

**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 March 31, 2023

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**  
(State or other jurisdiction of  
incorporation or organization)

**84-1475642**  
(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	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input checked="" type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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 May 5, 2023, the number of outstanding shares of the registrant's common stock, \$0.001 par value, was 240,627,055 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 and fund our planned operations;
- 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 research and development, preclinical studies and clinical 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.

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 recruit, hire 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.
- 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 development, which is 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.
- If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Global Select Market. Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock.
- We may effect a reverse stock split of our common stock, but it may not result in the intended benefits. If we implement a reverse stock split, liquidity of our common stock may be adversely affected.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

**Alaunos Therapeutics, Inc.**  
**CONDENSED BALANCE SHEETS**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	March 31, 2023	December 31, 2022
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 23,496	\$ 39,058
Restricted cash	13,938	13,938
Receivables	—	4
Prepaid expenses and other current assets	750	799
Total current assets	38,184	53,799
Property and equipment, net	7,889	8,460
Right-of-use assets	2,023	2,136
Deposits	42	42
Other non-current assets	500	500
Total assets	<u>\$ 48,638</u>	<u>\$ 64,937</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,380	\$ 1,389
Current portion of long-term debt	10,988	16,765
Accrued expenses	4,120	5,454
Lease liabilities, current	575	558
Total current liabilities	17,063	24,166
Lease liabilities, non-current	2,038	2,188
Other non-current liabilities	28	28
Total liabilities	<u>\$ 19,129</u>	<u>\$ 26,382</u>
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock \$0.001 par value; 420,000,000 shares authorized, 240,627,055 shares issued and outstanding at March 31, 2023 and 420,000,000 shares authorized, 240,410,761 shares issued and outstanding at December 31, 2022	241	240
Additional paid-in capital	919,943	918,942
Accumulated deficit	(890,675)	(880,627)
Total stockholders' equity	29,509	38,555
Total liabilities and stockholders' equity	<u>\$ 48,638</u>	<u>\$ 64,937</u>

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

**Alaunos Therapeutics, Inc.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	For the Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	6,504	5,580
General and administrative	3,168	3,505
Total operating expenses	9,672	9,085
Loss from operations	(9,672)	(9,085)
Other income (expense):		
Interest expense	(853)	(683)
Other income (expense), net	477	(20)
Other income (expense), net	(376)	(703)
Net loss	\$ (10,048)	\$ (9,788)
Basic and diluted net loss per share	\$ (0.04)	\$ (0.05)
Weighted average common shares outstanding, basic and diluted	239,679,352	214,946,569

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

Alaunos Therapeutics, Inc.

CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(unaudited)

(in thousands, except share and per share data)

**For the Three Months Ended March 31, 2023**

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	240,410,761	\$ 240	\$ 918,942	\$ (880,627)	\$ 38,555
Stock-based compensation	—	—	910	—	910
Issuance of common stock, net of expenses	216,294	1	91	—	92
Net loss	—	—	—	(10,048)	(10,048)
Balance at March 31, 2023	<u>240,627,055</u>	<u>\$ 241</u>	<u>\$ 919,943</u>	<u>\$ (890,675)</u>	<u>\$ 29,509</u>

**For the Three Months Ended March 31, 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	—	—	853	—	853
Cancelled restricted common stock	(176,882)	—	—	—	—
Net loss	—	—	—	(9,788)	(9,788)
Balance at March 31, 2022	<u>215,950,561</u>	<u>\$ 216</u>	<u>\$ 901,546</u>	<u>\$ (852,640)</u>	<u>\$ 49,122</u>

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

**Alaunos Therapeutics, Inc.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (10,048)	\$ (9,788)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	696	689
Amortization of financing costs	472	198
Stock-based compensation	910	853
Decrease in the carrying amount of right-of-use assets	113	180
Decrease in:		
Receivables	4	1,111
Prepaid expenses and other current assets	49	149
Other non-current assets	—	5
Decrease in:		
Accounts payable	(110)	(763)
Accrued expenses	(1,334)	(214)
Lease liabilities	(133)	(190)
Net cash used in operating activities	<u>(9,381)</u>	<u>(7,770)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(61)	(29)
Proceeds from the disposal of property and equipment	38	—
Net cash used in investing activities	<u>(23)</u>	<u>(29)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock	92	—
Repayment of long-term debt	(6,250)	—
Net cash used in financing activities	<u>(6,158)</u>	<u>—</u>
Net decrease in cash, cash equivalents and restricted cash	(15,562)	(7,799)
Cash, cash equivalents and restricted cash, beginning of period	52,996	76,054
Cash, cash equivalents and restricted cash, end of period	<u>\$ 37,434</u>	<u>\$ 68,255</u>
<b>Supplementary disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ 439</u>	<u>\$ 484</u>
Amounts included in accrued expenses and accounts payable related to property and equipment	<u>\$ 101</u>	<u>\$ 29</u>

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

**Alaunos Therapeutics, Inc.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(unaudited)**

**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 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 novel cancer mutation hotspot TCR library to design and manufacture personalized cell therapies that target neoantigens arising from common tumor-related 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 for the treatment of glioblastoma multiforme. The Company continues to seek a partner for this program.

As of March 31, 2023, there were 240,627,055 shares of common stock outstanding and an additional 36,235,588 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants.

The accompanying condensed 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, or 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 condensed financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the condensed financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (i) it is probable that the plans will be effectively implemented within one year after the date that the condensed financial statements are issued and (ii) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the condensed 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 March 31, 2023, the Company had approximately \$37.4 million of cash, cash equivalents and restricted cash. The restricted cash of \$13.9 million at March 31, 2023 is related to the Company’s debt agreement, which was subsequently repaid in its entirety on May 1, 2023 (see Note 4, *Debt*). The Company’s accumulated deficit at March 31, 2023 was approximately \$890.7 million. Given its current development plans and cash management efforts, the Company anticipates cash resources will be sufficient to fund operations into the fourth quarter of 2023. The Company’s ability to continue operations after its current cash resources are exhausted depends on future events outside of the Company’s control, including its ability to obtain additional financing or to achieve profitable results, as to which no assurances can be given. If adequate additional funds are not available when required, or if the Company is unsuccessful in entering into partnership agreements for further development of its product candidates, management may need to curtail its development efforts and planned operations to conserve cash until sufficient additional capital is raised. There can be no assurances that such a plan would be successful.

Based on the current cash forecast and the Company’s dependence on its ability to obtain additional financing to fund its operations after the current resources are exhausted, about which there can be no certainty, 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 condensed financial statements, and substantial doubt as to the Company’s ability to continue as a going concern exists. 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.

*Basis of Presentation*

The accompanying unaudited interim condensed 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 condensed 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

**NOTES TO CONDENSED FINANCIAL STATEMENTS  
(unaudited)**

and cash flows for the periods presented. The unaudited interim condensed financial statements should be read in conjunction with the audited condensed financial statements and the notes thereto for the year ended December 31, 2022, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on March 7, 2023, or the Annual Report.

The results disclosed in the statements of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the full fiscal year 2023.

*Use of Estimates*

The preparation of condensed 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 condensed 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, or the Loan and Security Agreement, with Silicon Valley Bank and affiliates of Silicon Valley Bank, or collectively, SVB. The Loan and Security Agreement provided for an initial term loan of \$25.0 million funded at the closing, or 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, or the Term B Tranche.

Effective December 28, 2021, the Company entered into a First Amendment to the Loan and Security Agreement. The First Amendment extended the interest-only period through August 31, 2022. The First Amendment also eliminated the Term B Tranche, which remained unfunded, leaving only the Term A Tranche, or the SVB Facility. Under the amended Loan and Security Agreement, the SVB Facility was to mature on August 1, 2023. On May 1, 2023, the Company repaid its outstanding debt obligations in their entirety.

Refer to Note 4, *Debt*, for further discussion of the Loan and Security Agreement and the First Amendment.

*2022 Equity Distribution Agreement*

On August 12, 2022, the Company entered into an Equity Distribution Agreement, or the Equity Distribution Agreement, with Piper Sandler & Co., or 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 months ended March 31, 2023, there have been no sales of the Company's common stock under the Equity Distribution Agreement.

*2022 Public Offering*

On November 29, 2022, the Company entered into an underwriting agreement, or the Underwriting Agreement, with Cantor Fitzgerald & Co., or the Underwriter, as the sole underwriter, relating to the issuance and sale in an underwritten offering, or the Offering, of 24,228,719 shares, or the Firm Shares, of the Company's common stock to the Underwriter at a price of \$0.6191 per share.

The net proceeds to the Company from the Offering were \$14.7 million (before accounting for the partial exercise of the Underwriter's option as described below) after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Under the terms of the Underwriting Agreement, the Company granted the Underwriter an option, exercisable for 30 days, to purchase up to an additional 3,634,307 shares of common stock, which we refer to, together with the Firm Shares, as the Shares, at the same price per share as the Firm Shares. On January 5, 2023, the Underwriter partially exercised its option to purchase an additional 216,294 shares of common stock.

**3. Summary of Significant Accounting Policies**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(unaudited)

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)	March 31, 2023	December 31, 2022
Loan and Security Agreement	\$ 11,395	\$ 17,395
Unamortized discount on Loan and Security Agreement	(407)	(630)
<b>Total debt</b>	<b>\$ 10,988</b>	<b>\$ 16,765</b>

On August 6, 2021, the Company entered into the Loan and Security Agreement with SVB. The Loan and Security Agreement provided for the funding of the Term A Tranche at the closing, with the Term B Tranche available if certain funding and clinical milestones were met by August 31, 2022. The SVB Facility and related obligations under the Loan and Security Agreement were secured by substantially all of the Company's properties, rights and assets, except for its intellectual property (which was subject to a negative pledge under the Loan and Security Agreement). In addition, the Loan and Security Agreement contained customary representations, warranties, events of default and covenants. As of March 31, 2023, the Company was in compliance with all debt covenants, as amended.

On December 28, 2021, the Company entered into the First Amendment to the Loan and Security Agreement. The First Amendment eliminated the unfunded Term B Tranche, among other things. The SVB Facility bore 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 March 31, 2023, interest on the outstanding loans was 12.5%. Commencing on September 1, 2022, aggregate outstanding borrowings became repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding obligations under the amended Loan and Security Agreement were due and payable on August 1, 2023. In connection with the payment of all of the Company's outstanding obligations, the Company also owed SVB 5.75% of the original principal amounts borrowed as a final payment, or the Final Payment.

Effective March 30, 2023, the Company entered into a Third Amendment to the Loan and Security Agreement, or the Third Amendment. Under the terms of the Third Amendment, the Company was no longer required to maintain all of its operating accounts, depository accounts and excess cash with SVB or one of its affiliates, and was instead only required to maintain a single operating or depository account at Silicon Valley Bank. The Third Amendment also modified the cash collateralization requirement, such that the Company was required to cash collateralize the entire sum of the outstanding principal amount of the SVB Facility plus an amount equal to the Final Payment, which amount was to be reduced commensurate with each regularly scheduled monthly payment of principal and interest on the SVB Facility.

On May 1, 2023, the Company paid SVB an amount equal to the entire outstanding principal amount under the SVB Facility, which was \$10.4 million as of March 31, 2023, all accrued and unpaid interest and the Final Payment of \$1.4 million. In accordance with the First Amendment, the payment was subject to a prepayment premium of 2.00%, or \$0.1 million. Recorded issuance costs associated with the SVB Facility as of March 31, 2023 were \$0.4 million.

In connection with its entry into the Loan and Security Agreement in August 2021, 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 First Amendment in December 2021, 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, with an exercise price of \$1.16 per share, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

The issuance costs for the Loan and Security Agreement, including the First Amendment, were approximately \$1.2 million and primarily related to the issuance of the SVB Warrants, which were amortized into interest expense over the term of the loan. Interest expense, including the amortization of issuance costs, was \$0.9 million for the three months ended March 31, 2023 and was \$0.7 million for the three months ended March 31, 2022.

The fair value of the amended Loan and Security Agreement as of March 31, 2023 approximates its face value.

**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(unaudited)

**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 March 31, 2023 and December 31, 2022 are as follows:

(\$ in thousands)

Description	Balance as of March 31, 2023	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 2,479	\$ 2,479	\$ —	\$ —

(\$ in thousands)

Description	Balance as of December 31, 2022	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 38,058	\$ 38,058	\$ —	\$ —

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 three months ended March 31, 2023. We had no financial assets or liabilities that were classified as Level 2 or Level 3 as of December 31, 2022, nor during the three months ended March 31, 2023.

**6. Net loss per share**

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period, plus the dilutive effect of outstanding options and warrants, using the treasury stock method and the average market price of the Company's common stock during the applicable period, unless their effect on net loss per share is antidilutive. The effect of computing diluted net loss per common share was antidilutive for any potentially issuable shares of common stock from the conversion of stock options, unvested restricted stock and warrants and, as such, have been excluded from the calculation. Such potentially dilutive shares of common stock consisted of the following as of March 31, 2023 and 2022:

	March 31,	
	2023	2022
Common stock options	13,313,246	10,969,654
Unvested restricted stock	898,125	993,879
Warrants	22,922,342	22,922,342
	<u>37,133,713</u>	<u>34,885,875</u>

NOTES TO CONDENSED FINANCIAL STATEMENTS  
(unaudited)**7. Related Party Transactions***Joint Venture with TriArm Therapeutics/Eden BioCell*

On December 18, 2018, the Company and TriArm Therapeutics, Ltd., or TriArm, launched Eden BioCell, Ltd., or 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 contributed \$10.0 million to Eden BioCell and has committed up to an additional \$25.0 million to this joint venture. TriArm also managed 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 months ended March 31, 2023, 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. The joint venture agreement has been terminated and the Eden BioCell entity is in the process of being dissolved. Refer to Note 12, *Joint Venture*, for further details.

**8. Leases**

On April 19, 2023, the Company terminated its Boston office lease, which was set to expire on August 31, 2026. In connection with the termination, the Company also assigned to the landlord its sub-lease of the Boston office space, which had a term to June 30, 2025 with an option to extend through July 31, 2026. As of March 31, 2023, the Boston office right-of-use asset is \$0.5 million and the associated lease liability is \$0.8 million. Termination costs for the Boston office lease are \$0.2 million.

**9. Commitments and Contingencies***Exclusive License Agreement with Precigen*

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. The Company refers to PGEN and Precigen together as Precigen. Pursuant to the terms of the License Agreement, the Company had 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 License and Collaboration Agreement effective March 27, 2015 between the Company, Precigen and ARES TRADING S.A., a subsidiary of Merck KGaA, as assigned by Precigen to PGEN. Under the License Agreement, the Company also had 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 was responsible for all aspects of the research, development and commercialization and was required to use commercially reasonable efforts to develop certain products.

In consideration of the licenses and other rights granted by Precigen, the Company was required to pay Precigen an annual license fee of \$0.1 million, reimburse Precigen for certain historical costs, pay Precigen milestones up to an additional \$52.5 million for each exclusively licensed program upon the achievement of certain milestones, and pay Precigen tiered royalties up to a maximum royalty amount of \$100.0 million in the aggregate. The Company was also obligated to pay Precigen 20% of any sublicensing income received by us relating to the licensed products. The Company was responsible for all development costs associated with each of the licensed products.

Precigen was obligated to pay the Company royalties up to a maximum royalty amount of \$100.0 million. No royalty amounts were incurred during the three months ended March 31, 2023 and 2022.

On April 3, 2023, the Company entered into the Amended and Restated Exclusive License Agreement with Precigen, or the A&R License Agreement, which restated and amended the License Agreement in full. Under the A&R License Agreement, the Company still has exclusive, worldwide rights to research, develop and commercialize TCR products designed for neoantigens or driver mutations for the treatment of cancer and non-exclusive rights to use non-driver mutation TCRs. The Company further

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maintains its 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 remains solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. The (i) products utilizing Precigen's RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products and (ii) 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 License and Collaboration Agreement effective March 27, 2015 between the Company, Precigen and ARES TRADING S.A., a subsidiary of Merck KGaA, as assigned by Precigen to PGEN are no longer exclusively licensed to the Company. The Company is no longer obligated to use commercially reasonable efforts for the exclusively licensed products. The A&R License Agreement further eliminates any royalty or milestone obligations to Precigen, with an annual license fee of \$75 thousand due on the anniversary of the A&R License Agreement effective date. Precigen is no longer obligated to pay the Company royalties on the net sales derived from the sale of Precigen's CAR 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 a license agreement, or the MD Anderson License, with MD Anderson (which Precigen subsequently assigned to PGEN). Pursuant to the MD Anderson License, the Company, together with Precigen, 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.

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 Research and Development Agreement, or the 2019 R&D Agreement, which the Company entered into on October 22, 2019, with MD Anderson, pursuant to which the Company agreed to collaborate with respect to the TCR program.

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, Precigen, and MD Anderson.

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

Under the 2019 R&D Agreement, the Company and MD Anderson 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.

