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 September 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 November 9, 2022, the number of outstanding shares of the registrant's common stock, $0.001 par value, was 216,182,042 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
- the impact on our business from a pandemic, epidemic or outbreak, including the COVID-19 pandemic.

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, we were 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 cellular 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.

Table of Contents

Item 1. Financial Statements

Alaunos Therapeutics, Inc.

BALANCE SHEETS
(unaudited)

(in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 37,807	$ 76,054
Restricted cash	13,938	—
Receivables	2,911	1,111
Prepaid expenses and other current assets	849	1,666
Total current assets	55,505	78,831
Property and equipment, net	9,050	10,941
Right-of-use asset	2,247	4,420
Deposits	42	42
Other non-current assets	500	631
Total assets	$ 67,344	$ 94,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,984	$ 1,368
Current portion of long-term debt	22,668	7,868
Accrued expenses	7,675	6,076
Lease liability, current	542	729
Total current liabilities	32,869	16,041
Long-term debt	—	16,250
Lease liability, non-current	2,334	4,518
Other non-current liabilities	28	—
Total liabilities	$ 35,231	$ 36,809
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock $0.001 par value; 420,000,000 shares authorized, 216,182,042 shares issued and outstanding at September 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	903,365	900,693
Accumulated deficit	(871,468)	(842,852)
Total stockholders' equity	32,113	58,057
Total liabilities and stockholders' equity	$ 67,344	$ 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 2,911	$ 398	$ 2,911	$ 398
Operating expenses:				
Research and development	7,893	14,521	19,411	41,427
General and administrative	3,282	8,173	10,217	25,469
Gain on lease modification	—	—	(133)	—
Total operating expenses	11,175	22,694	29,495	66,896
Loss from operations	(8,264)	(22,296)	(26,584)	(66,498)
Other income (expense):				
Interest expense	(841)	(444)	(2,266)	(444)
Other income (expense), net	254	7	279	(15)
Other income (expense), net	(587)	(437)	(1,987)	(459)
Net loss	$ (8,851)	$ (22,733)	$ (28,571)	$ (66,957)
Basic and diluted net loss per share	$ (0.04)	$ (0.11)	$ (0.13)	$ (0.31)
Weighted average common shares outstanding, basic and diluted	215,098,995	214,542,465	215,015,377	214,310,349

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 September 30, 2022

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2022	216,174,542	$ 216	$ 902,536	$ (862,572)	$ 40,180
Stock-based compensation	—	—	808	—	808
Exercise of employee stock options	26,250	—	21	—	21
Repurchase of common stock	(18,750)	—	—	(45)	(45)
Net loss	—	—	—	(8,851)	(8,851)
Balance at September 30, 2022	216,182,042	$ 216	$ 903,365	$ (871,468)	$ 32,113

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

For the Nine Months Ended September 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	—	—	2,651	—	2,651
Restricted stock awards	280,000	—	—	—	—
Cancelled restricted common stock	(232,901)	—	—	—	—
Exercise of employee stock options	26,250	—	21	—	21
Repurchase of common stock	(18,750)	—	—	(45)	(45)
Net loss	—	—	—	(28,571)	(28,571)
Balance at September 30, 2022	216,182,042	$ 216	$ 903,365	$ (871,468)	$ 32,113

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

For the Three Months Ended September 30, 2021

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2021	215,559,148	$ 216	$ 896,390	$ (808,325)	$ 88,281
Stock-based compensation	—	—	2,371	—	2,371
Restricted stock awards	875,000	—	—	—	—
Cancelled restricted common stock	(288,344)	—	—	—	—
Issuance of warrants	—	—	788	—	788
Net loss	—	—	—	(22,733)	(22,733)
Balance at September 30, 2021	216,145,804	$ 216	$ 899,549	$ (831,058)	$ 68,707

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

For the Nine Months Ended September 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	—	—	9,857	—	9,857
Exercise of employee stock options	363,109	—	1,037	—	1,037
Restricted stock awards	1,601,224	1	(1)	—	—
Cancelled restricted common stock	(410,435)	—	—	—	—
Issuance of warrants	—	—	788	—	788
Net loss	—	—	—	(66,957)	(66,957)
Balance at September 30, 2021	216,145,804	$ 216	$ 899,549	$ (831,058)	$ 68,707

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

Alaunos Therapeutics, Inc.

STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (28,571)	$ (66,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,065	1,892
Amortization of financing costs	634	148
Stock-based compensation	2,651	9,857
Decrease (increase) in the carrying amount of right-of-use assets	2,306	(529)
Gain on lease modification	(133)	—
(Increase) decrease in:		
Receivables	(1,800)	3,155
Prepaid expenses and other current assets	817	7,646
Other non-current assets	131	508
Increase (decrease) in:		
Accounts payable	616	503
Accrued expenses	1,525	(3,169)
Lease liabilities	(2,371)	604
Other non-current liabilities	28	—
Net cash used in operating activities	(22,102)	(46,342)
Cash flows from investing activities:		
Purchases of property and equipment	(100)	(2,964)
Net cash used in investing activities	(100)	(2,964)
Cash flows from financing activities:		
Proceeds from long-term debt borrowing	—	25,000
Debt issuance costs	—	(75)
Proceeds from the exercise of stock options	21	1,037
Repurchase of common stock	(45)	—
Repayment of long-term debt	(2,083)	—
Net cash provided by (used in) financing activities	(2,107)	25,962
Net decrease in cash, cash equivalents and restricted cash	(24,309)	(23,344)
Cash, cash equivalents and restricted cash, beginning of period	76,054	115,069
Cash, cash equivalents and restricted cash, end of period	$ 51,745	$ 91,725
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 1,603	$ 136
Amounts included in accrued expenses and accounts payable related to property and equipment	$ 74	$ 348

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 autologous 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 September 30, 2022, the Company had approximately $37.8 million of cash and cash equivalents and $13.9 million of restricted cash related to the Company's debt agreement (see Note 4). The Company's accumulated deficit at September 30, 2022 was approximately $871.5 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, 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 September 30, 2022, there were 216,182,042 shares of common stock outstanding and an additional 33,545,557 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 nine months ended September 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.

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 extended the interest-only period through August 31, 2022. The Amended Milestones (as defined below) were not met by the Company on or prior to August 31, 2022, and therefore, the interest-only period was not extended beyond August 31, 2022. The Amendment also 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.

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

2022 Equity Distribution Agreement

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 $50.0 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. During the three and nine months ended September 30, 2022, there have been no sales of the Company's common stock under the Equity Distribution 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)	September 30, 2022	December 31, 2021
Loan and Security Agreement	$ 23,461	$ 25,209
Unamortized discount on Loan and Security Agreement	(793)	(1,091)
Total debt	$ 22,668	$ 24,118

As of September 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 September 30, 2022, interest on the outstanding loans was 10.75%. The Amended Loan and Security Agreement provided for an interest-only period through August 31, 2022. On or prior to August 31, 2022, the Company had not (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, nor (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”), and, therefore, the interest-only period was not extended beyond August 31, 2022. Commencing on September 1, 2022, aggregate outstanding borrowings are payable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023. 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 amount being prepaid, ranging from 1.00% to 2.00%, of the SVB Facility, each such prepayment to be at least $5.0 million plus all accrued and unpaid interest on the portion being prepaid.

As a result of not achieving the Amended Milestones on or prior to August 31, 2022, the Amended Loan and Security Agreement required 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. As of September 30, 2022, the Company has collateralized $13.9 million, which is classified as restricted cash on the balance sheet. So long as no event of default has occurred and subject to certain other terms related to the remaining outstanding balance under the SVB Facility being satisfied, $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. 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 achieved 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 $0.8 million for the three months ended September 30, 2022 and was $2.3 million for the nine months ended September 30, 2022, compared to $0.4 million for the three and nine months ended September 30, 2021.

The fair value of the Amended Loan and Security Agreement as of September 30, 2022 approximates its face value.

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 September 30, 2022 and December 31, 2021 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of September 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	$ 36,807	$ 36,807	$ —	$ —

($ 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.

There have been no changes to the valuation methods during the nine months ended September 30, 2022. We had no financial assets or liabilities that were classified as Level 2 or Level 3 during the nine months ended September 30, 2022.

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 September 30, 2022 and 2021, respectively:

	September 30,	
	2022	2021
Common stock options	10,623,215	11,072,894
Inducement stock options	-	97,500
Unvested restricted stock	940,000	1,510,655
Warrants	22,922,342	22,705,571
	34,485,557	35,386,620

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 nine months ended September 30, 2022, the Company recorded no expenses for Vineti, compared to $0.1 million of expenses for the three months ended September 30, 2021 and $0.4 million for the nine months ended September 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 nine months ended September 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 April 2022, the Company modified its real estate lease agreement executed on December 15, 2020 with MD Anderson for office space in Houston, which 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 recorded on the lease modification during the nine months ended September 30, 2022.

