent represents that it has not made and agrees that, unless it obtains the prior written consent of the Company, it will not make any offer relating to the Shares that would constitute an "issuer free writing prospectus," as defined in Rule 433 under the Securities Act, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405 under the Securities Act, required to be filed with the Commission. Any such free writing prospectus consented to by the Company and the Agent is hereinafter referred to as a *"Permitted Free Writing Prospectus."* The Company represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely Commission filing where required, legending and record keeping.

(o) *Representation Date and Opinions of Counsel*. On or prior to the date of the first Placement Notice, and thereafter during the term of this Agreement, each time the Company (A) files an amendment to the Registration Statement or Prospectus (other than relating solely to the offering of securities other than the Shares), (B) files an Annual Report on Form 10-K under the Exchange Act or files its Quarterly Reports on Form 10-Q under the Exchange Act; and (C) files a report on Form 8-K containing amended financial statements (other than an earnings release) under the Exchange Act (each of the dates in (A), (B) and (C) are referred to herein as a *"Representation Date"*), the Company shall cause Covington & Burling LLP, counsel for the Company, to furnish to the Agent the opinion and negative assurance statement of such counsel, dated as of such date and addressed to the Agent, in form and substance reasonably satisfactory to the Agent; *provided, however*, only a negative assurance statement of such counsel shall be required for each subsequent Representation Date.

Notwithstanding the foregoing, the requirement to provide counsel opinions under this Section 3(o) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the date the Company delivers a Placement Notice to the Agent. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Representation Date when the Company relied on such waiver and did not provide the Agent with opinions under this Section 3(o), then before the Agent sells any Shares pursuant to Section 2(a), the Company shall cause the opinions (including the opinion pursuant to Section 3(o) if not delivered on the date of the prior Form 10-K), comfort letter, certificates and documents that would be delivered on a Representation Date to be delivered.

(p) *Representation Date and Comfort Letter*. On or prior to the date of the first Placement Notice and thereafter during the term of this Agreement, on each Representation Date to which a waiver does not apply, the Company shall cause RSM US LLP, or other independent accountants reasonably satisfactory to the Agent (the *"Accountants"*), to deliver to the Agent a letter, dated as of such date and addressed to the Agent, confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualifications of accountants under Rule 2-01 of Regulation S-X of the Commission, and stating the conclusions and findings of said firm with respect to the financial information and other matters covered by its letter in form and substance satisfactory to the Agent of the same tenor as the first such letter received hereunder.

(q) *Representation Date and Representation Certificate*. On or prior to the date of the first Placement Notice and thereafter during the term of this Agreement, on each Representation Date to which a waiver does not apply, the Company shall furnish to the Agent a certificate (the *"Representation Certificate"*), substantially in the form of Schedule 3 hereto and dated as of such date, addressed to the Agent and signed by the chief executive officer and the principal financial officer or principal accounting officer of the Company.

(r) *Disclosure of Shares Sold*. The Company shall disclose in its Quarterly Reports on Form 10-Q and in its Annual Report on Form 10-K the number of the Shares sold through the Agent under this Agreement, the net proceeds to the Company and the compensation paid by the Company with respect to sales of the Shares pursuant to this Agreement during the relevant quarter.

(s) *Continued Listing of Shares*. The Company shall use its commercially reasonable efforts to maintain the listing of the Common Stock on the Exchange.

(t) *Notice of Changes*. At any time during the term of this Agreement, as supplemented from time to time, the Company shall advise the Agent as soon as practicable after it shall have received notice or obtained knowledge of any information or fact that would alter or affect any opinion, certificate, letter or other document provided to the Agent pursuant to this Section 3.

(u) *Maximum Amount*. The Company will not instruct the Agent to sell or otherwise attempt to sell Shares pursuant to this Agreement in excess of the Maximum Amount.

(v) *Principal Accounting Officer Certificate.* Prior to the date of the first Placement Notice and thereafter during the term of this Agreement, on each Representation Date to which a waiver does not apply, the Company shall furnish to the Agent a certificate, dated the date of such Representation Date and addressed to the Agent, of its principal financial officer or principal accounting officer with respect to certain portions of such information contained in the Prospectus, providing "management comfort" with respect to such information, in form and substance reasonably satisfactory to the Agent.

4. Conditions of Agent's Obligations. The obligations of the Agent hereunder are subject to (i) the accuracy, as of the date of this Agreement, each Representation Date, each Notice Date,

each Applicable Time, and each Settlement Date (in each case, as if made at such date) of and compliance with all representations, warranties and agreements of the Company contained herein, (ii) the performance by the Company of its obligations hereunder and (iii) the following additional conditions:

(a) *Continuing Amendments; No Stop Order*. If filing of the Prospectus, or any amendment or supplement thereto, or any Permitted Free Writing Prospectus, is required under the Securities Act, the Company shall have filed the Prospectus (or such amendment or supplement) or such Permitted Free Writing Prospectus with the Commission in the manner and within the time period so required (without reliance on Rule 424(b)(8) or Rule 164(b) under the Securities Act); the Registration Statement shall be effective; no stop order suspending the effectiveness of the Registration Statement or any part thereof, any registration statement filed pursuant to Rule 462(b) under the Securities Act, or any amendment thereof, nor suspending or preventing the use of the Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or, to the knowledge of the Company, threatened; and any request of the Commission for additional information (to be included in the Registration Statement, the Prospectus or otherwise) shall have been complied with to the Agent's satisfaction.

(b) *Absence of Certain Events*. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) *No Material Misstatement or Omission*. The Agent shall not have advised the Company in writing that the Registration Statement or the Prospectus contains an untrue statement of fact which, in the Agent's opinion, is material, or omits to state a fact which, in the Agent's opinion, is material and is required to be stated therein or necessary to make the statements therein not misleading.

(d) *No Adverse Changes*. Except as contemplated in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus, the Company shall not have incurred any material liabilities or obligations, direct or contingent,

or entered into any material transactions, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock; and there shall not have been any change in the capital stock (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares of Common Stock upon the exercise or vesting of outstanding options or warrants or awards granted pursuant to any Specified Equity Plan), or any material change in the short-term or long-term debt of the Company, or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock of the Company (other than pursuant to a Specified Equity Plan), or any Material Adverse Effect (whether or not arising in the ordinary course of business, or any loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, incurred by the Company, the effect of which, in any such case described above, in the Agent's reasonable judgment, makes it impractical or inadvisable to offer or deliver the Shares on the terms and in the manner contemplated in the Prospectus.

(e) *No Rated Securities*. There are no debt securities or preferred shares issued, or guaranteed, by the Company that are rated by a "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act.

(f) *Compliance with Certain Obligations*. The Company shall have performed each of its obligations under Sections 3(o) – 3(q) and Section 3(v).