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The Company will own all inventions and intellectual property developed under the 2019 R&D Agreement and the Company will retain all rights to all intellectual property, patentable or not, 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 to develop and commercialize autologous TCR products manufactured using viral gene transfer technologies and any products outside the field of oncology and a non-exclusive license for allogenic 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 March 31, 2023, the Company incurred clinical expenses of \$0.2 million from MD Anderson related to this agreement compared to \$0.1 million for the three months ended March 31, 2022.

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. 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 March 31, 2023, 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 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 paid during the year ended December 31, 2022 upon the initiation of the Company's TCR-T Library Phase 1/2 Trial, which was a qualifying Phase 1 clinical trial under the terms of the Patent License.

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

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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 each of the three months ended March 31, 2023 and 2022, the Company recognized \$0.3 million in license payments to the NCI under this agreement.

*Cooperative Research and Development Agreement (CRADA) with the NCI*

On January 9, 2017, the Company entered into a Cooperative Research and Development Agreement, or 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 decides 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. 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; however, for the third and fourth quarters of 2021, the Company was not required to make payments toward the program as agreed with the NCI. 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, or 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 recorded expenses of \$0.3 million under the CRADA for the three months ended March 31, 2023, as compared to \$0 for the three months ended March 31, 2022.

*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

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fees that the Company may receive from a possible sublicense under certain circumstances. During the three months ended March 31, 2023 and 2022, the Company did not incur any milestone expenses or 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., or 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, or, 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 months ended March 31, 2023 and 2022, the Company did not earn collaboration revenue or royalty revenues on net sales under the Solasia License and Collaboration Agreement.

#### 10. Stock-Based Compensation

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

<i>(in thousands)</i>	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
Research and development	176	315
General and administrative	735	538
Stock-based compensation expense	<u>\$ 910</u>	<u>\$ 853</u>

The Company granted an aggregate of 3,065,168 stock options during the three months ended March 31, 2023, with a weighted-average grant date fair value of \$0.39 per share, and granted an aggregate of 2,690,000 stock options during the three months ended March 31, 2022, with a weighted-average grant date fair value of \$0.47 per share.

For the three months ended March 31, 2023 and 2022, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

	<b>For the Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Risk-free interest rate	3.58 – 3.87%	1.63 – 2.43%
Expected life in years	5.06 - 6.25	6.25
Expected volatility	89.69 - 95.63%	74.49 – 76.27%
Expected dividend yield	—%	—%

Stock option activity under the Company's stock option plans for the three months ended March 31, 2023 is as follows:

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<i>(in thousands, except share and per share data)</i>	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2022	10,408,622	\$ 1.84		
Granted	3,065,168	0.52		
Cancelled	(160,544)	1.90		
Outstanding, March 31, 2023	<u>13,313,246</u>	<u>\$ 1.54</u>	<u>8.80</u>	<u>\$ 364</u>
Options exercisable, March 31, 2023	<u>4,553,574</u>	<u>\$ 2.31</u>	<u>7.99</u>	<u>\$ —</u>
Options exercisable, December 31, 2022	<u>3,891,598</u>	<u>\$ 2.46</u>	<u>8.08</u>	<u>\$ —</u>
Options available for future grant, March 31, 2023	<u>12,555,464</u>			

At March 31, 2023, total unrecognized compensation costs related to unvested stock options outstanding amounted to \$6.6 million. The cost is expected to be recognized over a weighted-average period of 1.96 years.

A summary of the status of unvested restricted stock for the three months ended March 31, 2023 is as follows:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested, December 31, 2022	939,062	\$ 1.40
Vested	(40,937)	0.90
Unvested, March 31, 2023	<u>898,125</u>	<u>\$ 1.43</u>

At March 31, 2023, total unrecognized compensation costs related to unvested restricted stock outstanding amounted to \$0.9 million. The cost is expected to be recognized over a weighted-average period of 1.72 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, or 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, or 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 months ended March 31, 2023 and 2022, 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

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rate of 1.31%, expected life of ten years and no dividends. On December 28, 2021, the Company entered into the First 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, with an exercise price of \$1.16 per share. The SVB Warrants expire on August 6, 2031 and were fully vested upon issuance.

**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.

For the three months ended March 31, 2023 and 2022, Eden BioCell incurred a net loss. In September 2021, TriArm and the Company mutually agreed to dissolve the joint venture, which has now been terminated. The Eden BioCell entity is in the process of being dissolved.

**13. Subsequent Events**

The Company has evaluated subsequent events from the balance sheet date through the date on which these condensed financial statements were issued. Other than as described in the notes above, the Company did not have any other material subsequent events that impacted its condensed financial statements or disclosures.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial information and related notes included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC, on March 7, 2023, or the Annual Report.*

*Except for the historical financial information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to contain forward-looking statements that reflect our plans, estimates and beliefs. 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 could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those risks identified under Part II, Item 1A. Risk Factors.*

### **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 12 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 three months ended March 31, 2023, we had a net loss of \$10.0 million, and as of March 31, 2023, we have incurred approximately \$890.7 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 and scale out the 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 continued actively enrolling patients in our TCR-T Library Phase 1/2 Trial targeting *KRAS*, *TP53* and *EGFR* hotspot mutations across six solid tumor indications throughout the first quarter of 2023. Early translational data from the program from the first three patients treated in the trial will be highlighted in a poster at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in June 2023. We currently expect to provide an interim data update on multiple new patients in the third quarter and continue to anticipate Phase 2 readiness with a recommended Phase 2 dose by the end of 2023. We anticipate treating between nine and 12 patients by the end of 2023 in order to complete the Phase 1 portion of the trial.

As previously disclosed, we have enhanced our manufacturing process to move from fresh to cryopreserved cell product and have successfully manufactured multiple cryopreserved products in the first quarter of 2023, enabling greater flexibility for patient scheduling and treatment. Initiatives to further optimize the manufacturing process continue in 2023.

#### *hunTR® Platform*

The hunTR® platform for TCR discovery continues to make progress identifying and validating proprietary TCRs. We have added infrastructure to increase the screening throughput potential of hunTR while maintaining a high success rate of TCR discovery. We aim to add three new TCRs to the library by the end of 2023. We believe that successfully increasing throughput of the hunTR platform has the potential to generate out-licensing or partnering opportunities.

#### *mbIL-15 Program*

We are advancing our mbIL-15 TCR-T cell therapy program towards an IND filing anticipated in the second half of 2023. We believe mbIL-15 has the potential to increase the survival of TCR-T cells in the harsh tumor microenvironment and deepen clinical responses. In addition, we continue to conduct translational assessments of treated patients to guide next generation TCR-T therapy approaches including potential combination and multiplexed TCR-T cell therapies.

#### *Debt Repayment*

On May 1, 2023, we paid all amounts outstanding under our amended Loan and Security Agreement (as defined below) with Silicon Valley Bank and affiliates of Silicon Valley Bank, or collectively, SVB, comprised of the entire outstanding principal amount under the SVB Facility (as defined below), which was \$10.4 million as of March 31, 2023, all accrued and unpaid interest and the Final Payment (as defined below). The payment was subject to a prepayment premium of 2.00%, or \$0.1 million. Recorded issuance costs associated with the SVB Facility as of March 31, 2023 were \$0.4 million.

#### *Precigen A&R License Agreement*

On April 3, 2023, we and Precigen, Inc., or Precigen, entered into an Amended and Restated Exclusive License Agreement, or the A&R License Agreement. The A&R License Agreement amended and restated in its entirety the original Exclusive License Agreement dated October 5, 2018 by and between us and Precigen, or the License Agreement. Under the A&R License Agreement, all rights under the License Agreement with respect to the IL-12 products and CAR products are now held exclusively by Precigen, and we are no longer obligated to develop or commercialize any CD19, IL-12 or TCR products. We retained exclusive, worldwide rights to research and develop and commercialize TCR products designed for neoantigens or driver mutations for the treatment of cancer. Additionally, all royalty and milestone obligations between us and Precigen have been removed, and annual license payments due to Precigen have been reduced from \$100 thousand to \$75 thousand. The A&R License Agreement also modified the license provision so that patents granted to us will expire upon the expiration or abandonment of the last-to-expire valid claim, or the Patent Term, and not the later of such expiration or abandonment and 12 years following the first commercial sale. The exclusive license granted to us with respect to know-how will become non-exclusive following the Patent Term.

#### *Board of Directors*

On March 29, 2023, Christopher Bowden, M.D. delivered notice of his resignation from the board of directors, effective March 30, 2023. On March 30, 2023, the board of directors appointed Robert Hofmeister, Ph.D. to fill the vacancy created by Dr. Bowden's resignation. Dr. Hofmeister was also appointed to the Corporate Governance and Nominating Committee and the Compensation Committee of the board of directors, replacing Dr. Bowden.

### **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, or CROs, in conjunction with clinical trials, fees paid to CROs 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 seek additional, external sources of financing from time-to-time in order to continue with our product development strategy or reduce or eliminate our activities in one or more of our programs. 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.

#### *Other Income (Expense)*

Other income (expense) consists primarily of interest expense associated with our amended Loan and Security Agreement (as defined below), interest income on our cash balances and sublease income.

### **Results of Operations**

#### ***Three Months Ended March 31, 2023 Compared to Three Months Ended March 31, 2022***

##### *Research and Development Expenses*

Research and development expenses during the three months ended March 31, 2023 and 2022 were as follows:

(\$ in thousands)	Three Months Ended March 31,		Change	
	2023	2022		
Research and development expenses	\$ 6,504	\$ 5,580	\$ 924	17%

Research and development expenses for the three months ended March 31, 2023 increased by \$0.9 million when compared to the three months ended March 31, 2022, primarily due to higher program-related costs of \$1.7 million related to increased manufacturing activities for our TCR-T Library Phase 1/2 Trial and research and development efforts related to our hunTR discovery engine, partially offset by a \$0.7 million decrease in employee-related expenses due to lower salary and severance-related costs and a \$0.1 million decrease in facilities and lease expenses following the reduction of our real estate footprint in 2022.

For the three months ended March 31, 2023, 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 months ended March 31, 2023 and 2022 were as follows:

(\$ in thousands)	Three Months Ended March 31,		Change	
	2023	2022		
General and administrative expenses	\$ 3,168	\$ 3,505	\$ (337)	(10)%

General and administrative expenses for the three months ended March 31, 2023 decreased by \$0.3 million as compared to the three months ended March 31, 2022, primarily due to lower professional fees of \$0.2 million as a result of reducing our use of consultants and a \$0.1 million decrease in other expenses primarily due to lower insurance costs and lease expenses following the reduction of our real estate footprint in 2022.

## Other Income (Expense), Net

Other income (expense), net during the three months ended March 31, 2023 and 2022 was as follows:

(\$ in thousands)	Three Months Ended March 31,		Change	
	2023	2022		
Interest expense	\$ (853)	\$ (683)	\$ (170)	25%
Other income (expense), net	477	(20)	497	(2485)%
Total	\$ (376)	\$ (703)	\$ 327	(47)%

Other expense, net for the three months ended March 31, 2023 decreased by \$0.3 million as compared to the three months ended March 31, 2022, primarily due to higher interest income of \$0.5 million as a result of increasing interest rates, partially offset by higher interest expense of \$0.2 million associated with our amended Loan and Security Agreement.

## Liquidity and Capital Resources

### Sources of Liquidity

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

To date, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible equity securities, term debt and collaborations. Through March 31, 2023, we have received an aggregate of \$729.2 million from issuances of equity and \$25.0 million from our amended Loan and Security Agreement.

On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation and the Federal Deposit Insurance Corporation was appointed as receiver. During March 2023, we established a banking relationship with a financial institution in addition to SVB.

We follow the guidance of Accounting Standards Codification, or 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 condensed 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 fourth 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 condensed 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 Public Offering*

On November 29, 2022, we entered into an underwriting agreement, or the Underwriting Agreement, with Cantor Fitzgerald & Co., or the Underwriter, as the sole underwriter, relating to the issuance and sale in an underwritten offering, or the Offering, of 24,228,719 shares of our common stock, or the Firm Shares, to the Underwriter at a price of \$0.6191 per share.

Our net proceeds from the Offering were \$14.7 million (before accounting for the partial exercise of the Underwriter's option as described below) after deducting underwriting discounts and commissions and offering expenses payable by us.

Under the terms of the Underwriting Agreement, we granted the Underwriter an option, exercisable for 30 days, to purchase up to an additional 3,634,307 shares of common stock, or, together with the Firm Shares, the Shares, at the same price per share as the Firm Shares. On January 5, 2023, the Underwriter partially exercised its option to purchase an additional 216,294 shares of common stock.

### *2022 Equity Distribution Agreement*

On August 12, 2022, we entered into an Equity Distribution Agreement, or the Equity Distribution Agreement, with Piper Sandler & Co., or 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 months ended March 31, 2023, 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, or 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, or 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 SVB Facility and related obligations under the Loan and Security Agreement were secured by substantially all of our properties, rights and assets, except for our intellectual property (which was subject to a negative pledge under the Loan and Security Agreement). In addition, the Loan and Security Agreement contained customary representations, warranties, events of default and covenants. As of March 31, 2023, we were in compliance with all debt covenants, as amended.

Effective December 28, 2021, we entered into the First Amendment to the Loan and Security Agreement. Under the terms of the First Amendment, the additional tranche, which remained unfunded, was eliminated, leaving only the Term A Tranche, which is referred to as the SVB Facility. The SVB Facility bore 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%. Commencing on September 1, 2022, aggregate outstanding borrowings became repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding obligations under the amended Loan and Security Agreement were due and payable on August 1, 2023. We also owed SVB \$1.4 million as a final payment, or the Final Payment.

Effective March 30, 2023, we entered into a Third Amendment to the Loan and Security Agreement, or the Third Amendment. Under the terms of the Third Amendment, we were no longer required to maintain all of our operating accounts, depository accounts and excess cash with SVB, and were instead only required to maintain a single operating or depository account at Silicon Valley Bank. The Third Amendment also modified the cash collateralization requirement, such that we were required to cash collateralize the entire sum of the outstanding principal amount of the SVB Facility plus an amount equal to the Final Payment, which amount was to be reduced commensurate with each regularly scheduled monthly payment of principal and interest on the SVB Facility.

On May 1, 2023, we paid SVB all amounts outstanding under the amended Loan and Security Agreement, comprised of the entire outstanding principal amount under the SVB Facility, all accrued and unpaid interest and the Final Payment. The payment was subject to a prepayment premium of 2.00%.

In connection with our entry into the Loan and Security Agreement in August 2021, 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 First Amendment in December 2021, 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, with an exercise price of \$1.16 per share, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

### ***Cash Flows***

The following table summarizes our net decrease in cash and cash equivalents for the three months ended March 31, 2023 and 2022:

(\$ in thousands)	Three Months Ended March 31,	
	2023	2022
Net cash used in:		
Operating activities	\$ (9,381)	\$ (7,770)
Investing activities	(23)	(29)
Financing activities	(6,158)	—
Net decrease in cash and cash equivalents	\$ (15,562)	\$ (7,799)

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Cash flows from operating activities are 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 three months ended March 31, 2023 was \$9.4 million, as compared to net cash used in operating activities of \$7.8 million for the three months ended March 31, 2022. The increase was primarily related to the increase of our net loss by \$0.2 million, non-cash adjustments and working capital impacts.

The net cash used in operating activities for the three months ended March 31, 2023 was primarily due to our net loss of \$10.0 million, adjusted for \$2.2 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 \$0.1 million decrease in lease liabilities and a \$1.5 million decrease in accrued expenses.

Net cash used in investing activities was \$23 thousand for the three months ended March 31, 2023, compared to \$29 thousand for the three months ended March 31, 2022.

Net cash used in financing activities for the three months ended March 31, 2023 was \$6.2 million, compared to \$0 for the three months ended March 31, 2022. The increase was primarily related to the \$6.3 million in repayments of long-term debt, partially offset by \$0.1 million in proceeds from the issuance of common stock.

### Operating Capital and Capital Expenditure Requirements

We anticipate that losses will continue for the foreseeable future. As of March 31, 2023, our accumulated deficit was approximately \$890.7 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 as we rebuild our workforce with a focus 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 March 31, 2023, we had approximately \$37.4 million of cash, cash equivalents and restricted cash. Our restricted cash of \$13.9 million related to the amended Loan and Security Agreement, which was fully repaid as of May 1, 2023. Given our current development plans, we anticipate our cash resources will be sufficient to fund our operations into the fourth 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, or if we are unsuccessful in entering into partnership agreements for further development of our product candidates, management may need to curtail its development efforts and planned operations.

Working capital, which excludes restricted cash, as of March 31, 2023 was \$7.2 million, consisting of \$24.2 million in current assets and \$17.0 million in current liabilities. Working capital as of December 31, 2022 was \$15.7 million, consisting of \$39.9 million in current assets and \$24.2 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 April 2022, we modified our real estate lease agreement executed on December 15, 2020 with MD Anderson. The modification reduced our 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.

In June 2022, we executed an agreement to sub-sublease 4,772 square feet of our subleased office space in Boston. The term of the sub-sublease was from July 1, 2022 to June 30, 2025 and provided the sub-tenant with an option to extend through to July 31, 2026. For the three months ended March 31, 2023, we recognized \$43 thousand in lease income, which is classified within other income (expense), net in the condensed statement of operations.