In June 2022, the Company executed an agreement to sub-sublease 4,772 square feet of subleased office space in Boston. The term of the sub-sublease is from July 1, 2022 to June 30, 2025 and provides the sub-subtenant with an option to extend through to July 31, 2026. For the three and nine months ended September 30, 2022, the Company recognized $44 thousand in lease income, which is classified within other income (expense), net in the statement of operations.

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 September 30, 2022, the Company incurred clinical expenses of $0.3 million from MD Anderson related to this agreement compared to $0 for the three months ended September 30, 2021. For the nine months ended September 30, 2022, the Company incurred clinical expenses of $0.7 million from MD Anderson related to this agreement compared to $0 for the nine months ended September 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 September 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 was 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 nine months ended September 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 September 30, 2022, the Company recognized $0.1 million in license payments to the NCI under this agreement, compared to $0.3 million for the three months ended September 30, 2021. For the nine months ended September 30, 2022,

the Company recognized $0.5 million in license payments to the NCI under this agreement, compared to $0.6 million for the nine months ended September 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 nine months ended September 30, 2022, as compared to $0 for the three months ended September 30, 2021 and $1.3 million for the nine months ended September 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 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 nine months ended September 30, 2022, $2.5 million was expensed as a one-time milestone payment under the terms of the agreement, compared to $0.1 million for the three and nine months ended September 30, 2021. During the three and nine months ended September 30, 2022 and 2021, the Company did not incur royalty expenses on sales under this 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 (as so amended, the "Solasia License and Collaboration Agreement"). Pursuant to the Solasia 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 Solasia License and Collaboration Agreement, will receive a portion of all milestone and royalty payments made by Solasia to the Company in accordance with the terms of the Solasia License and Collaboration Agreement with the licensors, as described above.

In June 2022, Solasia announced that darinaparsin had been approved from relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the three and nine months ended September 30, 2022, the Company recorded $2.9 million of collaboration revenue under the Solasia License and Collaboration Agreement primarily related to Solasia's achievement of certain sales-based milestones in Japan. During the three and nine months ended September 30, 2021, the Company recorded $0.4 million of collaboration revenue under the Solasia License and Collaboration Agreement. During the three and nine months ended September 30, 2022 and 2021, the Company did not record royalty revenues on net sales of darinaparsin under this agreement.

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 September 30,		For the Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Research and development	145	535	673	2,115
General and administrative	663	1,836	1,978	7,742
Stock-based compensation expense	$ 808	$ 2,371	$ 2,651	$ 9,857

The Company granted an aggregate of 1,275,000 stock options during the three months ended September 30, 2022, with a weighted-average grant date fair value of $1.52 per share, and granted an aggregate of 4,667,500 stock options during the nine months ended September 30, 2022, with a weighted-average grant date fair value of $0.67 per share. The Company granted an aggregate of 2,755,000 stock options during the three months ended September 30, 2021, with a weighted-average grant date fair value of $1.08 per share, and granted an aggregate of 7,150,438 stock options during the nine months ended September 30, 2021, with a weighted-average grant date fair value of $1.91 per share.

For the three and nine months ended September 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.94 – 3.62%	0.89 – 0.96%	1.63 – 3.62%	0.50 – 1.15%
Expected life in years	6.23 - 6.25	6.00 - 6.25	5.27 - 6.25	5.50 - 6.25
Expected volatility	82.43 - 85.89%	72.53 - 72.84%	74.49 - 85.89%	72.53 - 74.80%
Expected dividend yield	—%	—%	—%	—%

Stock option activity under the Company's stock option plans for the nine months ended September 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	4,667,500	1.08		
Exercised	(26,250)	0.80		
Cancelled	(4,683,904)	3.40		
Outstanding, September 30, 2022	10,623,215	$ 1.85	8.27	$ 3,572
Options exercisable, September 30, 2022	3,211,631	$ 2.69	7.01	$ 510
Options exercisable, December 31, 2021	4,410,312	$ 3.85	7.53	$ —
Options available for future grant, September 30, 2022	15,245,494			

At September 30, 2022, total unrecognized compensation costs related to unvested stock options outstanding amounted to $7.1 million. The cost is expected to be recognized over a weighted-average period of 2.01 years.

A summary of the status of unvested restricted stock for the nine months ended September 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	(305,679)	2.28
Cancelled	(232,901)	3.15
Unvested, September 30, 2022	940,000	$ 1.41

At September 30, 2022, total unrecognized compensation costs related to unvested restricted stock outstanding amounted to $1.2 million. The cost is expected to be recognized over a weighted-average period of 1.83 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 nine months ended September 30, 2022 and September 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 nine months ended September 30, 2022 and September 30, 2021, Eden BioCell incurred a net loss. The Company continues to have no commitment to fund its operations.

13. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through the date on which these financial statements were issued. The Company did not have any material subsequent events that impacted its financial statements or disclosures.

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 and treating patients for a Phase 1/2 clinical trial evaluating 10 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.

We have not generated any product revenue and have incurred significant net losses in each year since our inception. For the nine months ended September 30, 2022, we had a net loss of $28.6 million, and as of September 30, 2022, we have incurred approximately $871.5 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

TCR-T Library Phase 1/2 Trial

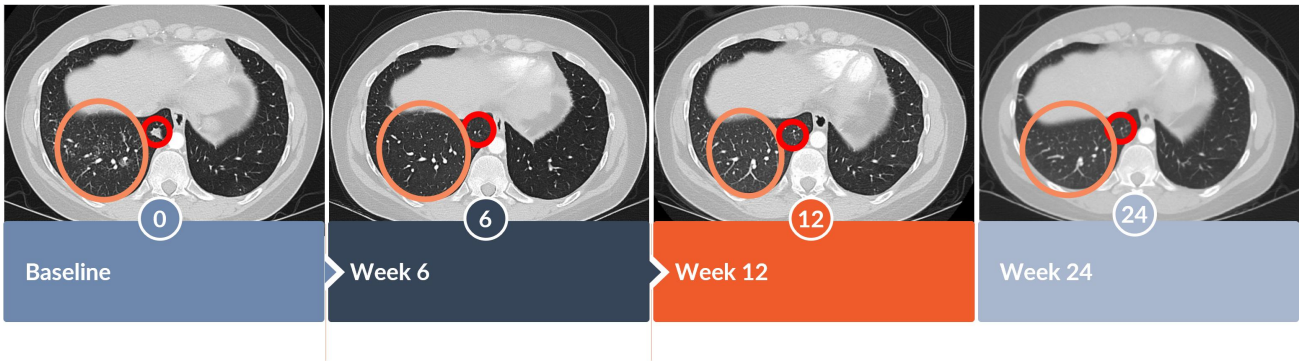
We have seen encouraging early clinical safety, persistence and efficacy data in our first-in-human *Sleeping Beauty* TCR-T Library Phase 1/2 Trial that is actively enrolling patients with solid tumor cancers at MD Anderson Cancer Center. We presented information on the first two patients treated in September 2022 at the CRI-ENCI-AACR International Cancer Immunotherapy Conference, or CICON. We continue to perform translational assessments to assess the biological activity of our TCR-T cells in the first two patients. We believe that these data provide early clinical validation of the potential of *Sleeping Beauty* TCR-T cell therapy in high value indications with significant unmet need. Key takeaways from the clinical experience to date are:

- Patients 1 and 2 demonstrated manageable safety profiles with no dose limiting toxicities (DLTs) or immune effector cell-associated neurotoxicity syndrome (ICANS);
- Persistence of the TCR-T cells were evident in both patients. Patient 1 had persistence at 24 weeks with approximately 30% of the patient's total CD3+ T cells comprising TCR-T cells in peripheral blood after treatment with KRAS-G12D/HLA-A*11:01 mutation-specific TCR-T cells at dose level 1 ($9x10^9$ cells). Patient 2 had persistence at 12 weeks with approximately 20% of the patient's total CD3+ T cells comprising TCR-T cells in peripheral blood after treatment with TP53-R175H/HLA-A*02:01 mutation-specific TCR-T cells at dose level 2 ($64x10^9$ cells);
- Demonstrating six month progression-free survival, Patient 1 had best overall response of objective, partial response with regression of greater than 50% of target lesions at 12 weeks post-cell therapy. Patient 2 had best overall response of stable disease at six weeks with 12 week progression-free survival. Progressive disease was observed in Patient 1 and Patient 2 at week 24 and week 12, respectively, and each patient subsequently went off study;
- The targeted mutations, KRAS-G12D and TP53-R175H, were detected in progressing tumor biopsies suggesting no antigen loss; and
- Tumor homing was observed in Patient 1 with infiltration of both CD4 and CD8 TCR-T cells six months post-TCR-T cell therapy.