(g) *Opinion of Agent Counsel*. On each Representation Date to which a waiver does not apply, there shall have been furnished to the Agent the opinion and negative assurance letter of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Agent, dated as of such Representation Date and addressed to the Agent, in a form reasonably satisfactory to the Agent, and such counsel shall have received such papers and information as they request to enable them to pass upon such matters; *provided, however*, the opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. shall only be required prior to the first Placement Notice, and thereafter, only a negative assurance letter of such counsel shall be required for each subsequent Representation Date.

(h) *Representation Certificate*. On or prior to the first Placement Notice, the Agent shall have received the Representation Certificate in form and substance satisfactory to the Agent and its counsel.

(i) *No Objection by FINRA*. FINRA shall have raised no objection to the fairness and reasonableness of the compensation terms and arrangements.

(j) *Timely Filing of Prospectus and Prospectus Supplement*. All filings with the Commission required by Rule 424 under the Securities Act to have been filed by the Settlement Date, as the case may be, shall have been made within the applicable time period prescribed for such filing by Rule 424 under the Securities Act.

(k) *Additional Documents and Certificates*. The Company shall have furnished to the Agent and the Agent's counsel such additional documents, certificates and evidence as they may have reasonably requested.

All opinions, certificates, letters and other documents described in this Section 4 will be in compliance with the provisions hereof only if they are reasonably satisfactory in form and substance to the Agent and the Agent's counsel. The Company will furnish the Agent with such conformed copies of such opinions, certificates, letters and other documents as the Agent shall reasonably request.

5. Indemnification and Contribution.

(a) *Company Indemnification*. The Company agrees to indemnify and hold harmless the Agent, its affiliates, directors, officers and employees, and each person, if any, who controls the Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any losses, claims, damages or liabilities, joint or several, to which the Agent may become subject, under the Securities Act or otherwise (including in settlement of any litigation), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon, in whole or in part:

(i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the Rule 430B Information (as defined below) and at any subsequent time pursuant to Rules 430A and 430B promulgated under the Securities Act, and any other information deemed to be part of the Registration Statement at the time of effectiveness, and at any subsequent time pursuant to the Securities Act or the Exchange Act, and the Prospectus, or any amendment or supplement thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference into the Prospectus), any Permitted Free Writing Prospectus, or any roadshow as defined in Rule 433(h) under the Securities Act (a ***"road show"***), or an omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading,

(ii) any inaccuracy in the representations and warranties of the Company contained herein;

(iii) any investigation or proceeding by any governmental authority, commenced or threatened (whether or not the Agent is a target of or party to such investigation or proceeding);

(iv) any failure of the Company to perform its respective obligations hereunder or under law;

and will reimburse the Agent for any legal or other expenses reasonably incurred and documented by it in connection with investigating or defending against such loss, claim, damage, liability or action; *provided, however,* that the Company shall not be liable in any such case of (i) through (iv) to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Prospectus, or any such amendment or supplement, in reliance upon and in conformity with written information furnished to the Company by the Agent specifically for use in the preparation thereof. ***"Rule 430B Information,"*** as used herein, means information with respect to the Shares and the offering thereof permitted to be omitted from the Registration Statement when it becomes effective pursuant to Rule 430B.

In addition to its other obligations under this Section 5(a), the Company agrees that, as an interim measure during the pendency of any claim, action, investigation, inquiry or other proceeding arising out of or based upon any statement or omission, or any alleged statement or omission, described in this Section 5(a), it will reimburse the Agent on a monthly basis for all reasonable and documented legal fees or other expenses incurred in connection with investigating or defending any such claim, action, investigation, inquiry or other proceeding, notwithstanding the absence of a judicial determination as to the propriety and enforceability of the Company's obligation to reimburse the Agent for such expenses and the possibility that such payments might later be held to have been improper by a court of competent jurisdiction. Any such interim reimbursement payments which are not made to the Agent within 30 days of a request for reimbursement shall bear interest at the WSJ Prime Rate (as published from time to time by the Wall Street Journal).

(b) *Agent Indemnification*. The Agent will indemnify and hold harmless the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any losses, claims, damages or liabilities to which the Company may become subject, under the Securities Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Agent), but only insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Prospectus, any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in conformity with written information furnished to the Company by the Agent specifically for use in the preparation thereof, it being understood and agreed that the only information furnished by the Agent for use in the Registration Statement or the Prospectus consists of the statements set forth in the eighth paragraph under the caption "Plan of Distribution" in the Prospectus, and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending against any such loss, claim, damage, liability or action.

(c) *Notice and Procedures*. Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof; but the omission so to notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure. In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the

defense thereof other than reasonable costs of investigation; *provided*, *however*, that if, in the sole judgment of the Agent, it is advisable for the Agent to be represented by separate counsel, the Agent shall have the right to employ a single counsel to represent the Agent, in which event the reasonable fees and expenses of such separate counsel shall be borne by the indemnifying party or parties and reimbursed to the Agent as incurred (in accordance with the provisions of the second paragraph in subsection (a) above).

The indemnifying party under this Section 5 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by this Section 5, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into, and (iii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent (a) includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and (b) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) *Contribution; Limitations on Liability; Non-Exclusive Remedy*. If the indemnification provided for in this Section 5 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other from the offering of the Shares, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Agent on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Agent on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total commissions received by the Agent (before deducting expenses) from the sale of the Shares. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the

Agent agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this subsection (d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities referred to in this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim which is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

6. Representations and Agreements to Survive Delivery. All representations, warranties, and agreements of the Company herein or in certificates delivered pursuant hereto, including but not limited to the agreements of the Agent and the Company contained in Section 5 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of the Agent or any controlling person thereof, or the Company or any of its officers, directors, or controlling persons, and shall survive delivery of, and payment for, the Shares to and by the Agent hereunder.

7. Termination of this Agreement.

(a) The Company shall have the right, by giving three (3) days' written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that (i) with respect to any pending sale, through the Agent for the Company, the obligations of the Company, including in respect of compensation of the Agent, shall remain in full force and effect notwithstanding the termination and (ii) the provisions of Section 3(g), Section 5 and Section 6 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) The Agent shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that the provisions of Section 3(g), Section 5 and Section 6 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c) Unless earlier terminated pursuant to this Section 7, this Agreement shall automatically terminate upon the earlier to occur of the issuance and sale of all of the Shares through the Agent on the terms and subject to the conditions set forth herein, except that the provisions of Section 3(g), Section 5 and Section 6 of this Agreement shall remain in full force and effect notwithstanding such termination.

(d) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 7(a), (b) or (c) above or otherwise by mutual agreement of the parties; provided that any such termination by mutual agreement shall in all cases be deemed to provide that Section 3(g), Section 5 and Section 6 shall remain in full force and effect.

(e) Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of the Shares, such sale shall settle in accordance with the provisions of Section 2(a)(vii) of this Agreement.

8. Default by the Company. If the Company shall fail at any Settlement Date to sell and deliver the number of Shares which it is obligated to sell hereunder, then this Agreement shall terminate without any liability on the part of the Agent or, except as provided in Section 3(g) hereof, any non-defaulting party. No action taken pursuant to this Section shall relieve the Company from liability, if any, in respect of such default, and the Company shall (A) hold the Agent harmless against any loss, claim or damage arising from or as a result of such default by the Company and (B) pay the Agent any commission to which it would otherwise be entitled absent such default.