In April 2023, we executed an agreement to terminate the lease for our remaining office space in Boston. Under the terms of the lease termination, we were required to pay a \$0.2 million termination fee. Additionally, we have been released from our sub-sublease signed in June 2022 as it has been assigned to the Boston office space's landlord in conjunction with the agreement to terminate the lease for the remaining office space.

### *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 March 31, 2023 and 2022, we recognized \$0.3 million related to royalty payments under the Patent License. As of March 31, 2023, we have paid a total of \$0.8 million in minimum annual royalty payments under the Patent License.

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 TCR-T Library Phase 1/2 Trial. 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. No payments were made during the three months ended March 31, 2023 and 2022.

On October 5, 2018, we entered into the License Agreement with PGEN Therapeutics, Inc., or PGEN, a wholly owned subsidiary of Precigen. We refer to PGEN and Precigen together as Precigen. Under the License Agreement, we were obligated to pay Precigen an annual licensing fee of \$0.1 million expected to be paid through the term of the License Agreement and we had also agreed to reimburse certain historical costs of Precigen up to \$1.0 million.

Pursuant to the terms of the License Agreement, we were 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 were also required to pay Precigen 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 as well as royalties ranging from low-single digits to mid-single digits on the net sales derived from the sales of any approved TCR products, up to a maximum royalty amount of \$100.0 million in the aggregate. We were also required to pay Precigen 20% of any sublicensing income received by us relating to the licensed products. We were also responsible for all development costs associated with each of the licensed products. Precigen was required to pay us royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of Precigen's CAR products, up to a maximum royalty amount of \$100.0 million. Pursuant to the A&R License Agreement, all royalty and milestone obligations between us and Precigen have been removed, and annual license payments due to Precigen have been reduced from \$100 thousand to \$75 thousand. Payment of the licensing fee is scheduled annually in the fourth

quarter; therefore, in accordance with the terms of the agreement, no amounts were paid during the three months ended March 31, 2023 and 2022.

In June 2022, Solasia Pharma K. K., or 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 months ended March 31, 2023 and 2022, the Company did not record collaboration revenue under the License and Collaboration Agreement, dated March 7, 2011, as amended on July 31, 2014 between Solasia and us.

### **Critical Accounting Policies and Significant Estimates**

In our Annual Report on Form 10-K for the year ended December 31, 2022, 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 months ended March 31, 2023.

### ***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 March 31, 2023. 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 March 31, 2023, 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 March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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 March 31, 2023, 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 three months ended March 31, 2023, we had a net loss of \$10.0 million, and, as of March 31, 2023, our accumulated deficit since inception in 2003 was \$890.7 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 March 31, 2023, we have approximately \$37.4 million of cash and cash equivalents, including \$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 fourth quarter of 2023. We have no committed sources of additional capital at this time. We follow the guidance of Accounting Standards Codification, or 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 condensed 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 condensed 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 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. Effective December 28, 2021, we entered into the First Amendment to the Loan and Security Agreement to, among other things, eliminate the additional tranche so that the \$25.0 million we had drawn down was the full amount available under the SVB Facility. In connection with entering into the Amended Loan and Security Agreement we also amended and restated the warrants. These SVB Warrants provide for the purchase of up to 649,615 shares of our common stock, in the aggregate, with an exercise price of \$1.16 per share. On May 1, 2023, we paid SVB all amounts outstanding under the amended Loan and Security Agreement, comprised of the entire outstanding principal amount of the SVB Facility, all accrued and unpaid interest and the Final Payment.

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 may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our condensed 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 Securities Exchange Act of 1934, as amended, or 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 condensed 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 condensed 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 are employing technologies such as the technology licensed from MD Anderson pursuant to the MD Anderson License described above, from Precigen, pursuant to the A&R 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 the 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 delivery of the potential products, which may increase the risk of adverse side effects of the chemotherapy itself or 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, some of which has been generated through trials conducted by MD Anderson and the NCI, rather than solely 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 decide to advance could negatively affect the timing of our potential future clinical trials. Such an impact on timing could increase research and process 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 all 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 that 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 and for the first two patients in November 2022. The first two patients enrolled in our TCR-T Library Phase 1/2 Trial have been removed from the trial due to subsequent disease progression. 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 certain solid tumors and plan to develop product candidates for use in those certain 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 recruit, hire 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.***

We may not be able to attract or retain qualified management and commercial, scientific, manufacturing 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, Athenex, BioNTech, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Kite (a Gilead company), Lion TCR, Lyell Immunopharma, Medigene, Neogene Therapeutics (a member of the AstraZeneca group), NexImmune, Nurix Therapeutics, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, T-Cure BioScience, T-knife 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 Therapeutics (a member of the AstraZeneca group), PACT Pharma, 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, TScan Therapeutics and several companies developing CRISPR technology, including Captain T Cell and 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, Immatics, Immunocore, Incyte, Merck, Mirati and Roche.

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 Precigen, 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, Precigen 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 Precigen, 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 A&R License Agreement 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, Precigen 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 Precigen 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 Precigen, 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 Precigen's technology suite and licensed to us by Precigen, 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 Precigen 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 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 we 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 us or 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 us or Precigen and may be terminated by the mutual written agreement of us, Precigen and MD Anderson.

Under the Patent License, we received an exclusive, worldwide license to certain intellectual property and patents from the 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 the Patent License, including by failing to meet the defined milestones by the required dates, and have not cured such breach within 90 days of receiving notice of such alleged breach. The NCI may also terminate the Patent License immediately upon our receipt of written notice of certain insolvency events. 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, or the CRADA Fourth Amendment, which, among other things, extended the term of the CRADA until January 9, 2025. If the NCI deprioritizes the work they are doing with us or otherwise limits their cooperation with us, our business may be negatively impacted.

***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.

***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.

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

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

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

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

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

***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 CROs 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.

***\*Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.***

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, in March and May of 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, Signature Bank was closed by New York's Department of Financial Services and First Republic Bank was closed by the California Department of Financial Protection and Innovation, and in each case the Federal Deposit Insurance Corporation was appointed as receiver. Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, or result in breaches of our financial and/or contractual obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

***\*A failure or the perceived risk of a failure to raise the statutory debt limit of the United States could have an adverse effect on our business, financial condition and results of operations.***

The U.S. government reached its debt limit of \$31.4 trillion in January 2023. Since then, the U.S. Department of Treasury implemented extraordinary measures to prevent default.

It is unclear if Congress and the President will reach an agreement to increase the U.S. government's debt limit in a timely manner. The political stalemate over legislation to fund U.S. government operations and raise the U.S. government's debt limit may increase the possibility of a default by the U.S. government on its debt obligations and related credit-rating downgrades. This creates uncertainty in the U.S. financial markets, domestic political conditions and interest rates which could have an adverse impact on our business and financial condition. Any disruption to the financial markets or an increase in interest rates may negatively impact our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. If the United States is unable to increase the U.S. government's debt limit in a timely manner, the U.S. federal government, including agencies like the FDA, could shut down for a period of time and the United States could default or delay on payment of its obligations or both, which could have an adverse impact on financial markets and economic conditions in the United States and worldwide and an adverse effect on our business, financial condition and results of operations. Any government shutdown may delay our clinical development plans and increase costs related to funding and clinical development.

## **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 have experienced, and may continue to experience, difficulties in patient enrollment in our ongoing TCR-T Library Phase 1/2 Trial and any future clinical trials 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;
- Patient insurance approvals of trial participation; 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 our clinical trial is in, and our future clinical trials may be 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, which would require 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 and 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, New Drug Application, 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 regulatory approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request and 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 dosing 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, or 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 significant 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 significant 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 were 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 product 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 requires 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 DNA plasmids, 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 some 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, or source product on commercially reasonable terms, which could be due to, among other things, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, supply chain

issues or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our ability to conduct clinical trials, which could significantly harm our business.

In addition, some of the reagents and products used by us 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. In 2021, we began manufacturing our product candidates at our in-house current good manufacturing practices, or cGMP, manufacturing facility at our leased headquarters in Houston, Texas. Our ability to manufacture our product candidates depends on our hiring and retaining personnel with the appropriate background and training to staff and operate the facility on a daily basis. Should we be unable to hire 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. Although 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. We recently amended our clinical trial IND to use cryopreservation-based storage of clinical products. This process is new and we may experience manufacturing failures or difficulties producing sufficient quantities of our clinical products as a result of this change.

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 are subject to review and oversight by the FDA. We are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. Our license to manufacture product candidates is 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.

***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 preclinical development work came from healthy donors. As we work 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 development and commercialization, if 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 manufacture 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 you 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 product candidates, 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 studies and clinical trials 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 geographies; 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 product candidates 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 would require 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, if approved, 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 the 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 product candidates 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. The ACA, among other things, imposed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, promoted a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program and imposed a number of substantial new compliance provisions related to pharmaceutical companies' interactions with healthcare practitioners. The ACA also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research and a new 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.

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 Act. Further, President Biden issued an executive order that 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. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and implementing a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact 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 30, 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 IRA delayed the implementation of the rule to January 1, 2032. 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 1, 2032. 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. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. 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.

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 prescribers 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 during the preceding calendar 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 any consulting agreements with physicians who may 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.

**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 the NCI, as well as with respect to the Precigen technology,

including *Sleeping Beauty*. Under the MD Anderson License, future patent applications require the agreement of each of MD Anderson, Precigen 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 Precigen instead may control such activities. Although under the License Agreement MD Anderson has agreed to review and incorporate any reasonable comments that we or Precigen may have regarding licensed patents and patent applications, we cannot guarantee that our comments will be solicited or implemented. 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 implemented. Under our A&R License Agreement Precigen 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. Precigen 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 A&R License Agreement Precigen 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 Precigen, as applicable, to keep us advised of prosecution, particularly in foreign jurisdictions where prosecution information may not be publicly available. We anticipate that we, the NCI and Precigen 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, the NCI or Precigen 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, the NCI and Precigen 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.***

Annuitants 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 the MD Anderson License, the Patent License and the A&R License Agreement. 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.

***\*If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Global Select Market. Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock.***

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Global Select Market or if we are unable to transfer our listing to another stock market. On January 4, 2023, we were notified by The Nasdaq Stock Market LLC, or Nasdaq, that we were in breach of Listing Rule 5450(a)(1), or the Minimum Bid Price Rule, for continued listing on the Nasdaq Global Select Market because the minimum bid price of our listed securities for 30 consecutive business days had been less than \$1 per share. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we have been provided a period of 180 calendar days, or until July 3, 2023, or the Compliance Date, to regain compliance with the Bid Price Requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at \$1.00 or more for a minimum of 10 consecutive business days as required under the Compliance Period Rule, Nasdaq will provide us written notification that we have regained compliance with the Bid Price Requirement, unless Nasdaq exercises its discretion to extend this ten-day period.

During this 180-day period, we anticipate reviewing our options to regain compliance with the Minimum Bid Price Rule, including conducting a reverse stock split. On April 25, 2023, we filed a definitive proxy statement, which included a proposal to effect a reverse stock split, if needed in the discretion of our board of directors to regain compliance with the Minimum Bid Price Rule, at a ratio between the range of 1-for-5 and 1-for-15, inclusive. On May 5, 2023, the closing price of our common stock was \$0.59 per share. If we are unable to continue to meet the requirements for listing on the Nasdaq Global Select Market we may apply to Nasdaq to list our common stock on the Nasdaq Capital Market, which may also provide us up to an additional 180 days to regain compliance with the Minimum Bid Price Rule. Nasdaq would have to accept our application to list on the Nasdaq Capital Market and we would need to show our compliance with the other listing standards and provide Nasdaq written notice of our intention to cure the Bid Price deficiency. Should Nasdaq determine that we are not eligible to list on the Nasdaq Capital Market or we elect not to submit an

application to transfer to the Nasdaq Capital Market, we will receive written notice that our common stock will be delisted, at which point we will have the opportunity to appeal that decision. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, deterring broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, the price of our common stock may decline, and although our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. If our common stock is delisted from Nasdaq, trading in our securities may be subject to the SEC's "penny stock" rules. These "penny stock" rules will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities.

Further, if our common stock is delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our shareholders to sell our common stock in the secondary market.

***\*We may effect a reverse stock split of our common stock, but it may not result in the intended benefits.***

As described above, we are seeking approval from our stockholders to effect, if needed in the discretion of our board of directors, a reverse stock split of the issued and outstanding shares of our common stock, our treasury stock, and a proportionate reduction in the shares of our authorized common stock in order to regain compliance with the Minimum Bid Price Rule. However, there can be no assurance that the reverse stock split will be approved by our stockholders. Further, there can be no assurance that the market price per new share of our common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of our common stock outstanding before the reverse stock split. Other factors, such as our financial results, market conditions and the market perception of our business may adversely affect the market price of our common stock and there can be no assurance that a reverse stock split, if completed, will result in the intended benefits, that the market price of our common stock will increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split or that the market price of our common stock will not decrease in the future. If the market price of our common stock does not increase the price per share of our common stock above Nasdaq's minimum bid price threshold of \$1.00 per share or if the market price of our common stock does not remain above Nasdaq's minimum bid price threshold of \$1.00 per share, our common stock may still be delisted from Nasdaq.

***\*If we implement a reverse stock split, liquidity of our common stock may be adversely affected.***

If we do effect a reverse stock split, the liquidity of the shares of our common stock may be affected adversely by any such reverse stock split given the reduced number of shares of common stock that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split.

Following any reverse stock split, the resulting market price of our common stock may not attract new investors and may not satisfy the investing requirements of those investors. Although we believe a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

***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 amended and restated 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 Delaware 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 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. If our common stock is delisted by Nasdaq, the impact of analysts ceasing to cover our securities may negatively impact the price of our common stock more dramatically.

***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 March 31, 2023, 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. As of March 31, 2023, under the 2020 Equity Incentive Plan and our 2012 Equity Incentive Plan, 13,313,246 shares were issuable upon the exercise of outstanding options at a weighted average exercise price of \$1.54 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 March 31, 2023, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 22.5% 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 either (i) our public float exceeds \$250 million, as of the last business day of our most recently completed second quarter, if our annual revenues equal or exceed \$100 million in our most recently completed fiscal year, or (ii) our public float exceeds \$700 million, as of the last business day of our most recently completed quarter, if our annual revenues are less than \$100 million in our most recently completed fiscal year.

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

None.

**Item 3. Defaults upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation of the Registrant, and all amendments thereto (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed June 17, 2022).</u></a>
3.2	<a href="#"><u>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).</u></a>
10.1+**	<a href="#"><u>Amended and Restated Exclusive License Agreement, dated, April 3, 2023, by and between the Registrant and Precigen, Inc.</u></a>
10.2+	<a href="#"><u>Offer Letter, dated October 29, 2018, between the Registrant and Drew Deniger.</u></a>
10.3+	<a href="#"><u>Severance Agreement, dated July 29, 2019, between the Registrant and Drew Deniger.</u></a>
10.4+	<a href="#"><u>Employment Agreement, dated November 29, 2021, by and between the Registrant and Melinda K. Lackey.</u></a>
31.1+	<a href="#"><u>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.</u></a>
32.1++	<a href="#"><u>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.</u></a>
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.
**	Portions of this document (indicated by “[**]”) have been omitted because such information is not material and is the type of information that the Registrant treats as private or confidential.

**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: May 10, 2023

By:

/s/ Michael Wong  
Michael Wong  
Vice President, Finance  
*(Principal Accounting Officer)*  
Dated: May 10, 2023

Certain identified information marked with [\*\*\*] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

## AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT

This **AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT** (the “**Agreement**”) is entered into as of April 3, 2023 (the “**Effective Date**”) replaces in its entirety the Exclusive License Agreement entered into on October 5, 2018 (the “**ELA Agreement**”) by and between **Alaunos Therapeutics** (formerly known as ZIOPHARM ONCOLOGY, INC.), a Delaware corporation, with its principal place of business at 8030 El Rio, Houston TX 77054 (“**Alaunos**”), and **PRECIGEN, INC.**, a Virginia corporation, with its principal place of business at 20358 Seneca Meadows Parkway, Germantown, MD 20876 (“**Precigen**”). Alaunos and Precigen are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### RECITALS

**WHEREAS**, Precigen possesses certain intellectual property related to Licensed Products (as defined below);

**WHEREAS**, Alaunos is a biopharmaceutical company focused on development of TCR Products (as defined below);

**WHEREAS**, Precigen and Alaunos are parties to certain agreements that, by this Agreement, are being terminated and/or amended;

**WHEREAS**, in consideration of entering into this Agreement, the Parties have agreed to amend certain rights, obligations and payment terms; and

**WHEREAS**, in connection with the Parties entering into this Agreement, the Parties have agreed to release each other from certain claims that either such Party may have under any prior agreement or arrangement between the Parties.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

**1.1 “2015 MDACC License”** means that certain License Agreement by and among Intrexon Corporation, Alaunos and MDACC with an effective date of January 13, 2015, as amended, and as assigned by Intrexon and assumed by Precigen effective as of January 1, 2018.