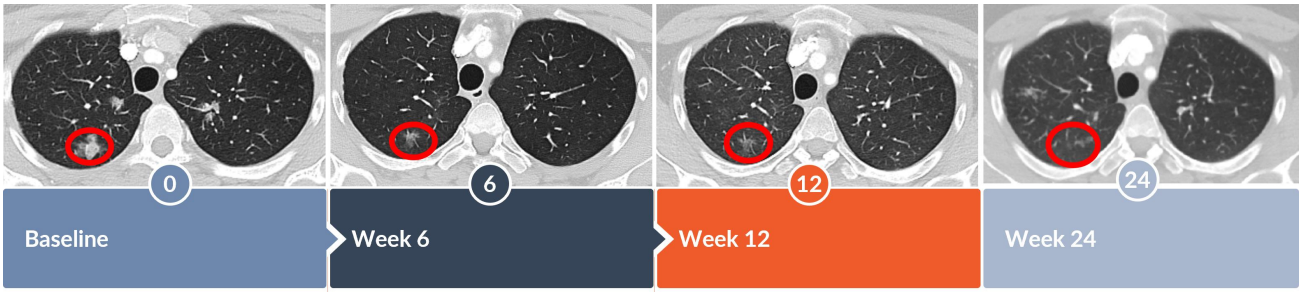
To our knowledge, achievement of an objective clinical response resulting from treatment with KRAS-G12D and HLA-A*11:01 specific TCR-T cells has not been reported until Patient 1 in our TCR-T Library Phase 1/2 Trial. Patient 1's infusion product was high quality with 97.3% viability, 99.7% CD3+ purity and 95.2% TCR positivity. Patient 1's target lesions were reduced compared to baseline by 46% at six weeks, 51% at 12 weeks and 46% at 24 weeks. At six months following treatment, an elective tumor biopsy of non-measurable disease in the right lung showed continued presence of tumor cells, KRAS-G12D mutation and HLA-A*11:01 allele which was corroborated by another elective scan at seven months. Patient 1 is now off study.

Scans of Patient 1's target lesions suggest the depth of the clinical response with evidence of durable and complete resolution of the right lower lobe target lesion (red circle) and non-measurable lymphogenic spread (orange circle) through week 24 (Image A) and reduction in the size of the three target lesions. Similar sustained reduction of the right upper lobe lesion (red circle) was observed through week 24 (Image B). The hilar lymph node (red circles) and non-measurable right lung disease (orange circle) appear to have reduced in size at week 24 compared to baseline measurements (Image C). Measurements of Patient 1's lesions are provided at Table D.

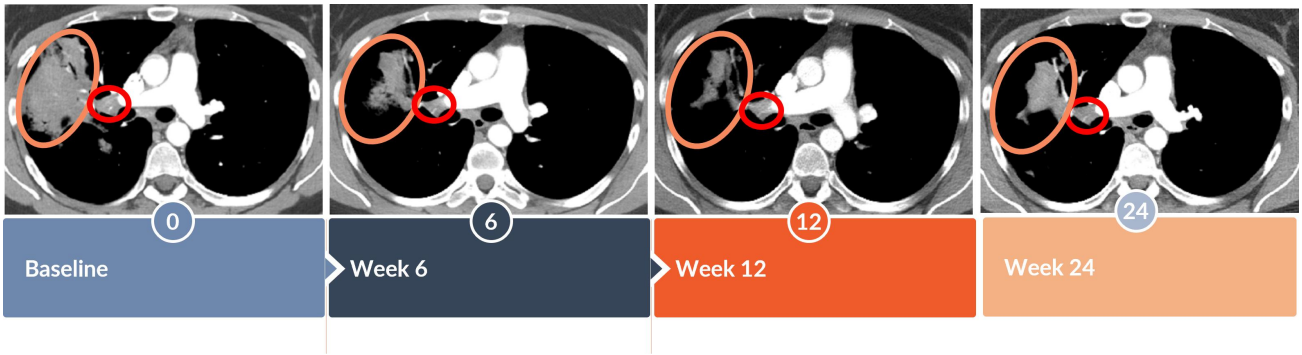
(A)



(B)



(C)



(D)

	Baseline	Week 6	Week 12	Week 24
Target Lesions				
#1: Right lower lobe (mm)	13	0	0	0
#2: Right upper lobe (mm)	13	11	10	10
#3: Right hilar lymph node (mm)	15	11	10	12
Sum of Diameters (mm)	41	22	20	22
Percent Change		(46.3%)	(51.2%)	(46.3%)
Non-measurable Disease		Decreased	Decreased	Increased
Overall Response		Partial Response	Partial Response	Progressive Disease

Patient 2's treatment was the first-in-human *Sleeping Beauty* TCR-T cell therapy targeting *TP53* hotspot mutations and was well tolerated. The TCR-T cells demonstrated persistence and the patient showed signs of clinical efficacy. The same TCR used by the NCI to treat breast cancer, which resulted in a 6-month confirmed, objective partial response, was used to treat Patient 2. Patient 2 received highly pure TCR-T cells (92.5% viability, 99% CD3+ purity, and 92% TCR positivity). Reduction of target lesions by 15% from baseline was observed at six weeks post-infusion, but we observed 21.8% growth of lesions from the week six measurements and appearance of new liver and lung metastases at week 12 signaled progressive disease in Patient 2, who is now off study. Lesion measurement data for Patient 2 are available at Table E. We anticipate treating our next patient before the end of 2022 and presenting an update on our TCR-T Library Phase 1/2 Trial in 2023.