9. Notices. Except as otherwise provided herein, all communications under this Agreement shall be in writing and, if to the Agent, shall be delivered via overnight delivery services to (i) Piper Sandler & Co., U.S. Bancorp Center, 800 Nicollet Mall, Minneapolis, Minnesota 55402, Attention: Equity Capital Markets, with a copy to Piper Sandler General Counsel at 800 Nicollet Mall, Minneapolis, MN 55402 and [***]; and (ii) the Company at Alaunos Therapeutics, Inc., 8030 El Rio Street, Houston, TX 77054, Attention: Legal Counsel and [***], with a copy to Covington & Burling LLP, 620 Eighth Avenue, New York, NY 10018, Attention: Brian K. Rosenzweig and [***]; or in each case to such other address as the person to be notified may have requested in writing. Any party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose.

10. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 5. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term "successors and assigns" as herein used shall not include any purchaser, as such purchaser, of any of the Shares from the Agent.

11. Absence of Fiduciary Relationship. The Company, having been advised by counsel, acknowledges and agrees that: (a) the Agent has been retained solely to act as a sales agent in connection with the sale of the Shares and that no fiduciary, advisory or agency relationship between the Company (including any of the Company's affiliates (including directors), equity holders, creditors, employees or agents, hereafter, *"Company Representatives"*), on the one hand, and the Agent on the other, has been created or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Agent has advised or is advising the Company on other matters and irrespective of the use of the defined term "Agent;" (b) neither the Agent nor any of its affiliates (including directors), equity holders, creditors, employees or agents (hereafter, *"Agent Representatives"*) shall have any duty or

obligation to the Company or any Company Representative except as set forth in this Agreement; (c) the price and other terms of any Placement executed pursuant to this Agreement, as well as the terms of this Agreement, are deemed acceptable to the Company and its counsel, following discussions and arm's-length negotiations with the Agent; (d) the Company is capable of evaluating and understanding, and in fact has evaluated, understands and accepts the terms, risks and conditions of any Placement Notice to be executed pursuant to this Agreement, and any other transactions contemplated by this Agreement; (e) the Company has been advised that the Agent and the Agent Representatives are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Agent and the Agent Representatives have no obligation to disclose any such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship, or otherwise; (f) the Company has been advised that the Agent is acting, in respect of any Placement and the transactions contemplated by this Agreement, solely for the benefit of the Agent, and not on behalf of the Company; and (g) the Company and the Company Representatives waive, to the fullest extent permitted by law, any claims that they may have against the Agent or any of the Agent Representatives for breach of fiduciary duty or alleged breach of fiduciary duty in respect of any Placement or any of the transactions contemplated by this Agreement and agree that the Agent and the Agent Representatives shall have no liability (whether direct or indirect, in contract, tort or otherwise) to the Company or any of the Company Representatives in respect of any person asserting any claim of breach of any fiduciary duty on behalf of or in right of the Company or any of the Company Representatives.

12. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that the Agent qualifies as a Covered Entity and becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from the Agent of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that the Agent qualifies as a Covered Entity and becomes subject, or a BHC Act Affiliate of the Agent becomes subject, to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against the Agent are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

(c) As used in this section:

"BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k);

"Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term

is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b);

"Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and

"U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

13. Governing Law and Waiver of Jury Trial. This Agreement and any transaction contemplated by this Agreement and any claim, controversy or dispute arising under or related thereto shall be governed by and construed in accordance with the laws of the State of New York without regard to principles of conflict of laws that would results in the application of any other law than the laws of the State of New York. THE COMPANY (ON ITS OWN BEHALF AND ON BEHALF OF ITS STOCKHOLDERS AND AFFILIATES) HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

14. Submission to Jurisdiction, Etc. Each party hereby submits to the exclusive jurisdiction of the U.S. federal and New York state courts sitting in the Borough of Manhattan, City of New York, in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. The parties hereby irrevocably and unconditionally waive any objection to the laying of venue of any lawsuit, action or other proceeding in such courts, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such lawsuit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

15. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile or electronic mail (including, without limitation, "pdf", "tif" or "jpg") and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

16. Construction. The section and exhibit headings herein are for convenience only and shall not affect the construction hereof. References herein to any law, statute, ordinance, code, regulation, rule or other requirement of any governmental authority shall be deemed to refer to such law, statute, ordinance, code, regulation, rule or other requirement of any governmental authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules and regulations promulgated thereunder. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit.

[Signature Pages Follow]

Please sign and return to the Company the enclosed duplicates of this letter whereupon this letter will become a binding agreement between the Company and the Agent in accordance with its terms.

Very truly yours,

ALAUNOS THERAPEUTICS, INC.

By: /s/ Kevin S. Boyle, Sr.
Name: Kevin S. Boyle, Sr.
Title: Chief Executive Officer

Confirmed as of the date first
above mentioned.

PIPER SANDLER & CO.

By: /s/ Michael Bassett
Name: Michael Bassett
Title: Managing Director

SCHEDULE 1

FORM OF PLACEMENT NOTICE

No Facsimile and No Voicemail

From: Alaunos Therapeutics, Inc.

To: Piper Sandler & Co.

Attention:

Neil A. Riley
[***]

Michael W. Bassett
[***]

Connor N. Anderson
[***]

Tom Wright
[***]

Jay A. Hershey
[***]

Date: [•], 20[•]

Subject: Equity Distribution Agreement – Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Equity Distribution Agreement between Alaunos Therapeutics, Inc. ("**Company**"), and Piper Sandler & Co. ("**Agent**") dated August 12, 2022 (the "**Agreement**"), the Company hereby requests that Agent sell up to [•] shares of the Company's common stock, par value $0.001 per share, at a minimum market price of $[•] per share. Sales should begin on the date of this Placement Notice and shall continue until [•] /[all shares are sold].

SCHEDULE 2

NOTICE PARTIES

Alaunos Therapeutics, Inc.

Kevin S. Boyle, Sr.
[***]

Michael Wong
[***]

Piper Sandler & Co.