**1.2 “2018 MDACC License”** means that certain License Agreement by and among Precigen, Alaunos and MDACC with an effective date of January 8, 2018, as amended.

**1.3 “AAA”** has the meaning set forth in Section 11.2.

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1.4“**AAA Rules**” has the meaning set forth in Section 11.2.

1.5“**Accessory Material Agents**” means those materials as set forth in a letter agreement dated as of the date hereof by and between the Parties for use in the Field with Licensed Products.

1.6“**Activator Ligand**” means (i) veledimex and all formulations covered by the Drug Master File for a Formerly Licensed Product developed by Alaunos, and (ii) changes to the subject matter described in the foregoing (i) and made by Alaunos to advance a Formerly Licensed Product (“**Alaunos Veledimex Alterations**”).

1.7“**Affiliate**” means, with respect to a particular Party or other entity, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party or other entity. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

1.8“**Alaunos**” has the meaning set forth in the preamble.

1.9 “**Bankrupt Party**” has the meaning set forth in Section 12.2(a).

1.10“**BCMA CAR Products**” means any biological product, process or therapy developed under or arising from the B-cell maturation antigen (BCMA) CAR Program that is comprised of a CAR that is directed to BCMA, including all forms, formulations, presentations, doses, administrations and package configurations.

1.11“**BCMA CAR Program**” means a program(s) of Research and Development focused on using CAR cells directed to BCMA.

1.12“**Business Day**” means a day other than Saturday, Sunday or any day that banks in New York, New York, USA are required or permitted to be closed.

1.13“**CD19 CAR Products**” means any biological product, process or therapy developed under or arising from the CD19 CAR Program that is comprised of a CAR that is directed to CD19, including all forms, formulations, presentations, doses, administrations and package configurations. CD19 CAR Products include all product candidates that previously were under Development by Alaunos (and Precigen and its Affiliates) as of the Effective Date that contain a CAR that targets CD19.

1.14“**CD19 CAR Program**” means a program(s) of Research and Development focused on using CAR cells directed to CD19.

1.15 “**Chimeric Antigen Receptor**” or “**CAR**” means [\*\*\*].

1.16“**Chimeric Antigen Receptor T-Cell**” or “**CAR-T**” means [\*\*\*].

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**1.17“Claims”** has the meaning set forth in Section 8.1.

**1.18“Commercialization”** means the marketing, promotion, sale and/or distribution of products in the Territory, and all related manufacturing activities not included in the definition of Development. Commercialization, in relation to a Licensed Product, shall include commercial activities conducted in preparation for Licensed Product launch. **“Commercialize”** has a correlative meaning.

**1.19“Confidential Information”** of a Party means any and all Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by Precigen pursuant to the ELA Agreement and its predecessor agreements shall be deemed to be Precigen’s Confidential Information disclosed hereunder, and all Information disclosed by Alaunos pursuant to the ELA Agreement and its predecessor agreements shall be deemed to be Alaunos’ Confidential Information disclosed hereunder; provided that any use or disclosure of any Information that is authorized under Section 9.2 or otherwise licensed or expressly contemplated by this Agreement shall not be restricted by, or be deemed a violation of, the surviving confidentiality provisions under the predecessor agreements.

**1.20“Construct”** means [\*\*\*].

**1.21“Control”** means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Information, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other legally enforceable arrangement with any Third Party.

**1.22“Cover”** means, with respect to a claim of a Patent and a product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such product (considering claims of patent applications to be issued as then pending). **“Covering”** and **“Covered”** shall have a correlative meaning.

**1.23“Covering Claim”** has the meaning set forth in Section 5.2(b).

**1.24“Development”** means all activities that relate to the pre-clinical and clinical development of a product or to (a) obtaining, maintaining or expanding Regulatory Approval of a product, or (b) developing the ability to manufacture clinical and commercial quantities of a product. This includes: (i) preclinical testing, toxicology, and clinical trials; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Governmental Authority to obtain, maintain or expand Regulatory Approval of a product; and (iii) manufacturing process development and scale-up, bulk production and fill/finish work associated with the supply of a product for preclinical testing and clinical trials, and related quality assurance and technical support activities. **“Develop”** and **“Developed”** have a correlative meaning.

**1.25“Dispute”** has the meaning set forth in Section 11.1.

**1.26“Dollar”** means a U.S. dollar, and **“\$”** shall be interpreted accordingly.

**1.27“Exclusive Products”** means TCR Exclusive Products. For clarity, Exclusive Products include all forms, formulations, presentations, doses, administrations and package configurations thereof.

**1.28“Exclusive Program”** means, as applicable, the TCR Exclusive Program.

**1.29“Executive Officer”** means, with respect to Precigen, its President or CEO, and with respect to Alaunos, its CEO.

**1.30“FD&C Act”** means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

**1.31“FDA”** means the U.S. Food and Drug Administration or any successor entity.

**1.32“Field”** means (a) use of a Licensed Product (including TCR Products), for Treatment of cancer in humans, including solid and hematological cancers, and (b) use of TCR Products in the HPV Field. Except to the extent permitted under clause (b), the Field shall not include the prophylaxis or amelioration of conditions or symptoms associated with cancer or infectious disease which may result in cancer.

**1.33“Formerly Licensed Product”** means, as described in the ELA Agreement (i) IL-12 Products or an IL-12 Program, (ii) CD19 CAR Products or a CD19 CAR Program, or (iii) a BCMA CAR Product or a BCMA CAR Program.

**1.34“Gamma Delta T Cells”** means T-Cells expressing gamma delta TCRs.

**1.35“Gorilla IL-12 Products”** means any biological product, process or therapy Developed under the Gorilla IL-12 Program that is comprised of the Gorilla IL-12 Construct, including all forms, formulations, presentations, doses, administrations and package configurations.

**1.36“Gorilla IL-12 Program”** means a program(s) of Research and Development dependent on use of the Gorilla IL-12 Construct.

**1.37“Governmental Authority”** means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.38“HPV Field”** means, the treatment and prevention of human papillomavirus (HPV) infection and/or *in vivo* replication or proliferation solely to the extent the primary reason for such treatment or prevention is to prevent cancer.

**1.39“Human IL-12 Products”** means any biological product, process or therapy Developed under the Human IL-12 Program, including all forms, formulations, presentations, doses, administrations and package configurations.

**1.40“Human IL-12 Program”** means a program(s) of Research and Development focused on the use of the human clinical adenovirus to express Constructs.

**1.41“IL-12 Products”** means the Human IL-12 Products and the Gorilla IL-12 Products.

**1.42“IL-12 Program”** means, as applicable, the Human IL-12 Program or the Gorilla IL-12 Program.

**1.43“IND”** means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.44“Indemnified Party”** has the meaning set forth in Section 8.3.

**1.45“Indemnifying Party”** has the meaning set forth in Section 8.3.

**1.46“Information”** means any data, results, technology, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, algorithms, technology, test data (including biological and chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

**1.47“Laws”** means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

**1.48“Licensed Intellectual Property”** means the Licensed Know-How and Licensed Patents and any Alaunos Veledimex Alterations.

**1.49“Licensed Know-How”** means all Information Controlled by Precigen or its Affiliates as of October 5, 2018 that (a) is reasonably required or useful to advance Licensed Products and (i) was generated by or on behalf of Precigen or its Affiliates and was actually provided to and/or used by or on behalf of Alaunos or its Affiliates in connection with a Program as of, or prior to, October 5, 2018 (as evidenced by such Party’s or its Affiliates’ contemporaneous records) or (ii) was actually generated by or on behalf of Alaunos or its Affiliates or (b) is reasonably required to manufacture Accessory Material Agents.

**1.50“Licensed Patent”** means (a) any patent or patent application listed on Exhibit A, together with all continuations, divisions, continuations-in-part, re-examinations, reissues, substitutions, confirmations, registrations, re-validations, patent term extensions, supplementary protection certificates, certificates of invention, and applications for certificates of invention, or the like, of any such patents and patent applications, and any patent application or patent to which any patent or patent application listed on Exhibit A claims priority and (b) any patent application filed after October 5, 2018 solely to the extent that such patent application Covers Licensed Know-How that was both in existence as of October 5, 2018 and necessary to use the Accessory Material Agents in connection with the Research, Development, manufacture or Commercialization of a Licensed Product in the Field.

**1.51“Licensed Product”** means any Exclusive Product or Non-Exclusive Product and “Licensed Products” collectively means Exclusive Products and Non-Exclusive Products.

**1.52“MDACC Research Agreement”** means certain Research and Development Agreement by and among Intrexon, Alaunos and The University of Texas M.D. Anderson Cancer Center (“**MDACC**”) with an effective date of August 17, 2015, and any amendments or statements of work thereto.

**1.53“Merck Agreement”** means that certain License and Collaboration Agreement by and among Intrexon, Ziopharm and Ares Trading S.A., a corporation organized and existing under the laws of Switzerland, having offices at Zone Industrielle de L’Ourietaz, 1170 Aubonne, Switzerland (“**Ares Trading**”) effective March 27, 2015, as amended.

**1.54“NDA”** means a New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA.

**1.55“Neo-antigens”** means [\*\*\*].

**1.56“New Product Marks”** has the meaning set forth in Section 6.6.

**1.57“NK Cells”** means natural killer cells.

**1.58“NK Cells and Gamma Delta T Cell Products”** means any pharmaceutical or biological product, process or therapy developed under or arising from the NK Cells and Gamma Delta T Cell Program, including all forms, formulations, presentations, doses, administrations and package configurations.

**1.59“NK Cells and Gamma Delta T Cell Program”** means a program(s) of Research and Development focused on NK Cells and Gamma Delta T Cells.

**1.60“Non-Exclusive Products”** means (a) NK Cells and Gamma Delta T Cell Products, and (b) TCR Non-Exclusive Products, in each case as generated or Developed by Alaunos. For clarity, Non-Exclusive Products include all forms, formulations, presentations, doses, administrations and package configurations thereof.

**1.61 “Oncology”** means the treatment or prevention of a human patient who has received a cancer diagnosis.

**1.62“Patents”** means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

**1.63“Precigen”** means the Virginia corporation, with its principal place of business at 20358 Seneca Meadows Parkway, Germantown, MD 20876 along with its wholly owned subsidiaries and Affiliates.

**1.64 “Potential Claims”** has the meaning set forth in Section 3.4(a).

**1.65 “Precigen Impact Situation”** has the meaning set forth in Section 6.2(a).

**1.66 “Precigen Indemnitees”** has the meaning set forth in Section 8.2.

**1.67 “Product Infringement”** has the meaning set forth in Section 6.3(b).

**1.68 “Program”** means, as applicable, the TCR Program and the NK Cells and Gamma Delta T Cell Program.

**1.69 “Regulatory Approval”** means all approvals that are necessary for the commercial sale of product in the applicable field in a given country or regulatory jurisdiction.

**1.70 “Regulatory Authority”** means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

**1.71 “Regulatory Materials”** means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Licensed Product in a particular country or jurisdiction.

**1.72 “Releasees”** has the meaning set forth in Section 3.4(a).

**1.73 “Released Claims”** has the meaning set forth in Section 3.4(a).

**1.74 “Research”** means non-clinical studies of a product conducted before the filing of an IND for such product.

**1.75 “Sleeping Beauty Intellectual Property”** means patent families [\*\*\*] and [\*\*\*] as detailed in Exhibit A.

**1.76 “Sublicensee”** means any Third Party granted a sublicense, covenant not to sue, forbearance agreement, co-promotion agreement or other similar arrangement (a “**Sublicense**”) by Alaunos to the rights licensed to Alaunos under Section 2.1(a) or Section 2.1(b).

**1.77 “T-Cell”** means a T-lymphocyte, including alpha beta T cells and gamma delta T cells.

**1.78 “TCR”** means T-cell receptor complex.

**1.79 “TCR Exclusive Product”** means any biological product, process or therapy that includes a TCR for a Neo-antigen, including all forms, formulations, presentations, doses, administrations and package configurations.

**1.80 “TCR Exclusive Program”** means a program(s) of Research and Development focused on Developing TCRs designed for Neo-antigens.

**1.81“TCR Non-Exclusive Product”** means any biological product, process or therapy that is comprised of a TCR, other than TCR Exclusive Products, including all forms, formulations, presentations, doses, administrations and package configurations.

**1.82“TCR Products”** means TCR Non-Exclusive Products and TCR Exclusive Products.

**1.83“Term”** has the meaning set forth in Section 5.2(b).

**1.84“Territory”** means all countries of the world.

**1.85“Third Party”** means any entity other than Precigen or Alaunos or an Affiliate of either of them.

**1.86“Third Party Licenses”** has the meaning set forth in Section 2.1(e).

**1.87 “Trademark”** means any word, name, symbol, color, shape, designation or device or any combination thereof, including any trademark, service mark, trade name, trade dress, brand name, product configuration, domain name, logo, design or business symbol, that functions as an identifier of source, origin or membership, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

**1.88“Treat”** means delivery of a therapy to a human patient who has received a cancer diagnosis for the treatment of that cancer, including the prevention of the reoccurrence of any such cancer. **“Treatment”** has its correlative meaning.

**1.89“U.S.”** means the United States of America, including all possessions and territories thereof.

**1.90“Valid Claim”** means a claim of an issued, unexpired patent within the Licensed Patents that has not been revoked, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction in an unappealed or unappealable decision.

**1.91“Ziopharm Agreement”** means that certain Exclusive Channel Partner Agreement by and between Intrexon and Ziopharm, dated January 6, 2011, as amended by the First Amendment to Exclusive Channel Partner Agreement effective September 13, 2011; the Second Amendment to the Exclusive Channel Partner Agreement effective March 27, 2015 (the **“Second ECP Amendment”**) and the Third Amendment to Exclusive Channel Partner Agreement effective June 29, 2016, as assigned by Intrexon to Precigen.

**1.92 “Alaunos Indemnitees”** has the meaning set forth in Section 8.1.

## **ARTICLE 2 LICENSES AND EXCLUSIVITY**

### **2.1License to Alaunos for Licensed Products.**

**(a) License to Alaunos for Exclusive Products.** Precigen hereby grants Alaunos a royalty-free, exclusive license (even as to Precigen and its Affiliates except as provided in Section 2.1(c) below), with the right to sublicense through multiple tiers in accordance with Section 2.1(d), under the Licensed Intellectual Property to research, develop, make, have made, use, sell, have sold, offer for sale and import Exclusive Products in the Field in the Territory.

**(b) License to Alaunos for Accessory Material Agents and Non-Exclusive Products.** Precigen hereby grants Alaunos (i) a non-exclusive, royalty-free license, with the right to sublicense through multiple tiers in accordance with Section 2.1(d), under the Licensed Intellectual Property to research, develop, make, have made, use, sell, have sold, offer for sale and import Non-Exclusive Products in the Field in the Territory, and (ii) an exclusive, royalty-free license, with the right to sublicense in accordance with Section 2.1(d), under the Sleeping Beauty Intellectual Property to research, develop, make, have made, use, sell, have sold, offer for sale and import TCR Non-Exclusive Products in the Field in the Territory. For clarity, the foregoing license grant includes the right to make and have made Accessory Material Agents for use in connection with Licensed Products in the Field.

**(c) Precigen Retained Rights.** Notwithstanding the rights granted to Alaunos in Section 2.1(a) and 2.1(b), Precigen may research, develop, manufacture and Commercialize (i) products outside of the Exclusive Products in the Field in the Territory (subject to the grant of the exclusive license under the Sleeping Beauty Intellectual Property with respect to TCR Non-Exclusive Products in the Field) and (ii) products outside the Field.

**(d) Sublicenses; Assignments.**

**(i)** Alaunos may grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(a) and Section 2.1(b) to its Affiliates.

**(ii)** Alaunos may grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(a) and Section 2.1(b), to Third Parties solely to the extent reasonably necessary for contract manufacturing activities or Commercialization of Licensed Products with respect to any Licensed Product developed by or on behalf of Alaunos or its Affiliates, following which Alaunos will provide written notice of any such grant to Precigen within 10 business days of such grant.

**(iii)** Alaunos may grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(a) and Section 2.1(b), to Third Parties in connection with any Research, Development or Commercialization collaboration of such Exclusive Product or TCR Non-Exclusive Product, following which Alaunos will provide written notice of any such grant to Precigen within 10 business days of such grant.

**(iv)** Except as set forth above, Alaunos shall not have the right to sublicense any or all of the rights granted under this Agreement to Third Parties to Research, Develop, manufacture or Commercialize products of Third Parties without Precigen's prior written consent.

**(v)** Each agreement in which Alaunos grants a sublicense shall be consistent with the relevant terms and conditions of this Agreement and Alaunos shall provide such information as reasonably necessary to determine compliance with Section 2.1(d). Alaunos shall

remain responsible for the compliance of its Sublicensees with the terms and conditions of this Agreement. Breach by Alaunos' Sublicensees shall be a breach by Alaunos. Alaunos will provide Precigen a quarterly update, if any with respect to terminations or modifications of sublicenses granted under Section 2.1(d).