(E)

	Baseline	Week 6	Week 12
Target Lesions			
#1: Pelvic Mass (mm)	65	49	67
#2: Retroperitoneal Lymph Node (mm)	27	30	28
Sum of Diameters (mm)	92	79	95
Percent Change		(15.2%)	21.9%
New Lesion		No	Liver/Lung
Overall Response		Stable Disease	Progressive Disease

We intend to file an IND amendment to incorporate cryopreserved TCR-T cells in our clinical protocol by the end of 2022. This process improvement will also shorten the manufacturing time from 30 days to 26 days. Our IND amendment will also include two new TCRs, expanding our clinical library and further increasing the addressable market. Three of these 10 TCRs already in our clinical library have been associated with confirmed partial responses in a clinical setting, giving us great confidence in the power of TCRs to treat solid tumors. We have also updated our standard operating procedures to allow for simultaneous manufacture of two product candidates in our cGMP suite. We have increased our existing manufacturing capacity to produce two products simultaneously.

mbIL-15 Program

We are continuing to advance our mbIL-15 program towards an IND filing in the second half of 2023 and believe that this program has the potential to increase the survival of TCR-T cells in the harsh tumor microenvironment and deepen clinical responses.

Solasia License and Collaboration Agreement

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. During the third quarter of 2022, the Company recorded $2.9 million of collaboration revenue under the Solasia License and Collaboration Agreement primarily related to Solasia's achievement of certain sales-based milestones in Japan.

Under the terms of a patent and technology license agreement with MD Anderson and the Texas A&M University System, following Solasia's achievement of sales-based milestones, the Company also recorded a one-time $2.5 million expense during the third quarter of 2022 to MD Anderson.

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 of interest expense associated with our Amended Loan and Security Agreement, as defined below, and sublease income, which started accruing on July 1, 2022.

Overview of Results of Operations

Three and Nine Months Ended September 30, 2022 Compared to Three and Nine Months Ended September 30, 2021

Collaboration Revenue

Collaboration revenue during the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
Collaboration revenue	$ 2,911	$ 398	$ 2,513	631%	$ 2,911	$ 398	$ 2,513	631%

Collaboration revenue during the three and nine months ended September 30, 2022 was $2.9 million as compared to $0.4 million during the three and nine months ended September 30, 2021, due to revenue earned under the Solasia License and Collaboration Agreement.

Research and Development Expenses

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
Research and development expenses	$ 7,893	$ 14,521	$ (6,628)	(46)%	$ 19,411	$ 41,427	$ (22,016)	(53)%

Research and development expenses for the three months ended September 30, 2022 decreased by $6.6 million when compared to the three months ended September 30, 2021 primarily due to a decrease in program-related costs of $3.6 million, mainly related to the winding down of our IL-12 and CAR-T programs, a $4.9 million decrease in employee related expenses due to our reduced headcount, including a $2.2 million restructuring charge in the third quarter of 2021, following our strategic restructuring event, a $0.4 million decrease in consulting expenses due to reduced use of consultants and a $0.2 million decrease in facilities costs due to the partial termination of one of our leases. These decreases were partially offset by a one-time $2.5 million expense to MD Anderson under the terms of our patent and technology license agreement.

Research and development expenses for the nine months ended September 30, 2022 decreased by $22.0 million when compared to the nine months ended September 30, 2021 primarily due to a decrease in program-related costs of $8.4 million, mainly related to the winding down of our IL-12 and CAR-T programs, a $14.7 million decrease in employee related expenses due to our reduced headcount, including a $2.2 million restructuring charge in the third quarter of 2021, following our strategic restructuring event, a $1.0 million decrease in consulting expenses due to reduced use of consultants and a $0.2 million decrease in facilities costs due to the partial termination of one of our leases. These decreases were partially offset by a one-time $2.5 million expense to MD Anderson under the terms of our patent and technology license agreement.