Neil A. Riley
[***]

Michael W. Bassett
[***]

Connor N. Anderson
[***]

Tom Wright
[***]

Jay A. Hershey
[***]

SCHEDULE 3

FORM OF REPRESENTATION CERTIFICATE
PURSUANT TO SECTION 3(q) OF THE AGREEMENT

[Date]

Piper Sandler & Co.
800 Nicollet Mall
Minneapolis, MN 55402

Sir:

The undersigned, the duly qualified and elected [ ] and [ ], of Alaunos Therapeutics, Inc., a Delaware corporation (the "**Company**"), do hereby certify in such capacities and on behalf of the Company, pursuant to Section 3(q) of the Equity Distribution Agreement, dated August 12, 2022 (the "**Equity Distribution Agreement**"), between the Company and Piper Sandler & Co., that to the best of their respective knowledge:

(i) the representations and warranties of the Company in the Equity Distribution Agreement are true and correct, in all material respects, as if made at and as of the date of the certificate, and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the date of the certificate;

(ii) no stop order or other order suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof or the qualification of the Shares for Registration Statement, nor suspending or preventing the use of the Prospectus or any Permitted Free Writing Prospectus, has been issued, and, to the Company's knowledge, no proceeding for that purpose has been instituted or is contemplated by the Commission or any state or regulatory body;

(iii) the Shares have been duly and validly authorized by the Company and all corporate action required to be taken for the authorization, issuance and sale of the Shares has been validly and sufficiently taken;

(iv) the Registration Statement, the Prospectus and any Permitted Free Writing Prospectus, and any amendments thereof or supplements thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference therein), comply in all material respects with the requirements of the Securities Act;

(v) each part of the Registration Statement and the Prospectus, or any amendment thereof or supplements thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference therein) does not contain as of the date hereof, and did not contain, when such part of the Registration Statement (or such amendment) became effective, any untrue statement of a material fact or omit to state, as of the date hereof, and did not omit to state, when such part of the Registration Statement (or such amendment) became effective, any material fact required to be stated therein or necessary to make the statements therein not misleading;

(vi) the Prospectus, as amended or supplemented, does not include as of the date hereof, and did not include as of its date, or the time of first use within the meaning of the Securities Act, any untrue statement of a material fact or omit to state, as of the date hereof, and did not omit to state, as of its date, or the time of first use within the meaning of the Securities Act, a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading;

(vii) except as stated in the Prospectus or any Permitted Free Writing Prospectus, the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, not in the ordinary course of business, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock, and except as disclosed in the Prospectus and any Permitted Free Writing Prospectus, there has not been any material change in the capital stock (other than a change in the number of outstanding Common Stock due to sales of Shares pursuant to the Equity Distribution Agreement and the issuance of shares of Common Stock upon the exercise or vesting of outstanding options or warrants or awards granted pursuant to any Specified Equity Plan), or any material change in the short-term or long-term debt of the Company, any Material Adverse Effect (whether or not arising in the ordinary course of business) or any loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, incurred by the Company; and

(viii) except as stated in the base prospectus, the Prospectus, and any Permitted Free Writing Prospectus, there is not pending, or, to the knowledge of the Company, threatened or contemplated, any action, suit or proceeding to which the Company is a party before or by any court or governmental agency, authority or body, or any arbitrator, which, if determined adversely to the Company, would reasonably be expected to result in a Material Adverse Effect.

Capitalized terms used herein without definition shall have the meanings given to such terms in the Equity Distribution Agreement.

Alaunos Therapeutics, Inc.

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____

Code of Ethics and Conduct

Introduction

The Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") Code of Ethics and Conduct (the "Code") describes the overall environment for Alaunos operating policy and procedures. Use of the term "employees" in this Code of Conduct includes all Alaunos directors, officers and employees.

1. General Policy

Understanding and Complying with the Code

The Company takes this Code very seriously. All employees must act honestly and ethically, following the ethical standards set forth in this Code, and are to report, in a timely fashion, any possible violations that they may witness or become aware of. Doing so is not an act of disloyalty, but rather an act that shows a sense of responsibility and fairness to fellow employees, customers, suppliers and stockholders. Reporting in good faith possible violations by others will not subject the reporting employee to reprisal. In fact, retaliation or punishment for reporting suspected unethical or illegal conduct by another employee as provided in this Code or for coming forward to alert the Company to a questionable situation is against the law.

It is the responsibility of employees to read carefully and understand this Code, but the Company does not expect this Code to answer every possible question an employee may have in the course of conducting business. Furthermore, if employees are concerned about an ethical situation or are not sure whether specific conduct meets the Company's standards of conduct as set forth in this Code, employees are responsible for asking their supervisors, managers or other appropriate personnel any questions that they feel are necessary to understand the Company's expectations of them and whether any situation is or is not a violation of the Code. A good basis for deciding when to get advice is to ask whether the conduct might be embarrassing to the Company or the employees involved if the details were disclosed to the public. If it might be embarrassing, employees should seek clarification from their supervisors, managers or other appropriate personnel.

Violations of the Code

Employees who fail to comply with the Code, including supervisors who fail to detect or report wrongdoing, may be subject to corrective action up to and including termination of employment. The following are examples of conduct that may result in corrective action under the Code:

- An employee's actions that violate a Company policy;
- Requesting others to violate a Company policy;

- Failure to promptly raise a known or suspected violation of a Company policy;
- Failure to cooperate in Company investigations of possible violations of a Company policy;
- Retaliation against another employee for reporting an integrity concern; or
- Failure to demonstrate the leadership and diligence needed to ensure compliance with Company policies and applicable law.

It is important to understand that violation of certain policies may subject the Company and the individual employee involved to civil liability and damages, regulatory sanction and/or criminal prosecution. The Company is responsible for satisfying the regulatory reporting, investigative and other obligations that may follow the identification of a violation.

Reporting Violations; Confidentiality

The Company has established the following procedures for employees to use in getting help with a potential issue or reporting a possible violation of the Code or other problem. When you believe you or another employee may have violated the Code or an applicable law, rule or regulation, it is your responsibility to immediately report the violation to your supervisor or to Human Resources. Similarly, if you are a supervisor and you have received information from an employee concerning activity that he or she believes may violate the Code or that you believe may violate the Code, you must report the matter to Human Resources.

In addition to the above, you may report such concerns to the head of the Legal Department (the "Chief Legal Officer") or the Chief Executive Officer.

All reports and inquiries will be handled confidentially to the greatest extent possible under the circumstances. Employees may choose to remain anonymous, though in some cases that could make it more difficult to follow up and ensure resolution of their inquiry. As mentioned above, no employee will be subject to retaliation or punishment for reporting in good faith suspected unethical or illegal conduct by another employee as provided in this Code or for coming forward to alert the Company of any questionable situation.

Certificate of Compliance

On an annual basis, the Company will ask its senior executives and select employees to certify that they are "aware of and are in compliance with the Company's policies on ethical behavior." The certificate also requires that these executives and other employees list any known or suspected violations or questionable activities they have witnessed or heard about, or certify that they are not aware of any such violations or activities.

Waiver of Compliance

In certain limited situations, the Company may waive application of the Code. Any such waiver requires the express approval of the full Board of Directors or the Audit Committee. Furthermore, the Company will promptly disclose to its stockholders any such waivers granted to any of its officers or directors as required by applicable laws, rules or regulations.

2. **Stock**

Because our common stock is publicly traded, certain activities of the Company are subject to certain provisions of the federal securities laws. These laws govern the dissemination or use of information about the affairs of the Company or its subsidiaries or affiliates, and other information which might be of interest to persons considering the purchase or sale of the Company's securities. Violations of the federal securities laws could subject you and the Company to criminal and civil penalties. Accordingly, the Company does not sanction and will not tolerate any conduct that risks a violation of these laws.