**(e) Third Party Licenses.** All Licensed Intellectual Property licensed to Precigen from a Third Party and sublicensed to Alaunos under this Agreement are subject to and subordinate to the terms of the applicable license agreements with Third Parties set forth on Exhibit B (the "**Third Party Licenses**"). Each Party will fully comply with the terms of any such Third Party License, and Alaunos shall remain solely responsible for the payment of any royalty, milestone, and other payment obligations, if any, due to Third Parties in connection with exercise of the licenses granted to Alaunos under this Agreement. Alaunos shall make all such payments timely in accordance with the terms of the applicable Third Party license. Precigen covenants not to, without the prior written consent of Alaunos, amend any Third Party License in such a manner that would diminish the rights granted to Alaunos under this Agreement, materially change any obligations under such Third Party License that would impact Alaunos hereunder or increase any payment obligation of Alaunos pursuant to such Third Party License.

**2.2Exclusivity.** Precigen hereby covenants that, during the Patent Term, neither it nor its Affiliates will (a) grant or offer any license or other rights to a Third Party, or otherwise discuss or negotiate with any Third Party the terms of any such license or rights, or (b) conduct any activities, whether independently or with or for the benefit of a Third Party, in each case of (a) and (b) with respect to the use of any Licensed Intellectual Property to research, develop, manufacture or Commercialize any Exclusive Product in the Field or with respect to the use of any Sleeping Beauty Intellectual Property as Covered by [\*\*\*] and [\*\*\*] to research, develop, manufacture or Commercialize any TCR Product in the Field.

**2.3Development Responsibilities.** Alaunos will have the exclusive right to conduct, and be solely responsible for all aspects of, the Research, Development and manufacture of Licensed Products and setting the regulatory strategy for seeking Regulatory Approvals for Licensed Products in the Field in the Territory.

**2.4Regulatory Responsibilities.** Alaunos shall have the exclusive right to prepare and shall own all Regulatory Materials (including all INDs, BLAs, NDAs, MAAs and Regulatory Approvals) for each Licensed Product in the Field in the Territory.

**2.5Commercialization Responsibilities.** Alaunos will have the exclusive right to conduct in its sole discretion, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Licensed Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of Licensed Products in the Territory; and (h) manufacturing of Licensed Products for commercial use.

**2.6 Development and Commercialization.** As of the Effective Date, Alaunos shall have no obligation to further Develop or Commercialize Licensed Products and shall not be liable to Precigen for any failure to do so.

**2.7 No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party. Precigen specifically reserves all rights not expressly granted to Alaunos under this Agreement.

### **ARTICLE 3 EXISTING AGREEMENTS**

**3.1 Termination of Exclusive License Agreement.** The Parties hereby agree to amend and restate the ELA Agreement and replace it in its entirety with this Agreement. The Parties acknowledge that the necessary assignments and transition services required under the ELA Agreement have been completed.

**3.2 Termination of Ziopharm Agreement.** The Parties previously agreed under the ELA Agreement to terminate the Ziopharm Agreement, and the termination of such agreement shall continue. Accordingly, all rights and licenses granted by Intrexon to Alaunos under the Ziopharm Agreement and all rights and licenses granted by Alaunos to Intrexon, such rights and licenses assigned by Intrexon to Precigen, under the Ziopharm Agreement shall terminate. For clarity, the Parties acknowledge and agree that the provisions of Section 10.4 of the Ziopharm Agreement did not apply to this termination of the Ziopharm Agreement by mutual written consent. Section 6.1 of the Second ECP Amendment did not survive termination of the Ziopharm Agreement. In the event of any conflict between the surviving terms of the Ziopharm Agreement and the terms of this Agreement, the terms of this Agreement shall control.

**3.3 MDACC Research Agreement and 2015 MDACC License.** Precigen shall retain rights to all intellectual property and materials received through the MDACC Research Agreement and 2015 MDACC License prior to the October 5, 2018, such right being licensed herein as part of the Licensed Intellectual Property.

#### **3.4 Mutual Release and Covenant Not to Sue.**

(a) The Parties, on behalf of themselves, their predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates and assigns, and its and their past, present, and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, insurers, managers, representatives, assigns and successors in interest, and all persons acting by, through, under or in concert with them, and each of them, hereby release and discharge the other Parties, together with their predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates and assigns and its and their past, present, and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest, and all persons acting by, through, under or in concert with them, and each of them (the Parties' "**Releasees**", as applicable), from all known and unknown charges,

complaints, claims, grievances, liabilities, obligations, promises, agreements, controversies, damages, actions, causes of action, suits, rights, demands, costs, losses, debts, penalties, fees, wages, medical costs, pain and suffering, mental anguish, emotional distress, expenses (including attorneys' fees and costs actually incurred) and punitive damages, of any nature whatsoever, known or unknown, which either Party has, or may have had, against the other Party, whether or not apparent or yet to be discovered, or which may hereafter develop ("**Potential Claims**"), for any acts or omissions, prior to the Effective Date, related to or arising from the ELA Agreement, the Ziopharm Agreement, including but not limited to the Second ECP Amendment, the Merck Agreement, the MDAAC Research Agreement, and each other agreement between Ziopharm and either Precigen or Intrexon, (the "**Released Claims**"). For avoidance of doubt, the Released Claims shall not include any Potential Claims: (a) for acts or omissions that occur on or after the Effective Date or (b) related to or arising from any rights or obligations set forth in this Agreement.

(b) Each Party agrees and hereby covenants that it will not, directly or indirectly, on its own behalf or acting on behalf of or through any other person or entity, initiate or maintain any lawsuit, arbitration or other proceeding, whether legal or equitable, against any other Party or its Releasees, arising from or related to the Released Claims.

(c) Alaunos hereby grants to Precigen a covenant not to sue for infringement for Precigen's Development or Commercialization of the Formerly Licensed Products based on any patent application filed by Alaunos prior to the Effective Date.

## **ARTICLE 4 TECHNOLOGY AND INVENTORY TRANSFER; REGULATORY**

### **4.1 Transfer of Licensed Know-How; Ongoing Transfers.**

(a) **Precigen Transfer to Alaunos.** All technology transfer and assignments due to Alaunos under the ELA Agreement are complete.

(b) **Alaunos Transfer to Precigen.** Within the sixty (60) day period following the Effective Date, Alaunos will provide Precigen copies of all electronic regulatory files, FDA communications and material data Information and materials including Accessory Material Agents solely relating to any of the Formerly Licensed Products previously developed by Alaunos, in each case that are in Alaunos' possession and Control, to the extent available to current employees of Alaunos after a reasonable search. Alaunos hereby grants to Precigen a right to reference all data Controlled by Alaunos as of the Effective Date solely pertaining to any of the Formerly Licensed Products previously developed by Alaunos. Alaunos agrees to execute any reasonable formalized letter necessary to grant Precigen's right of reference. With respect to hard copy of documents related to the Formerly Licensed Products, the Parties will work to complete any transfer or destruction (other than anything required for retention by the FDA) within six (6) months of the Effective Date.

**4.2 Historical GMP Materials and IL-12 Product Supply; Required Retention and Inventory Destruction.** Subject to any applicable statutes, regulations and written directives of the FDA, including which may require retention of information and samples of materials,

Alaunos shall be responsible for the destruction of its existing inventory of GMP materials related to CD-19, BCMA, and the IL-12 Product (including all final product, drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) that is then in the possession and Control of Alaunos or its Affiliates or Sublicensees, and shall provide notice of such destruction within sixty (60) days of confirmation by Precigen it does not wish to have any such materials transferred at Precigen request and cost. Precigen shall notify Alaunos with respect to such materials no later than sixty (60) days from the Effective Date.

**4.3DMF Transfer.** Within sixty (60) days following the Effective Date, Alaunos will execute documents necessary to assign or transfer the right to reference and use any Drug Master Files (DMFs) solely related to the Formerly Licensed Products developed by Alaunos, in each case that are in Alaunos' possession and Control, after a reasonable search.

## **ARTICLE 5 COMPENSATION**

**5.1Annual Licensing Payments.** Within five (5) Business Days after October 5, 2023 and each anniversary of the Effective Date during the Patent Term, Alaunos shall pay to Precigen an annual license payment of seventy-five thousand Dollars (\$75,000).

### **5.2No Alaunos Royalties on Licensed Products.**

(a) **Alaunos Exclusive and Non-Exclusive Products.** Alaunos shall not owe royalties to Precigen for the sale or sublicensing of any Exclusive or Non-Exclusive Product.

(b) **Term.** The “**Term**” with respect to the Licensed Patents shall be until the expiration or abandonment of the last-to-expire Valid Claim in such country Covering such Licensed Product (a “**Covering Claim**” in such country for such Licensed Product) (the “**Patent Term**”). The Term with respect to the Licensed Know-How shall be royalty-free, perpetual and irrevocable following the Term of the subject Licensed Patents (“**Perpetual Licensed Know-How**”). Notwithstanding the license grant, following expiration of the Patent Term on a case-by-case, country-by-country basis, the Perpetual Licensed Know-How will become non-exclusive.

### **5.3No Precigen Royalties.**

Precigen shall not owe any royalties to Alaunos for any products.

**5.4Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its income arising directly or indirectly from the efforts of the Parties under this Agreement.

## **ARTICLE 6 INTELLECTUAL PROPERTY MATTERS**

### **6.1Ownership of Inventions.**

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**(a) Activities by Alaunos.** Unless provided for otherwise herein, Alaunos shall own all Information and inventions, whether or not patentable, made in the course of Alaunos' Research, Development, manufacture and Commercialization of Licensed Products after the Effective Date.

**(b) Alaunos Veledimex Alterations.** Precigen shall own all Alaunos Veledimex Alterations, whether or not patentable, made in the course of Alaunos' Research, Development, manufacture and Commercialization of Formerly Licensed Products. Alaunos hereby assigns to Precigen any and all right, title and interest it may have in any such Alaunos Veledimex Alterations, and agrees to take such further actions as reasonably requested by Precigen to evidence such assignment. Alaunos will require all of its employees, consultants, agents and contractors, and will cause its Affiliates and subcontractors to require all of their employees, consultants, agents and contractors to assign all Alaunos Veledimex Alterations that are conceived, generated or otherwise made by such employees, consultants, agents and contractors to it, respectively, for further assignment according to the ownership principles described in this Section 6.1(b).

## **6.2 Prosecution of Licensed Patents.**

**(a) Generally.** Subject to Section 6.2(b), as between the Parties, Precigen shall have the right, but not the obligation, to prepare, file, prosecute and maintain the Licensed Patents in the Territory. As between the Parties, Precigen shall bear all costs incurred by Precigen in connection with the preparation, filing, prosecution or maintenance of any Licensed Patent. Precigen shall consult with Alaunos and keep Alaunos reasonably informed of the status of the Licensed Patents and shall promptly provide Alaunos with copies of all material correspondence received from any patent authority in connection therewith to the extent not publicly available. In addition, Precigen shall timely provide Alaunos with drafts of all proposed filings and correspondence to any patent authority with respect to the Licensed Patents (which could reasonably be considered to Cover a Licensed Product) in the Field for Alaunos' review and comment prior to the submission of such proposed filings and correspondence. Precigen shall confer with Alaunos and incorporate Alaunos' comments prior to submitting such filings and correspondence, provided, that Alaunos' comments do not require Precigen to take any action in connection with the Licensed Patents that could reasonably be expected to adversely affect Precigen's or its Affiliate's Development or Commercialization of (i) products (other than Licensed Products) claimed by such Licensed Patent inside or outside the Field in the Territory or (ii) Licensed Products claimed by such Licensed Patent outside the Field in the Territory (a "**Precigen Impact Situation**"). If in either Party's opinion, a Precigen Impact Situation could arise, such Party will promptly notify the other Party and the Parties shall discuss in good faith. Precigen shall have final decision authority with respect to whether or not to incorporate such comments. The Parties will work together to first determine if such claim could reasonably be considered to Cover a Licensed Product in the Field. If the claims in the pending case are determined not to Cover a Licensed Product, Precigen will not have an obligation to share prosecution for comment as opposed to for information only. However, if Precigen broadens the scope of the claims or files a continuation or divisional Precigen and Alaunos will again evaluate the claims to determine if the pending case Covers a Licensed Product.

**(b) New Patent Applications.** Notwithstanding Section 6.2(a), if after consultation with Alaunos, Precigen agrees that a new patent application (including, with respect

to Sleeping Beauty Intellectual Property, a divisional application) should be filed based on the Licensed Know-How, such patent applications shall be deemed Licensed Patents subject to further prosecution and maintenance in accordance with Section 6.2(a). Precigen shall reasonably consult with Alaunos regarding the drafting and filing of such new patent applications and shall reasonably consider any comments provided by Alaunos related thereto. For the avoidance of doubt, Precigen shall have authority with respect to such new patent applications (or divisional application) filing, prosecution and maintenance decisions in accordance with Section 6.2(a).

(c) **Abandonment.** If Precigen decides anywhere in the Territory to abandon any Licensed Patent in the Field, Alaunos may assume Precigen's rights and responsibilities under this Section 6.2 with respect to such Licensed Patent, and in connection with assuming such rights and responsibilities, Alaunos may apply for any extension (including a supplementary protection certificate or equivalent thereof) and Alaunos will thereafter be responsible for the prosecution and maintenance of such Licensed Patent in the Field in the Territory.

(d) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided above in this Section 6.2, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

### **6.3 Enforcement of Licensed Patents.**

(a) **Notification.** If either Party becomes aware of (i) any existing or threatened infringement of the Licensed Patents in the Field in the Territory (including the filing of an ANDA under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Licensed Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(IV), respectively), or (ii) a declaratory judgment action against any Licensed Patent in the Territory in connection with any infringement described in clause (i) (each of (i) and (ii), a "**Patent Infringement**"), it shall promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken with respect to such Patent Infringement.

(b) **Enforcement Rights.** For any Patent Infringement, each Party shall share with the other Party all Information available to it regarding such actual or alleged infringement. With respect to any Patent Infringement by a product that competes with an Exclusive Product in the Field (a "**Product Infringement**"). If a Licensed Patent is the only patent covering such Product Infringement, Alaunos will notify Precigen. Once Precigen confirms there are no other patents Alaunos could bring for Product Infringement and if the only Licensed Patent is a member of patent family [\*\*\*] then Alaunos shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, such Product Infringement, at Alaunos' cost and expense. Alaunos shall not settle any such suit or action in any manner that would reasonably be expected to (i) require Precigen to incur any liability (ii) require Precigen to make any payments, or (iii) would reasonably be expected to adversely affect Precigen's Development or Commercialization of products, in each case without the prior written consent of Precigen. If Alaunos does not, within one hundred eighty (180) days after its receipt or delivery of notice under Section 6.3(a), commence a suit to enforce the Licensed Patent

against such Product Infringement, take other action to terminate such Product Infringement or initiate a defense against such Product Infringement, Precigen shall have the right, but not the obligation, to commence such a suit or take such an action or defend against such Product Infringement in the Territory at its own cost and expense. Precigen shall not settle any such suit or action in any manner that (i) require Alaunos to incur any liability, (ii) require Alaunos to make any payments, or (iii) would reasonably be expected to adversely affect Alaunos' Development or Commercialization of products in each case without the prior written consent of Precigen. If such Product Infringement is related to [\*\*\*] and such Licensed Patent is the only patent covering such Product Infringement and Precigen has confirmed there are no other patents Alaunos could bring for Product Infringement, Precigen shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, such Product Infringement, at Precigen's cost and expense. Precigen shall not settle any such suit or action in any manner that would reasonably be expected to (i) require Alaunos to incur any liability or (iii) require Alaunos to make any payments, in each case without the prior written consent of Alaunos. If Precigen does not, within one hundred eighty (180) days after its receipt or delivery of notice under Section 6.3(a), commence a suit to enforce the Licensed Patent against such Product Infringement, take other action to terminate such Product Infringement or initiate a defense against such Product Infringement, Alaunos shall have the right, but not the obligation, to commence such a suit or take such an action or defend against such Product Infringement in the Territory at its own cost and expense. Alaunos shall not settle any such suit or action in any manner that would reasonably be expected to (i) require Precigen to incur any liability (ii) require Precigen to make any payments, or (iii) would reasonably be expected to adversely affect Precigen's Development or Commercialization of products, in each case without the prior written consent of Precigen.

**(c) Collaboration.** Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

**(d) Expenses and Recoveries.** The Party bringing or defending a claim, suit or action under Section 6.3(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Party or Parties in such litigation, and any remaining amounts shall be allocated [\*\*\*] between the Parties.

**6.4 Orange Book Listing.** Upon receipt of a notice of allowance (or equivalent) of an applicable Licensed Patent, Alaunos shall inform Precigen and request information reasonably required by Alaunos to list any Licensed Patent in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory with respect to such Licensed Product. Alaunos shall have the sole right to determine which Licensed Patent or other patent shall be included in the Orange Book for Licensed Products.