For the three and nine months ended September 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 nine months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
General and administrative expenses	$ 3,282	$ 8,173	$ (4,891)	(60)%	$ 10,217	$ 25,469	$ (15,252)	(60)%

General and administrative expenses for the three months ended September 30, 2022 decreased by $4.9 million as compared to the three months ended September 30, 2021, primarily due to a $3.2 million decrease in employee related expenses due to our reduced headcount, including a $1.3 million restructuring charge in the third quarter of 2021, following our strategic restructuring event and a $1.7 million decrease in consulting and professional services expenses due to lower legal costs and reduced use of consultants.

General and administrative expenses for the nine months ended September 30, 2022 decreased by $15.3 million as compared to the nine months ended September 30, 2021, primarily due to a $12.4 million decrease in employee related expenses due to our reduced headcount, including a $1.3 million restructuring charge in the third quarter of 2021, following our strategic restructuring event, a $2.8 million decrease in consulting and professional services expenses due to lower legal costs and reduced use of consultants and a $0.2 million decrease in facilities-related costs due to the expiration of two of our leases during 2021.

Gain on lease modification

Gain on lease modifications during the three and nine months ended September 30, 2022 and 2021 was as follows:

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

There was no gain on lease modification during the three months ended September 30, 2022 and 2021. Gain on lease modification during the nine months ended September 30, 2022 was $0.1 million as compared to $0 during the nine months ended September 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 nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change		2022	2021	Change	
($ in thousands)								
Interest expense	$ (841)	$ (444)	$ (397)	89%	$ (2,266)	$ (444)	$ (1,822)	410%
Other income (expense), net	254	7	247	3529%	279	(15)	294	(1960)%
Total	$ (587)	$ (437)	$ (150)	34%	$ (1,987)	$ (459)	$ (1,528)	333%

Other income (expense), net for the three months ended September 30, 2022 increased by $0.2 million as compared to the three months ended September 30, 2021, primarily due to $0.4 million of interest expense associated with our Amended Loan and Security Agreement, partially offset by $0.2 million of interest income.

Other income (expense), net for the nine months ended September 30, 2022 increased by $1.5 million as compared to the nine months ended September 30, 2021, primarily due to $1.8 million of interest expense associated with our Amended Loan and Security Agreement, partially offset by $0.3 million of interest income.

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 September 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.

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. During the three and nine months ended September 30, 2022, there were no 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, 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").

As of September 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 provided for an interest-only period which extended through August 31, 2022, as compared to March 31, 2022 in the Loan and Security Agreement. On or prior to August 31, 2022, we had not (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, nor (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”), and therefore, the interest-only period was not extended beyond August 31, 2022. Commencing on September 1, 2022, aggregate outstanding borrowings are repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023. 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, subject to a prepayment premium of the amount being prepaid, ranging from 1.00% to 2.00%, of the SVB Facility, each such prepayment to be at least $5.0 million plus all accrued and unpaid interest on the portion being prepaid.

As a result of not achieving the Amended Milestones on or prior to August 31, 2022, 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. As of September 30, 2022, we have collateralized $13.9 million, which is classified as restricted cash on the balance sheet. So long as no event of default has occurred and subject to certain other terms related to the remaining outstanding balance under the SVB Facility being satisfied, $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. 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 achieved 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 $0.8 million for the three months ended September 30, 2022 and was $2.3 million for the nine months ended September 30, 2022.

The fair value of the Amended Loan and Security Agreement as of September 30, 2022 approximates its face value.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
($ in thousands)		
Net cash provided by (used in):		
Operating activities	$ (22,102)	$ (46,342)
Investing activities	(100)	(2,964)
Financing activities	(2,107)	25,962
Net decrease in cash and cash equivalents	$ (24,309)	$ (23,344)

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 nine months ended September 30, 2022 was $22.1 million, as compared to net cash used in operating activities of $46.3 million for the nine months ended September 30, 2021. The net cash used in operating activities for the nine months ended September 30, 2022 was primarily due to our net loss of $28.6 million, adjusted for $7.5 million of non-cash items such as depreciation, stock-based compensation and a decrease in the carrying amount of right-of-use lease assets, a $2.4 million decrease in lease liabilities, a $1.8 million increase in accounts receivable, offset by an increase in accounts payable of $0.6 million, a $1.5 million increase in accrued expenses, and a decrease to prepaid expenses and other assets of $0.9 million.

Net cash used in investing activities was $0.1 million for the nine months ended September 30, 2022, compared to $3.0 million for the nine months ended September 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.