A. Disclosure of Transactions in the Company's Securities

The U.S. Securities and Exchange Commission (the "SEC") requires continuing disclosure of transactions in the Company's publicly traded securities by the Company and its directors, officers, major stockholders and other affiliated persons. We are committed to complying with obligations related to this disclosure.

B. Insider Trading

It is illegal for any person, either personally or on behalf of others, (i) to buy or sell securities while in possession of material nonpublic information, or (ii) to communicate (to "tip") material nonpublic information to another person who trades in the securities on the basis of the information or who in turn passes the information on to someone who trades. All employees and temporary insiders, such as accountants and lawyers, must comply with these "insider trading" restrictions.

For additional information regarding insider trading, consult the Company's Insider Trading Policy. All employees are required to comply with the Company's Insider Trading Policy.

3. **Business Conduct and Practices**

As a public company, we are also committed to carrying out all continuing disclosure obligations in a full, fair, accurate, timely and understandable manner. Depending on their position with the Company, employees may be called upon to provide information to ensure that the Company fulfills that commitment. The Company expects all of its employees to take this responsibility very seriously and to provide prompt and accurate answers to inquiries related to the Company's public disclosure requirements.

Employees should promptly report to the Company's principal financial officer, principal accounting officer and/or the Chair of the Audit Committee (each a "Finance Reporting Person") any conduct that the individual believes to be a violation of law, business ethics or any provision of the Code, including any transaction or relationship that reasonably could be expected to give rise to such a violation. Violations, including failures to report potential violations by others, will be viewed as a severe disciplinary matter that may result in personnel action, including termination of employment.

Accuracy and Retention of Business Records

Employees involved in the preparation of the Company's financial statements must prepare those statements in accordance with Generally Accepted Accounting Principles, consistently applied, and any other applicable accounting standards and rules so that the financial statements

fairly present, in all material respects, the business transactions and financial condition of the Company. Further, it is important that financial statements and related disclosures be free of material errors. In particular, Company policy prohibits any employee from knowingly making or causing others to make a materially misleading, incomplete or false statement to an accountant or an attorney in connection with an audit or any filing with any governmental or regulatory entity such as the SEC or Internal Revenue Service (the "IRS"). All employees responsible for reports and documents filed with the SEC or other communications to the public should ensure that the disclosure in the report, document or other communication is full, fair, accurate, timely and understandable.

It is also prohibited for any employee to, directly or indirectly, falsify or cause others to falsify any Company or client documentation. In addition, an employee must not omit or cause others to omit any material fact that is necessary to prevent a statement made in connection with any audit, filing or examination of the Company's financial statements from being misleading. Employees are prohibited from opening or maintaining any undisclosed or unrecorded corporate account, fund or asset or any account with a misleading purpose.

The Finance Department (as defined below) and the Company's accounting department have Company-wide responsibility for developing, administering and coordinating the record management program which establishes procedures for the retention, storage, retrieval and destruction of all records created or received by the Company. The records must be maintained in compliance with applicable statutory, regulatory and contractual requirements and consistent with prudent business practices. Employees can contact the Chief Legal Officer for specific information on record retention.

Destruction or falsification of any document that is potentially relevant to a violation of law or a government investigation may lead to prosecution for obstruction of justice. Therefore, if an employee has reason to believe that a violation of the law has been committed or that a government investigation has been or is about to be commenced, he or she must retain all records (including computer records) that could be relevant. Questions with regard to destruction or retention of documents in this context should be directed to the Chief Legal Officer.

All Company books, invoices, records, accounts, funds and assets must be created and maintained to reflect fairly and accurately and in reasonable detail the underlying transactions and disposition of Company business. No entries may be made that intentionally conceal or disguise the true nature of any Company transaction.

In addition, if an employee believes that the Company's books and records are not being properly maintained in accordance with these requirements, the employee should report the matter directly to his or her supervisor or to a Finance Reporting Person. Any complaints or concerns regarding accounting, internal controls or auditing matters should be reported directly to the Chair or another member of the Audit Committee.

Special Ethical Obligations For Employees With Financial Reporting Responsibilities

In addition to the Company's Chief Executive Officer, the Company's senior financial officers (the "Finance Department") bear a special responsibility for promoting integrity throughout the organization. The Chief Executive Officer and the Finance Department have a special role: both to adhere to these principles themselves and also to ensure that a culture exists throughout the Company that ensures the full, fair, accurate, timely and understandable reporting of the Company's financial results and condition.

Because of this special role, the Chief Executive Officer and the Finance Department are bound by the following additional Financial Officer Code of Ethics, and by accepting this Code, each agrees that he or she will:

- Act with honesty and integrity, avoiding actual or apparent conflicts of interest in personal and professional relationships;
- Provide information that is accurate, complete, objective, relevant, timely and understandable to ensure full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, government agencies and in other public communications;
- Comply with rules and regulations of federal, state, provincial and local governments and other appropriate private and public regulatory agencies;
- Act in good faith, responsibly, with due care, competence and diligence, without misrepresenting material facts or allowing one's independent judgment to be subordinated;
- Respect the confidentiality of information acquired in the course of his or her work;
- Not use confidential information acquired in the course of his or her work for personal advantage;
- Proactively promote and be an example of ethical behavior; and
- Use all assets and resources entrusted responsibly.

In addition, the Chief Executive Officer and the Finance Department are subject to the following policies:

A. The Chief Executive Officer and the Finance Department are responsible for full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the Company with the SEC. Accordingly, it is the responsibility of the Chief Executive Officer and each member of the Finance Department promptly to bring to the attention of a Finance Reporting Person any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings.

B. The Chief Executive Officer and each member of the Finance Department shall promptly bring to the attention of a Finance Reporting Person any information he or she may have concerning (a) significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's

financial reporting, disclosures or internal controls.

C. The Chief Executive Officer and each member of the Finance Department shall promptly bring to the attention of the Chief Legal Officer or the Audit Committee any information he or she may have concerning any violation of the Code, including any apparent conflicts of interest between personal and professional relationships, involving any employees who have a significant role in the Company's financial reporting, disclosures or internal controls.

D. The Chief Executive Officer and each member of the Finance Department shall promptly bring to the attention of the Chief Legal Officer or the Audit Committee any information he or she may have concerning evidence of a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof.

E. The Board of Directors shall determine, or designate appropriate persons to determine, appropriate actions to be taken in the event of violations of the Code by the Chief Executive Officer or any member of the Finance Department. Such actions shall be reasonably designed to deter wrongdoing and to promote accountability for adherence to the Code, and shall include written notices to the individual involved that the Board of Directors has determined that there has been a violation, censure by the Board of Directors, demotion or re-assignment of the individual involved, suspension with or without pay or benefits (as determined by the Board of Directors) and termination of the individual's employment. In determining what action is appropriate in a particular case, the Board of Directors or such designee shall take into account all relevant information, including the nature and severity of the violation, whether the violation was a single occurrence or repeated occurrences, whether the violation appears to have been intentional or inadvertent, whether the individual in question had been advised prior to the violation as to the proper course of action and whether or not the individual in question had committed other violations in the past.