## 6.5 Trademarks.

(a) **New Product Marks.** Alaunos and its Affiliates and Sublicensees shall have the right to brand the Licensed Products in the Territory using any Trademarks it determines appropriate for the Licensed Products, which may vary by country or within a country (the “**New Product Marks**”), provided that Alaunos shall not, and shall ensure that its Affiliates and Sublicensees will not, make any use of the trademarks or house marks of Precigen (including Precigen’s corporate name) or any trademark confusingly similar thereto. As between the Parties, Alaunos shall own all rights in the New Product Marks and shall register and maintain, in its discretion and at its own cost and expense, the New Product Marks in the countries and regions in the Territory that it determines to be appropriate. Alaunos shall have the sole right, in its discretion and at its expense, to defend and enforce the New Product Marks.

## ARTICLE 7 REPRESENTATIONS AND WARRANTIES

**7.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

(a) **Corporate Existence.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated.

(b) **Corporate Power, Authority and Binding Agreement.** As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **No Conflicts.** It has not entered into any agreement with any Third Party that is in conflict with the rights granted to any other Party under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to any other Party under this Agreement, or that would otherwise materially conflict with or adversely affect any other Party’s rights under this Agreement.

**7.2 Representations and Warranties of Alaunos.** Alaunos hereby represents and warrants to Precigen as follows:

(a) **No Ongoing Clinical Trials Relating to Formerly Licensed Products.** As of the Effective Date, Alaunos has terminated active enrollment in all clinical trials related to the Formerly Licensed Products but there are FDA-required long term follow up programs which continue which cannot be terminated.

(b) **Terminated Contracts Relating to Formerly Licensed Products.** Alaunos has terminated all contracts for research programs and collaborations it previously had with Third

Parties to the extent relating to the Formerly Licensed Products. Alaunos has no existing licenses with a Third Party to the Formerly Licensed Products.

**7.3 Representations and Warranties of Precigen.** Precigen hereby represents and warrants to Alaunos that it has the right to grant the licenses that it grants to Alaunos under this Agreement.

**7.4 Mutual Covenants.**

(a) **No Conflicts.** Each Party shall not enter into any agreement with any Third Party that is in conflict with the rights, licenses and obligations under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement.

**7.5 Disclaimer.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

**ARTICLE 8  
INDEMNIFICATION**

**8.1 Indemnification by Precigen.** Precigen shall defend, indemnify, and hold Alaunos and its Affiliates and their respective officers, directors, employees, and agents (the “**Alaunos Indemnitees**”) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation incurred by such Alaunos Indemnitees, resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, “**Claims**”) against such Alaunos Indemnitee to the extent arising from or based on (a) the Research, Development or Commercialization of any Formerly Licensed Products, including by or on behalf of, or under license of, Precigen or its Affiliates, after the Effective Date (b) the Merck Agreement, (c) the breach of any of Precigen’s obligations, representations or warranties under this Agreement, or (d) the willful misconduct or gross negligence of Precigen, its Affiliates, or the officers, directors, employees, or agents of Precigen or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Alaunos Indemnitees fail to comply with the indemnification procedures set forth in Section 8.3 and Precigen’s defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 8.2(b) or 8.2(c) for which Alaunos is obligated to indemnify the Precigen Indemnitees under Section 8.2.

**8.2 Indemnification by Alaunos.** Alaunos shall defend, indemnify, and hold Precigen, Intrexon and their Affiliates and their respective officers, directors, employees, and agents (the “**Precigen Indemnitees**”) harmless from and against damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation

incurred by such Precigen Indemnitees, resulting from any Claims against such Precigen Indemnitee to the extent arising from or based on (a) the Development or Commercialization of Licensed Products by or on behalf of Alaunos or its Affiliates or Sublicensees, (b) the Research, Development or Commercialization of any Formerly Licensed Products, including by or on behalf of, or under license of, Alaunos or its Affiliates, Third Party collaborators, or Sublicensees, prior to the Effective Date (c) the breach of any of Alaunos' obligations, representations or warranties under this Agreement, (d) Alaunos' breach of the MDACC Research Agreement or 2015 MDACC License, each as amended pursuant to the Agreement or (e) the willful misconduct or gross negligence of Alaunos, its Affiliates, or the officers, directors, employees, or agents of Alaunos or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Precigen Indemnitees fail to comply with the indemnification procedures set forth in Section 8.3 and Alaunos' defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 8.1(c) or 8.1(d) for which Precigen is obligated to indemnify the Alaunos Indemnitees under Section 8.1.

**8.3 Indemnification Procedures.** The Party claiming indemnity under this Section 8.3 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Section 8.3.

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

**8.5 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold by such Party and for the three (3) year period thereafter. It is

understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Section 8.5. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation or non-renewal of such insurance.

## **ARTICLE 9 CONFIDENTIALITY**

**9.1 Confidentiality.** Each Party agrees that, during the Term and for a period of ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties; provided, however, that any Confidential Information that is considered a "trade secret" shall remain subject to the confidentiality provisions herein for so long as such Confidential Information maintains its "trade secret" status. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

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

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

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

**9.2 Authorized Disclosure.** Notwithstanding the obligations set forth in Section 9.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent such disclosure is reasonable necessary in the following instances:

(a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) disclosure to its and its Affiliates' employees, agents, consultants and contractors, on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(d) disclosure to potential and actual: investors, acquirors (of part or all of the shares and/or assets of a Party or an Affiliate), collaborators, licensors, licensees and sublicensees and other financial or commercial partners, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, collaboration, license or sublicense; provided that in each case, the discloses are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement (provided that the term of such obligations may be shorter); or

(e) to comply with applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or order; provided that the Party subject to such Laws shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

Notwithstanding the foregoing, if a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 9.2(e), such Party shall notify the other Party of such required disclosure as far in advance as reasonably practicable (and in no event less than fifteen (15) Business Days prior to the anticipated date of disclosure) to provide the non-disclosing Party opportunity to review and comment upon the disclosure.

### **9.3 Publicity; Terms of Agreement.**

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 9.3 or Section 9.2. In addition, a Party may disclose such terms to the extent reasonably necessary to be disclosed to any bona fide potential or actual investor, acquiror or merger partner for the sole purpose of evaluating an actual or potential investment, acquisition or merger; provided that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such Confidential Information and ensure that each such disclosee is contractually obligated to treat such Confidential Information as confidential.

(b) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's reasonable comments thereon to the extent consistent with the legal requirements, with respect to the filing

Party, governing disclosure of material agreements and material information that must be publicly filed.

## **ARTICLE 10 TERM AND TERMINATION**

**10.1Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 10 shall remain in effect on a Licensed Product-by-Licensed Product and country-by-country basis, until the expiration of the Patent Term, except as provided in Section 5.2(b).

**10.2Unilateral Termination by Alaunos.** Alaunos may terminate this Agreement, on a country-by-country, Program-by-Program, or Licensed Patent-by-Licensed Patent basis or in its entirety, for any or no reason upon written notice to Precigen. Upon any such termination of this Agreement by Alaunos, the license rights with respect to the applicable country, Program or Licensed Patent, as the case may be, shall terminate, and the then remaining license rights under this Agreement shall continue and survive.

### **10.3Termination by Either Party for Breach.**

**(a) Breach.** Subject to Section 10.3(b), each Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party materially breaches its obligations under this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within sixty (60) days from the date of such notice; provided that if such breach is not reasonably capable of cure within such sixty (60)-day period, the breaching Party may submit a reasonable cure plan prior to the end of such sixty (60)-day period, in which case the other Party shall not have the right to terminate this Agreement for so long as the breaching Party is using commercially reasonable efforts to implement such cure plan.

**(b) Disputed Breach.** If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 10.3(a), and such alleged breaching Party provides the other Party notice of such dispute within such sixty (60)-day period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 10.3(a) unless and until the arbitrators, in accordance with Section 11.2, has determined that the alleged breaching Party has materially breached the Agreement and that such Party fails to cure such breach within sixty (60) days following such arbitrators' decision. During the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. Except with respect to breaches of payment obligations, the Parties agree that a breach with respect to a Licensed Product shall not itself be deemed to be a breach with respect to other Licensed Products and any termination of this Agreement shall be limited to the Licensed Product or Licensed Products for which a Party breached its obligations hereunder. Nothing in this Section 10.3 shall limit a Party's ability to seek remedies available under this Agreement in law or equity.

**10.4Survival.** Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Articles 1 (to the extent definitions are used in the following sections or portions thereof), Article 8, Article 9, Article 11, and Article 12 and individual Sections: 2.7, 3.4, 5.2., 5.3, 5.4, 6.1, 6.5, 7.5, 10.1 and 10.4. If this Agreement is terminated with respect to a given Licensed Product, but not in its entirety, then following such termination the foregoing provisions of this Agreement shall remain in effect with respect to the Licensed Product(s) for which the termination is applicable (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety) and all provisions not surviving in accordance with the foregoing shall terminate with respect to the relevant Licensed Product for which the termination applies, as applicable, upon the effective date of termination thereof.

## **ARTICLE 11 DISPUTE RESOLUTION**

**11.1Disputes.** It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a “**Dispute**”), then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Executive Officers of each Party. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 11.2.

**11.2Arbitration.** Any Dispute that is not resolved pursuant to Section 12.1 shall, subject to Section 12.10, be resolved by binding arbitration administered by the American Arbitration Association (“**AAA**”) (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection) (the “**AAA Rules**”), except as modified in this Agreement, which AAA Rules are deemed to be incorporated by reference into this clause. The decision rendered in any such arbitration will be final, binding and unappealable. The arbitration shall be conducted by a panel of three (3) arbitrators appointed in accordance with the AAA Rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party, their respective Affiliates or any Sublicensee. The place of arbitration shall be New York, New York, U.S., and all proceedings and communications shall be in English. It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrators, the Parties and their representatives shall

hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

**11.3Governing Law.** This Agreement shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

**11.4Award.** Any award to be paid by one Party to the other Party as determined by the arbitrator(s) as set forth above under Section 11.2 shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the losing Party. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 11.4, and agrees that, subject to the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16, judgment may be entered upon the final award in any United States District Court located in New York and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator(s). With respect to money damages, nothing contained herein shall be construed to permit the arbitrator(s) or any court or any other forum to award consequential, incidental, special, punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for consequential, incidental, special, punitive or exemplary damages. The only damages recoverable under this Agreement are direct compensatory damages.

**11.5Costs.** Each Party shall bear its own legal fees. The arbitrator(s) shall assess his or her costs, fees and expenses against the Party losing the arbitration.

**11.6Injunctive Relief.** Nothing in this Article 11 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. For the avoidance of doubt, nothing in this Section 11.6 shall otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 10.3.

**11.7Confidentiality.** The arbitration proceeding shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator(s), except as required in connection with the enforcement of such award or as otherwise required by applicable law.

**11.8Survivability.** Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

**11.9Jurisdiction.** For the purposes of this Article 11, the Parties acknowledge their diversity and agree to accept the jurisdiction of any United States District Court located in New York for the purposes of enforcing or appealing any awards entered pursuant to this Article 11 and for enforcing the agreements reflected in this Article 11 and agree not to commence any action, suit or proceeding related thereto except in such courts.

**11.10Patent and Trademark Disputes.** Notwithstanding any other provisions of this Article 11, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Licensed Patents shall be submitted to a court of competent jurisdiction in the country in which such Patent was filed or granted.

## **ARTICLE 12 MISCELLANEOUS**

**12.1Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, and the Related Agreements sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement or the Related Agreements. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

### **12.2Rights in Bankruptcy.**

(a) To the extent permitted under applicable Law, all rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Title 11 of the United States Code (“**Title 11**”), licenses of rights to “intellectual property” as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against either Party (the “**Bankrupt Party**”), the other Party shall have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. All rights of the Parties under this Section 12.2 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this Agreement, Title 11, and any other applicable Laws. The non-Bankrupt Party shall have the right to perform the obligations of the Bankrupt Party hereunder with respect to such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

(b) Any intellectual property provided pursuant to the provisions of this Section 12.2 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

**12.3Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such

excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

**12.4 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 12.4, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Precigen:  
Precigen, Inc.  
20374 Seneca Meadows Parkway  
Germantown, MD 20876  
Attn: Chief Legal Officer  
Email: [\*\*\*]

If to Alaunos:

Alaunos Therapeutics  
8030 El Rio  
Houston, Texas 77054  
Attn: General Counsel

Email: [\*\*\*]

**12.5 No Strict Construction; Headings.** This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

**12.6 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except that a Party may make such an assignment or transfer without the other Party's consent (a) to its Affiliates, (b) to a Third Party in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise or (c) to a Third Party in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to a Licensed Product, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 12.6 shall be null, void and of no legal effect.

**12.7 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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

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

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

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

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

{Signature page follows}

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**IN WITNESS WHEREOF**, the Parties have executed this Amended and Restated Exclusive License Agreement by their duly authorized officers as of the Effective Date.

**ALAUNOS THERAPEUTICS**

**PRECIGEN, INC.**

By: /s/ Melinda Lackey By: /s/ Donald P. Lehr

Name: Melinda Lackey

Name: Donald P. Lehr

Title: Senior Vice President, Legal and Administrative  
Title: Chief Legal Officer

Signature Page to Exclusive License Agreement

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**LIST OF EXHIBITS:**

Exhibit A: Licensed Patents

Exhibit B: Third Party Licenses

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## Exhibit A – Licensed Patents

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**Exhibit B - THIRD PARTY LICENSES**

- License Agreement by and among Intrexon Corporation, Alaunos and MDACC with an effective date of January 13, 2015, as amended, and as assigned by Intrexon and assumed by Precigen effective as of January 1, 2018.
  - License Agreement by and among Precigen, Alaunos and MDACC with an effective date of January 8, 2018, as amended.
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October 29, 2018

Drew Deniger

Dear Drew,

Thank you for considering employment with Ziopharm Oncology, Inc (the "Company"). We are impressed with your credentials and accomplishments. We believe your training and experience will make you a tremendous asset at this exciting time in the company's development. I am pleased, therefore, to formally offer you a Sr. Scientific/Management role at our Houston laboratory, reporting to Ellee de Groot. Over the coming months, we will work together to refine the title and job description.

Details of this offer and compensation are as follows:

- Your semi-monthly salary will be \$12,916.66 (\$310,000 if annualized). You will be scheduled for an annual performance review.
- You will be eligible for a discretionary performance bonus potential of up to 30% of your base salary.
- You will be eligible for a severance agreement in the amount of 3 months.
- You will be eligible to receive a one-time sign-on bonus in the amount of \$35,000
- The Company will reimburse you up to \$20,000 for moving expenses incurred in relocating your belongings to the Houston area. This includes direct bill for movers, all moving expenses, and house hunting travel for your spouse. The Company will not reimburse you for closing costs, rental money/mortgage, or furniture purchases.
- The Company will cover the cost of temporary housing in the Houston area for up to 3 months if needed.
- You will be entitled to all company benefits outlined in the accompanying Benefits Overview. Additional questions regarding the benefits can be directed to me at \_\_\_\_\_.
- You will be entitled to accrue paid vacation at the rate of 3 weeks per year.
- Subject to the approval of the Board of Directors of the Company, you will be eligible for a new hire stock option grant of 50,000 shares. Any such options will be granted on the later of the date on which you commence employment with the Company or the date of board approval will be evidenced by a stock option agreement and will vest, if at all, in accordance with that agreement and the Company's 2012 stock option plan.
- Please note that this offer is contingent upon the successful completion of an employment background check. We require that all ZIOPHARM Oncology, Inc. employees have a completed employment background check on file.

As with all Ziopharm employees, this is employment at-will and may be terminated by either party at any time, for any reason, without previous notice. This offer letter is not an employment contract and should not be construed as a contract; Ziopharm has the right to change or modify the terms of your employment at any time. No supervisor or other representative of the Company, except our CEO, has any authority to enter into any type of employment agreement with any employee. Any employment agreement entered into by Ziopharm must be in writing.

Enclosed, please find an Invention, Non-Disclosure and Non-Competition Agreement for your review. You will be required to sign this agreement upon commencement of your employment with Ziopharm. If you have any questions regarding this agreement, please do not hesitate to contact me.

Please indicate your acceptance of the terms of this offer by signing and returning one copy of this letter by scan/email (\_\_\_\_\_) by Thursday, November 1, 2018. If you agree to the terms of employment we can discuss a mutually agreed upon start date, but anticipate it will be no later than mid-August of 2019. Drew, we look forward to welcoming you as a member of the Ziopharm team!

Sincerely,

/s/ Amy Emery  
Amy Emery  
Human Resources Manager

I agree to the terms of employment as outlined above:

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/s/ Drew Deniger  
Drew Deniger

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10/31/2018  
Date

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## SEVERANCE AGREEMENT

This Severance Agreement ("Agreement") is made effective as of July 29, 2019 (the "Effective Date") between Drew Deniger ("Employee") and ZIOPHARM Oncology, Inc., a Delaware corporation (the "Company"). Employee and the Company are hereinafter collectively referred to as the "Parties."