Net cash used in financing activities for the nine months ended September 30, 2022 was $2.1 million, primarily related to the repayment of long-term debt. Net cash provided by financing activities during the nine months ended September 30, 2021 was $26.0 million, related primarily to proceeds from the issuance of long-term debt and 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 September 30, 2022, our accumulated deficit was approximately $871.5 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 September 30, 2022, we had approximately $37.8 million of cash and cash equivalents and $13.9 million of restricted cash related to the Amended Loan and Security Agreement. 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, which excludes restricted cash, as of September 30, 2022 was $8.7 million, consisting of $41.6 million in current assets and $32.9 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 sublease for a portion of office space at our office in Boston 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 in the second quarter of 2022.

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 months ended September 30, 2022 and 2021, we recognized $0 related to royalty payments under this agreement, and we recognized $0.3 million in royalty payments under this agreement for the nine months ended September 30, 2022 and 2021. As of September 30, 2022, we have paid a total of $0.5 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 was 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. Payments totaling $0 and $0.1 million were made during the three and nine months ended September 30, 2022 related to the first benchmark payment, as compared to $0 during the three and nine months ended September 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 License Agreement and we have also agreed to reimburse certain historical costs of PGEN up to $1.0 million. For the three and nine months ended September 30, 2022 and September 30, 2021, we have made licensing fee payments in accordance with the terms of the License 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 nine months ended September 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 September 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 September 30, 2022, our principal executive officer and principal accounting officer concluded that, as of such date, our disclosure controls and procedures were effective.

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 September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

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 September 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. 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 nine months ended September 30, 2022, we had a net loss of $28.6 million, and, as of September 30, 2022, our accumulated deficit since inception in 2003 was $871.5 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 September 30, 2022, we have approximately $37.8 million of cash and cash equivalents and $13.9 million of restricted cash related to the Amended Loan and Security Agreement. 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. 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. Global political and economic events, including the COVID-19 pandemic and increased inflation, have 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 or make the terms of any available financing less attractive, 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. The Amended Loan and Security Agreement also required 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 in the event we failed to achieve the Amended Milestones. We did not achieve the Amended Milestones and as of September 30, 2022, are required to hold $13.9 million in a restricted cash collateral account with SVB. The collateralized cash represents a significant portion of our cash and cash equivalents that we are not able to access to fund our operations.

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. 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, the Amended Loan and Security Agreement requires us 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. As of September 30, 2022 we deposited $13.9 million in cash into the cash collateral account pursuant to the terms of the Amended Loan and Security Agreement. 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 early clinical data for the first patient in September 2022. We do not know at this stage whether patient response data from additional patients in 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 including 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, and in August 2022, we hired Abhishek Srivastava as our Vice President, Technical Operations. Management transition is often difficult and inherently causes some loss of institutional knowledge.

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 2Seventy Bio, Achilles Therapeutics, Annoca, Adaptimmune Therapeutics, Affini-T Therapeutics, ArsenalBio, BioNTech, 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 we believe to have target discovery platforms like ours include Adaptive Biotechnologies, Affini-T Therapeutics, Enara Bio, Immatics, Neogene, 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 and Precision Biosciences, 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-cellular 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 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. 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. Patient enrollment and study visits 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.

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 number of 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 and treating 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 cellular 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. 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 statements by third parties like trial participants and clinical investigators regarding our current or future clinical trials;
- 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 global economic conditions;
- 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.

Public statements made by third parties such as trial participants and clinical investigators about our current or future clinical trials without our consent may adversely impact our stock price. We may not be aware of these third-party statements when made, may not be able to respond to these third-party statements and may not be able to defend our business or the public's legitimate interests due to restrictions on what we may say about our product candidates which may cause the price of our stock to fluctuate. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to 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 September 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, 10,623,215 shares were issuable upon the exercise of outstanding options at a weighted average exercise price of $1.85 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 September 30, 2022, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 44.4% 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

ISSUER PURCHASES OF EQUITY SECURITIES

Period	(a) Total number of shares purchased[(1)]	(b) Average price paid per share	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
July 1, 2022 - July 31, 2022	—	—	—	—
August 1, 2022 - August 31, 2022	18,750	$2.41	—	—
September 1, 2022 - September 30, 2022	—	—	—	—
Total	18,750	$2.41	—	—

(1) Included in this table are shares withheld during the 3-month period ended September 30, 2022 to satisfy a portion of the tax withholding obligations in connection with the vesting of shares of restricted stock granted under the 2020 Equity Incentive Plan.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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).
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: November 14, 2022

By:

/s/ Michael Wong
Michael Wong
Vice President, Finance
(Principal Accounting Officer)
Dated: November 14, 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 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: November 14, 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 September 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
November 14, 2022