4. **Company Property**

All employees should protect the Company's assets and ensure their efficient use. The Company's assets, whether tangible or intangible, are to be used only by authorized employees or their designees and only for legitimate business purposes of the Company.

Employees are not permitted to take or make use of, steal or knowingly misappropriate the assets of the Company or any customer or vendor, including confidential information of the Company, for the employee's own use, the use of another or for an improper or illegal purpose. Employees are not permitted to remove or dispose of anything of value belonging to the Company without the Company's consent. No employee may destroy Company assets without permission. Participation in unlawful activities or possession of illegal items or substances by an employee, whether on Company property or business or not, is prohibited.

5. **Fraud and Theft**

Company policy prohibits fraudulent activity and establishes procedures to ensure that incidents of fraud and theft relating to the Company are promptly investigated, reported and, where appropriate, prosecuted. Fraudulent activity can include actions committed by an employee that injure suppliers and customers, as well as those that injure the Company and its employees.

Employees who suspect that any fraudulent activity may have occurred must immediately report such suspicion to a Finance Reporting Person. Such Finance Reporting Person should be contacted before any action is taken with respect to the individual accused of perpetrating the suspected fraudulent activity. Such allegations, if proven to be factual, may lead to the dismissal of the employee, the involvement of local law enforcement and actions to recover Company funds or property. No employee or agent may sign a criminal complaint on behalf of the Company without prior written approval of the Chief Legal Officer.

6. **Payments and Gifts to Third Parties**

Any payment made by the Company to a third party must be made only for identifiable services that were performed by the third party for the Company. In addition, the payment must be reasonable in relation to the services performed. It is the Company's policy not to offer gifts or gratuities to persons, firms or entities with whom the Company does or might do business, except for modest items (modest is defined as less than $100.00).

Employees are not permitted to give, offer or promise payments or gifts with the intent to influence (or which may appear to influence) a third party or to place such party under an obligation to the donor. There are also other public, as well as private, institutions that have established their own internal rules regarding the acceptance of gifts or entertainment. Employees should become familiar with any such restrictions affecting those with whom they deal.

7. **Privacy**

It is Company policy to protect individual consumer, medical, financial and other sensitive personal information that the Company collects from or maintains about employees or individual consumers or customers by complying with all applicable privacy and data protection laws, regulations and treaties.

Employees must take care to protect individually identifiable employee, consumer or customer information and other sensitive personal information from inappropriate or unauthorized use or disclosure.

Employees may not acquire, use or disclose individual employee, consumer or customer information in ways that are inconsistent with the Company's privacy policies or with applicable laws, regulations or treaties. Finally, employees should consult with the Chief Legal Officer before establishing or updating any system, process or procedure to collect, use, disclose or transmit individual employee, consumer or customer information, medical or financial records or other sensitive personal information.

8. **Confidential Information**

Company assets also include confidential and proprietary information relating to the present or planned business of the Company that has not been released publicly by authorized Company representatives. Confidential information is information not generally known to the public that a company would normally expect to be nonpublic and that might be harmful to the Company's competitive position, or harmful to the Company or its customer, if disclosed, and includes, but is not limited to:

- Computer programs, data, formulas, software and compositions;
- Customer and supplier information;
- Financial data;
- Inventions;
- Marketing and sales programs;
- New product designs;
- Possible acquisition or divestiture activity;
- Pricing information and cost data;
- Regulatory approval strategies;
- Research and development information;
- Services techniques and protocols;
- Trade secrets and know-how; and
- Strategic business plans.

Except as specifically authorized or legally mandated, employees, consultants, agents and representatives are expected to maintain the confidentiality of information entrusted to them by the Company or its customers and shall not disclose or use, either during or subsequent to their employment by or the term of any other relationship with the Company, any such information they receive or develop during the course of Company employment or any such other relationship which is considered proprietary by the Company or its customers. Confidential information may be disclosed within the Company only on a need-to-know basis. Employees should not attempt to obtain confidential information that does not relate to their employment duties and responsibilities.

Employees, consultants, agents and representatives should not discuss confidential matters in the presence or within the hearing range of unauthorized persons, such as in elevators (even on Company property), restaurants, taxis, airplanes or other publicly accessible areas. Care should be used in the use of cellular telephones or other means of communication that are not secure. Confidential information should not be discussed with family, relatives or business or social acquaintances.

In instances where it is appropriate for business reasons to disclose Company confidential information to third parties, the Chief Executive Officer or the Chief Legal Officer or their designee, must be contacted before the disclosure for preparation of an appropriate agreement that includes the necessary safeguards.

Furthermore, obtaining confidential information from a third party without adequate legal safeguards is improper and may expose the Company to legal risks. Accordingly, no employee, consultant agent or representative may accept such information without the advice of the Chief Executive Officer or Chief Legal Officer, or their designee, and until an agreement in writing has been reached with the third party. After such information is obtained, its confidentiality must be protected as provided in the agreement.

No employee, consultant, agent or representative may disclose or use any confidential information gained during Company employment or any other Company relationship for personal profit or to the advantage of the employee or any other person.

9. **Computer Resources and Computer Security**

The Company's computer resources are Company assets. Computer resources include, but are not limited to, all of the Company's processing hardware, software, networks and networking applications and associated documentation. The Company expects all employees utilizing our computer and other electronic resources to observe the highest standard of professionalism at all times. This includes respecting and maintaining the integrity and security of all Company computer and communication systems and utilizing those systems only for the furtherance of Company business. It also includes respecting the values of the Company, and each individual within it, by creating and sending only appropriate messages. To this end, the following policies and principles apply:

- Employees are responsible for ensuring the integrity and confidentiality of their unique user identification codes and passwords; any suspected breach must be reported to appropriate management immediately.
- Employees are not permitted to access a computer without authorization or to exceed authorized access with the intent of securing information contained in the Company's financial records or records concerning clients or other employees.
- Employees are expected to log out of systems that do not support an automated log out process, when leaving them unattended.
- Employees are not permitted to alter, damage or destroy information without authorization.
- An employee's misappropriation, destruction, misuse, abuse or unauthorized use of computer resources is prohibited.
- Employees may not obstruct the authorized use of a computer or information.
- Employees are not permitted to use the Company's computer resources for personal gain.
- The Company reserves the right to monitor its computer resources in order to prevent their improper or unauthorized use.
- Access to systems, data and software must be restricted to authorized personnel, preauthorized by an employee's supervisor and consistent with such employee's job responsibilities.
- Employees may not utilize electronic mail systems, the Internet or other electronic facilities for inappropriate communication, and must adhere to applicable supervisory and regulatory requirements when utilizing such systems as part of their business function; the viewing, downloading or accessing of sexually explicit material is strictly prohibited.
- All employees must comply with applicable copyright laws which impose certain restrictions on the use of computer software.