WHEREAS, the Employee is employed by the Company in the position of VP, Immunology on the terms set forth in an offer letter dated October 29, 2018 (the "Offer Letter"); and

WHEREAS, pursuant to the terms of the Offer Letter, the Company intends to provide Employee with severance benefits in the event Employee's employment with the Company is terminated without Cause (as such term is hereinafter defined).

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, Employee and the Company hereby agree as follows:

1. Employment. Employee is employed by the Company on an at-will basis meaning that either party may terminate the relationship at any time, with or without cause, and without providing a reason for such termination.

2. Termination of Employment.

a. Termination for Cause. The Company may terminate the employment of Employee at any time for Cause (such termination being herein called a "Termination for Cause"). For purposes of this Agreement, the term "Cause" shall mean: (i) Employee's willful or negligent failure, disregard or refusal to perform his or her duties of employment; (ii) any act by Employee that in the opinion of the Chief Executive Officer of the Company, has the effect of injuring the business or reputation of the Company or any of its affiliates, including but not limited to, any officer, director, executive or shareholder of the Company or any of its affiliates; (iii) Employee's misconduct in respect of his or her duties or obligations, including, without limitation, insubordination with respect to lawful directions received by Employee from the Chief Executive Officer of the Company (or such other executive officer to whom Employee may report); (iv) Employee's indictment of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea); (v) the determination by the Company after a reasonable and good faith investigation by the Company following a written allegation by another employee of the Company, that Employee engaged in some form of harassment prohibited by law (including, without limitation, harassment that constitutes age, sex or race discrimination); (vi) any misappropriation or embezzlement of the property of the Company or its affiliates (whether or not constituting a misdemeanor or felony); (vii) Employee's breach of any of the provisions of the Company's Invention, Non-Disclosure and Non-Competition Agreement, as determined in the sole and absolute discretion of the Chief Executive Officer of the Company; or (viii) Employee's breach of any provision of this Agreement, as determined in the sole and absolute discretion of the Chief Executive Officer of the Company.

b. Termination Without Cause. The Company may terminate Employee's employment for any legal reason at any time, without notice and without Cause.

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3. Effect of Termination.

a. Termination by the Company Without Cause. If Employee is terminated by the Company other than for Cause, and other than by reason of retirement, death or disability, (i) the Company shall pay to Employee his or her accrued base salary through the date of Employee's termination, and (ii) a severance amount, payable in a single lump sum, equal to three (3) months of Employee's annualized base salary at the time of termination (excluding any benefits or bonuses) (the "Severance"). The Severance shall only be payable if Employee signs a general release with the Company, which release must be concluded and executed on or before the date that is two and one-half months after the end of the calendar year in which Employee's "separation from service" (as defined under Section 409A of the Internal Revenue Code of 1986, as amended) occurs, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment with, the Company, and which release shall be in form satisfactory to the Company (the "General Release").

b. Termination by the Company for Cause. Upon the termination of Employee's employment pursuant to a Termination for Cause, Employee will be entitled to receive only Employee's accrued base salary through the date of Employee's termination. If Employee is terminated for Cause, he or she will not be entitled to any Severance under Section 3(a) of this Agreement.

c. Voluntary Termination. If the Employee voluntarily terminates his or her employment with the Company, for any reason, Employee will be entitled to receive his or her base salary through the date of Employee's termination. If Employee terminates his or her employment with the Company, for any reason, Employee will not be entitled to any Severance under Section 3(a) of this Agreement. If the Company receives notice from the Employee of his or her intent to terminate employment with the Company and the Company elects to immediately end the employment relationship, Employee will not be entitled to any Severance under Section 3(a) of this Agreement.

d. Death or Disability of Executive. If Employee dies or becomes disabled during the term of this Agreement, Employee will be entitled to receive Employee's accrued base salary through the date of Employee's termination. If Employee's employment is terminated due to death or disability, Employee will not be entitled to any Severance under Section 3(a) of this Agreement.

4. Effect of Termination on Benefits.

a. If Employee's employment with the Company is terminated, Employee may elect to continue, and the Company shall continue to provide, Employee's existing medical and dental coverage under the Company's medical and dental insurance plans, if any, for a period of up to eighteen (18) months from the date of termination, with the entire cost of such medical and dental insurance coverage from and after the date of termination to be borne entirely by Employee; *provided, however*, that if Employee's employment is terminated by the Company (or its successor) without Cause and the Employee has provided the General Release as set forth above, the Company shall continue to pay its contributions for such medical and dental insurance coverage for the first three (3) months following the date of termination.

b. Except as otherwise specifically provided for in subsection (a) of this Section 4, or in Section 3 above, upon termination of Employee's employment, Employee shall have no further entitlement to any other compensation or benefits from the Company.

5. Prior Agreements. This Agreement and the Offer Letter contain the entire understanding of the parties with regard to all matters contained herein. There are no other agreements, conditions or representations, oral or written, expressed or implied relating to such matters.

6. Assignment. This Agreement shall be binding upon, and shall inure to the benefit of, the parties and their respective successors, assigns, heirs and personal representatives and any entity with which

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the Company may merge or consolidate or to which the Company may sell substantially all of its assets, provided that this Agreement may not be assigned by Employee.

7. Governing Law. This Agreement shall be construed in accordance with the laws of the Commonwealth of Massachusetts, applying to contracts fully executed and performed within the Commonwealth of Massachusetts.

8. Section Headings: Gender; Number. The section headings in this Agreement are for convenience only; they form no part of this Agreement and will not affect its interpretation. Words used herein, regardless of the number and gender specifically used, will be deemed and construed to include any other number, singular or plural, and any other gender, masculine, feminine or neuter, as the context requires.

The Parties have executed this Agreement effective as of the Effective Date.

/s/ Drew Deniger  
Drew Deniger

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## EMPLOYMENT AGREEMENT

This Employment Agreement (this “Agreement”) is made and entered into as of November 29, 2021 (the “Effective Date”), notwithstanding that this Agreement may be executed on a different date, by and between Ziopharm Oncology, Inc. (the “Company”), and Melinda K. Lackey (“Executive”). Each of the Company and Executive are referred to herein individually as a “Party” and collectively as the “Parties.”

### RECITALS

A. The Company is in the business of developing the next generation of immuno- oncology medicines.

B. The Company desires to employ Executive as Senior Vice President, Legal, and Executive desires to be employed by the Company in said capacity.

C. Executive acknowledges that she will have significant involvement in the operation of the Company and consequently, that she will be using the Company’s confidential and proprietary information in her capacity as Executive and that such information provided to Executive pursuant to this Agreement, including information that Executive has not previously received, gives rise to the Company’s interest in restraining Executive and that the restrictive covenants are necessary to protect the Company’s confidential and proprietary information, goodwill, or other business interest of the Company.

D. The Parties desire to agree to the various matters described herein and to memorialize those agreements herein.

### AGREEMENT

#### **1. Effectiveness; Employment Period.**

(a) This Agreement shall become effective and binding upon the Company and the Executive at 12:00 a.m. prevailing Central Standard Time, on the Effective Date.

(b) Subject to Section 4, Company hereby agrees to employ Executive, and Executive hereby agrees to be employed by Company, in accordance with the terms and provisions of this Agreement, for the period commencing as of the Effective Date and ending on the two year anniversary of the Effective Date (the “**Employment Period**”); provided, however, that the Employment Period shall automatically be renewed and extended for an additional period of twelve (12) months commencing on the day following the two year anniversary of the Effective Date (“**Extension Date**”) and expiring on the one year anniversary of the Extension Date, and on each successive anniversary thereafter, unless at least ninety (90) days prior to the ensuing expiration date (but no more than twelve (12) months prior to such expiration date), Company or Executive shall have given ninety (90) days written notice to the other that it or she, as applicable, does not wish to extend this Agreement (a “**Non-Renewal Notice**”). The term “**Employment Period**” as utilized in this Agreement, shall refer to the Employment Period as so automatically extended and the Employment Period shall be deemed to end on the Executive’s last day of actual employment with Company.

(c) During the term of Executive’s employment with Company, Executive shall serve as the Senior Vice President, Legal for the Company and in so doing, shall report to the Chief

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Executive Officer of the Company. Executive shall have supervision and control over, and responsibility for, such management and operational functions of the Company currently assigned to such positions, and shall have such other powers and duties as may from time to time be prescribed by the Board of Directors or a committee thereof (the "Board"), so long as such powers and duties are reasonable and customary for the Senior Vice President, Legal of an enterprise comparable to the Company.

(d) During the term of Executive's employment with Company, and excluding any periods of vacation and sick leave to which Executive is entitled, Executive agrees to devote substantially all of her business time to the business and affairs of Company and, to the extent necessary to discharge the responsibilities assigned to Executive hereunder or by the Board hereafter, to use Executive's reasonable best efforts to perform faithfully, effectively and efficiently such responsibilities. During the term of Executive's employment with Company, it shall not be a violation of this Agreement for Executive to (i) serve on corporate, civic or charitable boards or committees, provided that service on any corporate board or committee shall be subject to the prior approval of the Board, which shall not be unreasonably withheld, (ii) deliver lectures or fulfill speaking engagements, and (iii) manage personal investments, so long as such activities do not materially interfere with the performance of Executive's responsibilities as an employee of the Company in accordance with this Agreement.

(e) The parties expressly acknowledge that any performance of Executive's responsibilities hereunder shall necessitate, and the Company shall provide, access to or the disclosure of Confidential Information (as defined in Section 8(a) below) to Executive and that Executive's responsibilities shall include the development of the Company's goodwill through Executive's contacts with the Company's customers and suppliers.

## **2. Compensation.**

(a) *Base Salary.* Company shall pay Executive an annual base salary ("**Base Salary**") at the rate of \$325,000 for the period commencing on the Effective Date. For the avoidance of doubt, the Base Salary for calendar year 2021 will be pro-rated based on Executive's partial year of service. The Board shall review Executive's Base Salary at least annually and may at its discretion elect to increase Executive's Base Salary at any time if they deem an increase is warranted. Subject to Section 4(c)(ii) hereof, the Board may not decrease Executive's annual Base Salary without her prior written approval. Base Salary shall be payable in accordance with the ordinary payroll practices of Company, but in no event shall the Base Salary be paid to Executive less frequently than monthly. The term "Base Salary" as used in this Agreement shall refer to the Base Salary as it may be so adjusted from time to time.

(b) *Signing Bonus.* Company shall pay Executive a lump sum cash signing bonus of \$30,000 (the "**Signing Bonus**"); provided that, Executive shall repay the gross amount of the Signing Bonus if the Executive terminates the Executive's employment voluntarily or involuntarily for any reason on or before the one year anniversary of the Effective Date.

(c) *Annual Bonus.* Executive shall be eligible, beginning in 2022, to receive an annual cash bonus (the "**Annual Bonus**") in an amount to be determined by the Board or compensation committee of the Board ("**Committee**") based on performance goals established by the Board or Committee, as applicable; on an annual basis. The amount of the Executive's Annual Bonus for a target level of performance shall be equal to a percentage of the Executive's Base Salary as determined by the Board or Committee as applicable ("**Target Bonus**"). Initially, the percentage of the Executive's Base Salary for a Target Bonus will be forty percent (40%). For the avoidance of doubt, Executive is not eligible for an annual bonus for the 2021 performance year.

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(d) *Stock Options*. During 2021 Executive shall be granted an option to purchase 370,000 shares of the Company's common stock (the "**Option**") on the generally the same terms and conditions as stock options are granted under the Ziophram 2020 Equity Incentive Plan. The terms of such grant, when made, shall be set forth in a written award agreement. A quarter of the shares subject to the option shall vest one year after the vesting commencement date, specified in the award agreement evidencing the Option ("**Vesting Commencement Date**"); the balance of the shares vest in a series of twelve (12) successive equal quarterly installments measured from the first anniversary of the Vesting Commencement Date, subject to Executive's continued employment with the Company through each vesting date. Executive will be eligible for additional annual long-term incentive compensation grants beginning in 2023, as determined by the Board or Committee.

In addition, in the event of a Change in Control (as defined in the 2020 Equity Incentive Plan) and termination of Executive's employment without Cause or termination of Executive's employment for Good Reason (as defined in Section 4 of this Agreement), all remaining unvested options become immediately exercisable in full.

### **3. Employee Benefits.**

(a) During the Employment Period, Company shall provide Executive with coverage under all employee pension and welfare benefit programs, plans and practices, which Company makes available to its senior executives (including, without limitation, participation in health, dental, group life, disability, retirement and all other plans and fringe benefits to the extent generally provided to such senior executives), commensurate with her position in the Company, to the extent permitted under the employee benefit plan or program, and in accordance with the terms of the program and/or plan.

(b) Executive shall be entitled to vacation time in accordance with the Company's published vacation policy.

(c) Executive is authorized to incur reasonable expenses in carrying out her duties and responsibilities under this Agreement and promoting the business of the Company, including, without limitation, reasonable expenses for travel, lodgings, entertainment and similar items related to such duties and responsibilities. Company will promptly reimburse Executive for all such expenses upon presentation by Executive of appropriately itemized and approved (consistent with Company's policy) accounts of such expenditures, in accordance with the Company's expense reimbursement policy; provided, however, that in no event shall the expense reimbursement be made after the last day of the taxable year following the year in which the expense was incurred by Executive, although in the event that the reimbursement would constitute taxable income to Executive, such reimbursements will be paid no later than March 15th of the calendar year following the calendar year in which the expense was incurred. No reimbursement or expenses eligible for reimbursement in any taxable year shall affect the expenses eligible for reimbursement in any other taxable year, nor may the right to receive a reimbursement of expenses be subject to liquidation or exchanged for another benefit.

### **4. Termination of Employment.**

(a) *Termination without Cause or Resignation by Executive for Other than Good Reason*. Unless otherwise specified in a separate provision of this Section 4, either Executive or Company, by action of the Board, may terminate this Agreement, and Executive's employment by Company, for any reason after providing thirty (30) days written notice to the non-terminating party.

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(i) If Executive terminates this Agreement pursuant to this provision for a reason other than Good Reason, Company will pay Executive: (i) all accrued but unpaid Base Salary, (ii) a prorated amount of Executive's Base Salary for accrued but unused vacation days, and (iii) yet unpaid reimbursements for any reasonable and necessary business expenses incurred by Executive prior to the Date of Termination in connection with her duties hereunder (such amounts collectively, the "**Accrued Compensation and Reimbursements**").

(ii) Upon termination by Company of this Agreement pursuant to Section 4(a) without Cause or upon the expiration of the Employment Period due to the non-renewal of Executive's employment pursuant to the terms of a Non-Renewal Notice given by the Company under Section 1(b) of this Agreement, Company shall pay or provide to Executive the following "**Severance Payments**," provided that Executive has signed a Release (as defined in Section 7) and such Release has become non-revocable: (A) the Accrued Compensation and Reimbursements; (B) a lump sum payment equal to six (6) months of the Executive's Base Salary (at the rate in effect hereunder as of the Date of Termination).

(b) *Termination for Cause.* Company, by action of the Board may terminate this Agreement at any time for Cause. Upon termination by Company for Cause, Executive shall only be entitled to Accrued Compensation and Reimbursements. For purposes hereof, "**Cause**" means any of the following:

(i) Executive's commission of theft, embezzlement, or any act of fraud relating to her employment with Company or any willful and material violation of any law, rules or regulation applicable to the Company, including, but not limited to, those laws, rules or regulations established by the Securities and Exchange Commission, or any self-regulatory organization having jurisdiction or authority over Executive or the Company; or

(ii) Executive's conviction of, or Executive's plea of guilty or *nolo contendere* to, any felony or of any other crime involving fraud, dishonesty or moral turpitude; or

(iii) A determination by the Board that Executive has materially breached this Agreement (other than during any period of Disability, as defined below) where such breach is not remedied within ten business (10) days after written demand by the Board for substantial performance is actually received by Executive which specifically identifies the manner in which the Board believes Executive has so breached; or

(iv) Executive's willful and continued failure to perform her reasonable and customary duties as Senior Vice President, Legal, which such failure is not remedied within ten business (10) days after written demand by the Board for substantial performance is actually received by Executive which specifically identifies the nature of such failure.

Company, by action of the Board, may terminate Executive's employment for Cause only after:

- (i) providing written notice to Executive, which identifies the Cause for Executive's termination (which notice must be given within ninety (90) days after the actual discovery of the act(s) or omission(s) constituting such Cause) and
  - (ii) Executive has been given an opportunity, together with her counsel, to be heard by the Board at a time and location reasonably designated by the Board.
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(c) *Termination with Good Reason.* Executive may terminate this Agreement for Good Reason, and thereby resign her employment, after providing thirty (30) days' written notice to the Company of the act(s) or omission(s) constituting Good Reason (which notice must be given within ninety (90) days after the occurrence of such act(s) or omission(s) and describe the act(s) or omission(s) in reasonable detail) if such act(s) or omission(s) is/are not cured by the Company within thirty (30) days after Executive provides such written notice. For purposes hereof, "**Good Reason**" means any of the following reasons that occurs without Executive's written consent:

- (i) A material reduction in Executive's significant duties without Executive's consent;
- (ii) A reduction in Executive's Base Salary, other than a one-time reduction affecting senior management similarly and in no event more than 10% from the Base Salary in effect on the date hereof, or
- (iii) A reduction in Executive's annual bonus opportunity of more than ten (10%) below the level specified in Section 2(b), it being understood and expressly agreed that no Annual Bonus payment is guaranteed and that the Board's determination of Executive's actual Annual Bonus payment in any amount less than the Target Bonus shall not constitute Good Reason under this Section 4(c)(iii); or
- (iv) Relocation of Executive's principal place of business to a location fifty (50) or more miles from its location as of the Effective Date; or
- (v) A material breach by Company of this Agreement; or
- (vi) Company's failure to make any material payment to Executive required to be made under the terms of this Agreement.