10. **Intellectual Property**

The Company's intellectual property is a very valuable asset. Intellectual property includes such things as trade secrets, trademarks, copyrights, service marks and other proprietary information. Employees are required to protect and preserve the Company's intellectual property. In order to do so, employees are required to observe the following guidelines:

- Employees must treat the Company's intellectual property as a trade secret; outside commercial or personal use is strictly prohibited; any misappropriation of the Company's assets will be treated as a theft; in order to protect a trade secret, the information must be properly secured and treated as confidential.
- Innovations are ideas concerning products and may be eligible for patent, copyrights, trademark or other trade secret protection; unauthorized disclosures may jeopardize these valuable protections.
- Any intellectual property created on the Company's time and/or using the Company's resources is "work made for hire" under copyright law and all rights to such materials belong exclusively to the Company; employees are required to consult with the Chief Executive Officer or the Chief Legal Officer, or their designee, if they have any questions regarding such intellectual property.
- Copyright notice should appear on all materials and works produced at the Company, other than internal memoranda and routine correspondence.
- Employees must obtain permission from the Chief Executive Officer or the Chief Legal Officer, or their designee, prior to using the Company's name in marketing materials, press releases or press interview.

Not all intellectual property in use at the Company is owned by the Company. Employees must respect others' intellectual property, including our clients' proprietary information, and use such property only in accordance with the rights expressly granted to the Company.

As a general rule, United States copyright law makes it a federal crime to copy computer software or related documentation without the express authorization of the copyright owner. In addition, employees are not permitted to remove copyright notices from software or its documentation.

Copying copyrighted software and issuing additional copies for use by other employees of the Company or outside parties is prohibited. Modification of vendor personal computer programs is also prohibited unless the Company has been granted express rights to do so by the copyright owner. Failure to comply with software license agreements exposes the Company to potential litigation, and any employee misconduct in connection therewith is considered as a basis for termination.

Employees may not install software purchased personally on Company equipment for use by co-workers or others without permission and the appropriate license agreement.

"Multimedia" works—works which combine video, text, software and music—are also subject to copyrighted law. Therefore, all multimedia presentations that may have copyright issues should be reviewed by the Chief Executive Officer or the Chief Legal Officer, or their designee, before they are presented outside the Company to ensure that all licensing issues have been properly addressed.

11. **Family Members and Close Personal Relationships**

Conflicts of interest may arise when doing business with or competing with organizations in which employees' family members have an ownership or employment interest. Family members include spouses, parents, children, siblings and in-laws. Employees may not conduct business on behalf of the Company and may not use their influence to get the Company to do business with family members or an organization with which an employee or an employee's family member is associated unless specific approval has been granted in advance by the Chief Legal Officer.

Directors and executive officers may not seek or accept loans or guarantees of obligations from the Company for themselves or their family members. Other employees may not seek or accept new loans or guarantees of obligations from the Company for themselves or their family members without the consent of the Chief Legal Officer. In addition, employees may not seek or accept loans or guarantees of obligations (except from banks and other entities that are in the business of making such loans), for themselves or their family members, from any individual, organization or business entity doing or seeking to do business with the Company. Employees must report to their supervisor promptly all offers of the above type, even when refused.

Conflicts of interest may also arise where co-workers are family members (as defined above) or are in a consensual personal and/or sexual relationship, and a supervisory relationship exists. Any supervisory employee involved in such a relationship is required to report the relationship to his or her supervisor and to Human Resources. If such relationships arise, they will be considered carefully by Company officials, and appropriate action will be taken. Such action may include, but is not limited to, a change in the responsibilities of the individuals involved in such relationships or transfer within the Company.

12. **Ownership in Other Businesses**

Neither an employee nor his or her family members (individually or collectively) may own, directly or indirectly, a significant financial interest in any business entity that does or seeks to do business with, or is in competition with, the Company unless specific written approval has been granted in advance by the Chief Executive Officer or the Chief Legal Officer. A "significant financial interest" is defined as ownership of more than 5% of the outstanding securities/capital value of an entity or where such an interest represents more than 5% of the total assets of the employee and/or family members.

13. **Corporate Opportunities**

It is Company policy that employees may not take for themselves personally opportunities that are discovered through the use of Company property, information or position, nor may they use Company property, information or position for personal gain. Furthermore, employees should not compete with the Company unless such competition is disclosed to the Chief Executive Officer or the Chief Legal Officer and approved in advance. Employees have a duty to the Company to advance its legitimate interests when the opportunity to do so arises.

Employees are prohibited from directly or indirectly buying, or otherwise acquiring rights to, any property or materials, when such persons know that the Company may be interested in pursuing such opportunity.

14. **Outside Employment, Affiliations or Activities**

An employee's primary employment obligation is to the Company. Any outside activity, such as a second job or self-employment, must be kept completely separate from their activities with the Company. Employees may not use Company customers, suppliers, time, name, influence, assets, equipment, facilities or materials or services of other employees for outside activities unless specifically authorized by the Company, including in connection with charitable, political or other volunteer work.

Employees may not do any of the following without first disclosing that fact in writing to their immediate supervisor and to the Chief Executive Officer or the Chief Legal Officer.

- Accept business opportunities, commissions, compensation or other inducements, directly or indirectly, from persons or firms that are customers, vendors or business partners of the Company;
- Acquire Company property or services on terms other than those available to the general public or those specifically identified by the Company; or
- Engage in any conduct with customers, vendors or any other person or entity with whom the Company does business or seeks to do business when the conduct might or might appear to compromise the employee's judgment or loyalty to the Company.

Additionally, if an employee's family member works for a business that is itself in direct competition with the Company, this circumstance must be disclosed to the Chief Executive Officer or the Chief Legal Officer.

15. **Receiving Gifts, Gratuities and Entertainment**

Employees and their family members must not accept, directly or indirectly, gifts or gratuities from persons, firms or entities with whom the Company does or might do business that are greater than nominal in value. Any question you may have regarding whether a gift or benefit sought to be bestowed upon you is nominal should be brought to the Chief Legal Officer. Gifts or gratuities that affect or give the appearance that the employee's business judgment could be affected must be avoided and refused. Gifts or gratuities that are acceptable are only those that reflect common courtesies and responsible business practice.

There are some cases where refusal of a valuable gift would be offensive to the person offering it. This is particularly true when employees are guests in another country, and the gift is something from that country offered as part of a public occasion. All gifts greater than the nominal value (as previously defined) should be considered gifts to the Company for the benefit of the Company as a whole and not for the benefit of an individual employee. Accordingly, the employee to whom the gift was offered may accept the gifts on behalf of the Company, report it to a supervisor, and turn it over to the Company.

Entertainment by companies is an accepted business practice and persons, firms or entities with whom the Company does or might do business with may want to entertain Company employees from time to time. Such entertainment should be limited to events or activities that are reasonable and are considered normal business practice. Entertainment that may affect or give the appearance that it affects the employee's business judgment must be avoided and refused.

The Company, as a responsible corporate citizen, can make donations of money or products to worthy causes, including fundraising campaigns conducted by its customers. To remain an appropriate donation, the contribution should not be connected to any specific customer purchases or purchasing commitments. In addition, recognition for any donations made by the Company should be directed toward the Company and not an individual employee.

Customer requests for donations of significant sums of money should be forwarded to a senior-level manager. Employees are not permitted to make a donation at a customer's request and then seek reimbursement from the Company as a business expense. All corporate donations must be approved and paid by the Company.

16. **Fair Dealing**

Each employee should endeavor to deal fairly with the Company's customers, suppliers, competitors and other employees. No employee should take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practice.

17. **Relationships with Suppliers or Service Providers**

The Company encourages good supplier relations. However, employees may not benefit personally, whether directly or indirectly, from any purchase of goods or services for or from the Company. Employees whose responsibilities include purchasing (be it merchandise, fixtures, services, real estate or other), or who have contact with suppliers or service providers must not exploit their position for personal gain. Under no circumstances may any employee receive cash or cash equivalents from any supplier, whether directly or indirectly.

It is accepted business practice for vendors to distribute samples to potential purchasers. Company policy is that, to the extent necessary to make a reasoned appraisal of new products, samples of such products may be accepted in small quantities only by employees responsible for procuring or merchandising such products.

18. **Consultants and Agents**

Whenever it becomes necessary to engage the services of an individual or firm to consult for or represent the Company, special care must be taken to ensure that no conflicts of interest exist between the Company and the person or firm to be retained. Employees must also ensure that outside consultants and agents of the Company are reputable and qualified. Agreements with outside consultants or agents should be in writing.

No employee may, indirectly or through an agent, do anything prohibited under this Code. Agents are required to observe the same standards of conduct as Company employees when conducting business for the Company.

19. **Unfair Competition**

Federal and state laws prohibit unfair methods of competition and unfair or deceptive acts and practices. These laws are designed to protect competitors and consumers. While it is impossible to list all types of prohibited conduct, some examples include:

- Commercial bribery or payoffs to induce business or breaches of contract by others;
- Acquiring a competitor's trade secrets through bribery or theft;
- Making false, deceptive or disparaging claims or comparisons regarding competitors or their products; and
- Making affirmative claims concerning one's own products without a reasonable basis for doing so; in particular, all public statements by or on behalf of the Company, including in connection with advertising, promotional materials, sales representatives and guarantees, should always be truthful and have a reasonable basis in fact and should not be misleading or purposefully made easily susceptible of misinterpretation.

20. **Relations with Government Agencies and Outside Organizations**

Generally

The Company must take special care to comply with all the special legal and contractual obligations applicable to transactions with government authorities. Violations of such laws may result in penalties and fines, as well as debarment or suspension from government contracting, or possible criminal prosecution of individual employees or the Company.

Selling to Government Institutions

Employees must strictly adhere to the Anti-Kickback Act of 1986, which prohibits government contractors and subcontractors from giving or receiving anything of value in order to receive favorable treatment. The Chief Legal Officer should be consulted in connection with federal government contracts.

Political Contributions and Activities

Employees must obey the laws of the United States in promoting the Company's position to government authorities and in making political contributions. Political contributions by the Company to United States federal, state or local political candidates may be prohibited or regulated under the election laws. Employees may not use corporate funds to contribute to a political party, committee, organization or candidate in connection with a political campaign without the review and written approval of the Chief Executive Officer.

Personal Involvement

Employees are encouraged to participate in the political process. Voting, expressing views on public policy, supporting and contributing to candidates and political parties and seeking public office are a few of the ways employees may choose to be involved. In the conduct of their personal civic and political affairs, employees should at all times make clear that their views and actions are their own and are not those of the Company. The Company does not seek to limit the activities in which employees may participate on their own time, or the contributions they may voluntarily make with their own funds. Employees who seek elective office or accept appointive office must notify their manager and indicate how the duties of the office will affect their job performance.

Government Procurement

It is Company policy to sell to all customers, including government-related entities, in an ethical, honest and fair manner. Listed below are some of the key requirements of doing business with the government:

- Accurately representing which Company products are covered by government contracts;
- Providing high-quality products at fair and reasonable prices;
- Not offering or accepting kickbacks, bribes, gifts or other gratuities;
- Not soliciting or obtaining proprietary or source-selection information from government officials prior to the award of a contract;
- Hiring present and former government personnel only in compliance with applicable laws and regulations; and
- Complying with laws and regulations ensuring the ethical conduct of participants in procurement set forth by federal, state and municipal agencies.

Tax Violations

The Company and its employees, whether acting on behalf of the Company or individually, are not permitted to attempt to evade taxes or the payment of taxes. Employees may not solicit customers on the basis of, or actively participate in assisting customers in attempting to, evade tax laws. The Company and its employees, whether acting on behalf of the Company or individually, are not permitted to (i) make false statements to local tax authorities regarding any matter, (ii) file fraudulent returns, statements, lists or other documents, (iii) conceal property or withhold records from local tax authorities, (iv) willfully fail to file tax returns, keep required records or supply information to local tax authorities, or (v) willfully fail to collect, account for or pay a tax.

To comply with IRS regulations, the Company requires that prizes awarded by the Company (or any of its United States affiliates) to employees in connection with business-related contests and promotions be reported to the payroll department for inclusion in the employee’s reportable income.

The Company has additional tax obligations to its employees and local tax authorities. For example, it must provide wage statements to its employees, collect and deposit income and employment taxes.

In addition to complying with the tax laws, employees must, in cooperation with the Chief Legal Officer, cooperate fully with any regulatory entity or governmental authority. Moreover, employees may not interfere with the administration of the tax laws (e.g., bribing a tax agent). To this end, employees are required, in consultation with the Chief Legal Officer, to respond promptly to inquiries from a tax authority, including summons to testify or produce books, accounts, records, memoranda or other papers.

Revised and Approved: August 12, 2022

Code of Ethics and Conduct

Employee Acknowledgement Form

Attached to this acknowledgement is the Code of Ethics and Conduct of Alaunos Therapeutics, Inc. ("Alaunos"). The undersigned employee of Alaunos, by signing and returning this form to the Manager of Human Resources of Alaunos, hereby acknowledges that he or she has received the attached statement, has fully reviewed it, and will abide by its terms at all times.

_____ _____

Employee Date [if not Docusigned]

_____

Typed Name of Employee
[If not Docusigned]

This signed Employee Acknowledgement Form should be returned as soon as possible to the Human Resources Department.

PLEASE KEEP A COPY OF THE ATTACHED CORPORATE CODE OF ETHICS AND BUSINESS CONDUCT IN YOUR COMPANY WORKPLACE WITH ALL OTHER IMPORTANT COMPANY POLICIES

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Kevin S. Boyle, Sr., certify that:

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

Date: August 15, 2022

/s/ Kevin S. Boyle, Sr.
Kevin S. Boyle, Sr.
Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial 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

In connection with the Quarterly Report of Alaunos Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin S. Boyle, Sr., Principal Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Kevin S. Boyle, Sr.
Kevin S. Boyle, Sr.
Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer
August 15, 2022