Notwithstanding the foregoing, Executive may not resign for Good Reason unless and until Executive has: (a) provided Company, within ninety (90) days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided Company with an opportunity to cure the same within ten (10) days after the receipt of such notice; and (c) resigned employment with Company within thirty (30) days following Company's failure to cure.

Upon termination of this Agreement pursuant to this Section 4(c), Company shall pay Executive the Severance Payments at the time set forth in Section 4(a)(ii).

(d) *Termination by Disability.* Company, by action of the Board, may terminate this Agreement at any time if Executive shall be deemed in the reasonable judgment of the Board to have sustained a "**Disability**." Executive shall be deemed to have sustained a Disability if and only if she shall have been unable to substantially perform her duties as an employee of Company as a result of sickness or injury, and shall have remained unable to perform any such duties for a period of more than 180 consecutive days in any twelve (12) month period. Upon termination of this Agreement for Disability, Company shall pay Executive: (i) Accrued Compensation and Reimbursements, which amount shall be paid within ten (10) business days after the Date of Termination, (ii) any Annual Bonus for the year prior to the year in which the Date of Termination occurred that was earned but not yet paid, paid at the same time annual bonuses are paid to other executives (but in no event later than March 15th of the calendar year following the calendar year in which the Annual Bonus was earned, (iii) a pro rata Annual Bonus in respect of the number of

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months Executive was employed by the Company during the year in which the Executive is deemed by the Board to have sustained a Disability, based on actual performance and paid at the same time annual bonuses are paid to other senior management (but in no event later than March 15th of the calendar year following the calendar year in which the Annual Bonus was earned), and

(iv) any other amounts or benefits to which Executive may be entitled under a separate plan, policy or program maintained by the Company.

(e) *Termination by Death.* This Agreement will terminate automatically upon Executive's death. Upon termination of this Agreement because of Executive's death, Company shall pay or provide Executive's estate with the following: (i) Accrued Compensation and Reimbursements, which amount shall be paid within ten (10) business days after the Date of Termination, (ii) any Annual Bonus for the year prior to the year in which the Date of Termination occurred that was earned but not yet paid, paid at the same time annual bonuses are paid to other executives (but in no event later than March 15th of the calendar year following the calendar year in which the Annual Bonus was earned), (iii) a pro rata Annual Bonus in respect of the number of months Executive was employed prior to Executive's death, paid at the same time annual bonuses are paid to other executives (but in no event later than March 15th of the calendar year following the calendar year in which the Annual Bonus was earned), and (iv) any other amounts or benefits to which Executive may be entitled under a separate plan, policy or program maintained by the Company.

(f) *Date of Termination.* As used in this Agreement, "***Date of Termination***" means (i) if Executive's employment is terminated by her death, the date of her death; (ii) if Executive's employment is terminated as a result of a Disability or by Company for Cause or without Cause, then the date specified in a notice delivered to Executive by Company of such termination, (iii) if Executive's employment is terminated by Executive for Good Reason, then the date specified in the notice of such termination delivered to Company by Executive, (iv) if Executive's employment terminates due to the giving of a Non-Renewal Notice, the last day of the Employment Period, and (v) if Executive's employment is terminated for any other reason, the date specified therefore in the notice of such termination.

## **5. Employment.**

Upon termination of this Agreement, Executive's employment shall also terminate and cease, and Executive shall be deemed to have voluntarily resigned from all positions and the Board, if Executive is a member of the Board. Executive shall confirm the foregoing resignation(s) by submitting to the Company written confirmation of Executive's resignation(s), and the Company's obligations to pay the Severance Payment shall be subject to the Company's receipt of such written confirmation.

## **6. Mitigation.**

Upon termination of this Agreement for any reason, amounts to be paid per the express terms of this Agreement shall not be reduced whether or not Executive obtains other employment.

## **7. Release.**

Notwithstanding any other provision in this Agreement to the contrary, as a condition precedent to receiving any severance payments or benefits set forth in this Agreement (other than the Accrued Compensation and Reimbursements) in connection with any applicable termination scenario, Executive agrees to execute (and not revoke) a customary severance and release agreement, including a waiver of all claims, reasonably acceptable to the Company (the

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“**Release**”), within the twenty-one (21) day period immediately following the Date of Termination. All revocation rights and timing restrictions shall be set forth in such Release. If Executive fails to execute and deliver the Release, or revokes the Release, Executive agrees that she shall not be entitled to receive any severance payments or benefits set forth in Section 4 of this Agreement (other than the Accrued Compensation and Reimbursements) in connection with any applicable termination scenario. For purposes of this Agreement, the Release shall be considered to have been executed by Executive if it is signed by her legal representative in the case of legal incompetence or on behalf of Executive’s estate in the case of her death.

## **8. Nondisclosure.**

(a) It is understood that Executive during her tenure with the Company has received and will continue to receive access to some or all of the Company’s various trade secrets and confidential or proprietary information, including information she has not received before, consisting of, but not limited to, information relating to (i) business operations and methods, (ii) existing and proposed investments and investment strategies, (iii) financial performance, (iv) compensation arrangements and amounts (whether relating to the Company or to any of its employees), (v) contractual relationships, (vi) business partners and relationships, and (vii) inventions, products, processes, methods, techniques, formulas, compositions, compounds; (viii) manufacturing information, (ix) technical information, strategies, research data, clinical data, financial data, personnel data, computer programs, (x) customer and supplier lists, and (xi) contacts at or knowledge of actual or prospective customers, suppliers, vendors, clinical sites, or collaborators of the Company (all of the forgoing, “**Confidential Information**”). Confidential Information shall not include: (A) information that Executive may furnish to third parties regarding her obligations under this Section 8 and under Section 10 or (B) information that (1) is general knowledge of Executive or information that becomes generally available to the public by means other than Executive’s breach of this Section 8 (for example, not as a result of Executive’s unauthorized release of marketing materials), (2) is in Executive’s possession, or becomes available to Executive, on a non-confidential basis, from a source other than the Company or (3) Executive is required by law, regulation, court order or discovery demand to disclose; provided, however, that in the case of clause (3), Executive gives the Company, to the extent permitted by law, reasonable notice prior to the disclosure of the Confidential Information and the reasons and circumstances surrounding such disclosure to provide the Company an opportunity to seek a protective order or other appropriate request for confidential treatment of the applicable Confidential Information.

(b) Executive agrees that all Confidential Information, whether prepared by Executive or otherwise coming into her possession, shall remain the exclusive property of the Company during Executive’s employment with the Company. Executive further agrees that Executive shall not, except for the benefit of the Company pursuant to the exercise of her duties in accordance with this Agreement or with the prior written consent of the Company, use or disclose to any third party any of the Confidential Information described herein, directly or indirectly, either during Executive’s employment with the Company or at any time following the termination of Executive’s employment with the Company.

(c) Upon termination of this Agreement, Executive agrees that all Confidential Information and other files, documents, materials, records, notebooks, customer lists, business proposals, contracts, agreements and other repositories containing information concerning the Company or the business of the Company (including all copies thereof) in Executive’s possession, custody or control, whether prepared by Executive or others, shall remain with or be returned to the Company as soon as practicable after the Date of Termination.

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(d) Nothing in this Agreement will preclude, prohibit or restrict Executive from (i) communicating with, any federal, state or local administrative or regulatory agency or authority, including but not limited to the Securities and Exchange Commission (the "SEC"); (ii) participating or cooperating in any investigation conducted by any governmental agency or authority; or (iii) filing a charge of discrimination with the United States Equal Employment Opportunity Commission or any other federal state or local administrative agency or regulatory authority. Nothing in this Agreement, or any other agreement between the parties, prohibits or is intended in any manner to prohibit, Executive from (A) reporting a possible violation of federal or other applicable law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the SEC, the U.S. Congress, and any governmental agency Inspector General, or (B) making other disclosures that are protected under whistleblower provisions of federal law or regulation. This Agreement does not limit Executive's right to receive an award (including, without limitation, a monetary reward) for information provided to the SEC. Executive does not need the prior authorization of anyone at the Company to make any such reports or disclosures, and Executive is not required to notify the Company that Executive has made such reports or disclosures. Nothing in this Agreement or any other agreement or policy of the Company is intended to interfere with or restrain the immunity provided under 18 U.S.C. §1833(b). Executive cannot be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (i) (A) in confidence to federal, state or local government officials, directly or indirectly, or to an attorney, and (B) for the purpose of reporting or investigating a suspected violation of law; (ii) in a complaint or other document filed in a lawsuit or other proceeding, if filed under seal; or (iii) in connection with a lawsuit alleging retaliation for reporting a suspected violation of law, if filed under seal and does not disclose the trade secret, except pursuant to a court order. The foregoing provisions regarding protected disclosures are intended to comply with all applicable laws. If any laws are adopted, amended or repealed after the execution of this Agreement, this Section 8(d) shall be deemed to be amended to reflect the same.

**9. Non-Disparagement.** Executive agrees and covenants that Executive will not at any time make, publish, or communicate to any person or entity or in any public forum any defamatory or disparaging remarks, comments, or statements concerning the Company or its businesses, or any of its employees, officers. **Non-Competition and Non-Solicitation.** As part of the consideration for the compensation and benefits to be paid to Executive hereunder, to protect Confidential Information of the Company and its customers and clients that have been and will be entrusted to Executive, the business goodwill of the Company and its subsidiaries that will be developed in and through Executive and the business opportunities that will be disclosed or entrusted to Executive by the Company and its subsidiaries, and as an additional incentive for the Company to enter into this Agreement, Executive will not (other than for the benefit of the Company pursuant to this Agreement), anywhere in the United States directly or indirectly:

(i) from the date hereof through the first anniversary of the Date of Termination, anywhere in the United States, engage in the business of researching, developing, designing, producing, manufacturing marketing or selling (or assisting any other person in researching, developing, designing, producing, manufacturing, marketing or selling) (i) DNA-based therapies involving the delivery of IL-12 for the treatment of cancer, (ii) chimeric antigen receptor T-cell (CAR+ T) or T-cell receptors T-cell TCR+ T (TCR) therapies for the treatment of cancer or (iii) other products or product candidates that are otherwise substantially similar to those that have been or are being developed, designed, produced, commercially marketed, sold or rendered by the Company, solely to the extent the Company has directly engaged in such business within the 12-month period prior to the Date of Termination ("***Competing Business***") as an individual proprietor, partner, stockholder, officer, employee, director, joint venturer, investor, lender, consultant, or in any other capacity whatsoever;

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(ii) from the date hereof through the first anniversary of the Date of Termination, solicit, divert, take away or do business with, or attempt to solicit, divert, take away or do business with, any of the clients, customers or accounts, or prospective clients, customers or accounts, or other business relation of the Company with whom Executive had direct business contact in dealings during the Employment Period in the course of her employment with the Company;

(iii) from the date hereof through the first anniversary of the Date of Termination, induce or attempt to induce any clients, customers or accounts, or prospective clients, customers or accounts, or other business relation of the Company to cease doing business with the Company or in any way interfere with the relationship between any such clients, customers or accounts, or prospective clients, customers or accounts, or other business relation; or

(iv) from the date hereof through the second anniversary of the Date of Termination, recruit, solicit, or hire any employee, contractor, or consultant of the Company (who was employed or engaged by the Company at any time during Executive's employment with the Company), or induce or attempt to induce any such employee, contractor or consultant of the Company to terminate his/her employment or engagement with, or otherwise cease his/her relationship with, the Company, in each case, other than general solicitations not specifically directed at employees of the Company.

(b) Notwithstanding the foregoing restrictions of this Section 10, nothing in this Section 10 shall prohibit, restrict, or impede Executive from: (i) directly or indirectly, holding not more than one percent (1%) of the combined voting power of the outstanding stock of a publicly held company; (ii) exercising protected rights to the extent that such rights cannot be waived by agreement or from complying with any applicable law or regulation; or (iii) engaging in the practice of law.

(c) Executive acknowledges that each of the covenants of Section 10 are in addition to, and shall not be construed as a limitation upon, any other covenant provided in Section 10. Executive agrees that the geographic boundaries, scope of prohibited activities, and time duration of each of the covenants set forth in Section 10(a) are reasonable in nature and are no broader than are necessary to maintain the confidentiality and the goodwill of the Company's proprietary and Confidential Information, plans and services and to protect the other legitimate business interests of the Company, including without limitation the goodwill developed by Executive with Company's customers, suppliers, licensees and business relations.

(d) If, during any portion of the non-competition and non-solicitation periods, Executive is not in compliance with the terms of Section 10, the Company shall be entitled to, among other remedies, compliance by Executive with the terms of Section 10 for an additional period of time (*i.e.*, in addition to the non-competition and non-solicitation periods stated in Section 10(a)) that shall equal the period(s) over which such noncompliance occurred.

(e) The parties hereto intend that the covenants contained in Section 10 be construed as a series of separate covenants. Except for geographic coverage, each such separate covenant shall be deemed identical in terms to the applicable covenant contained in Section 10. Furthermore, each of the covenants in Section 10 shall be deemed a separate and independent covenant, each being enforceable irrespective of the enforceability (with or without reformation) of the other covenants contained in Section 10.

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**11. Notices.**

All notices and other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given if delivered personally, mailed by certified mail (return receipt requested) or sent by overnight delivery service to the parties to Company at its principal executive offices in care of the General Counsel, and any notice to be given to the Executive shall be addressed to the Executive at the most recent address for the Executive shown in Company's records.

Notice so given shall, in the case of mail, be deemed to be given and received on the fifth calendar day after posting, and in the case overnight delivery service, on the date of actual delivery.

**12. Severability and Reformation.**

If any one or more of the terms, provisions, covenants or restrictions of this Agreement shall be determined by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions shall remain in full force and effect, and the invalid, void or unenforceable provisions shall be deemed severable. Moreover, if any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be reformed by limiting and reducing it to the minimum extent necessary, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

**13. Assignment.**

This Agreement shall be binding upon and inure to the benefit of the heirs and legal representatives of Executive and the permitted assigns and successors of Company, but neither this Agreement nor any rights or obligations hereunder shall be assignable or otherwise subject to hypothecation by Executive without the express written consent of Company (except in the case of death by will or by operation of the laws of intestate succession) or by Company, except that Company may assign this Agreement to any successor (whether by merger, purchase or otherwise) to all or substantially all of the stock assets or businesses of Company, if such successor expressly agrees to assume the obligations of Company hereunder.

**14. Amendment.**

This Agreement may be amended only by writing signed by both Executive and by a duly authorized representative of Company (other than Executive).

**15. Assistance in Litigation.**

Executive shall reasonably cooperate with the Company in the defense or prosecution of any claims or actions now in existence or that may be brought in the future against or on behalf of the Company that relate to events or occurrences that transpired while Executive was employed by the Company. Executive's cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. Executive also shall cooperate fully with the Company in connection with any investigation or review by any Federal, state, or local regulatory authority as any such investigation or review relates, to events or occurrences that transpired while Executive was employed by the Company.

**16. Beneficiaries; References.**

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Executive shall be entitled to select (and change, to the extent permitted under any applicable law) a beneficiary or beneficiaries to receive any compensation or benefit payable hereunder following Executive's death, and may change such election, in either case by giving the Company written notice thereof. In the event of Executive's death or a judicial determination of her incompetence, reference in this Agreement to Executive shall be deemed, where appropriate, to refer to her beneficiary, estate or other legal representative. Any reference to the masculine gender in this Agreement shall include, where appropriate, the feminine.

**17. Use of Name, Likeness and Biography and Announcements.**

The Company shall have the right to make public announcements concerning the execution of this Agreement and the terms contained herein, at the Company's discretion. Likewise, the Company shall have the right (but not the obligation) to use, publish and broadcast, and to authorize others to do so, the name, approved likeness and approved biographical material of Executive to advertise, publicize and promote the business of the Company and its affiliates, but not for the purposes of direct endorsement without Executive's consent. This right shall terminate upon the termination of this Agreement. An "approved likeness" and "approved biographical material" shall be, respectively, any photograph or other depiction of Executive, or any biographical information or life story concerning the professional career of Executive.

**18. Governing Law and Venue.**

THIS AGREEMENT SHALL BE CONSTRUED, INTERPRETED AND GOVERNED IN ACCORDANCE WITH THE LAWS OF THE STATE OF TEXAS WITHOUT REFERENCE TO RULES RELATING TO CONFLICTS OF LAW. EXCEPT AS PROVIDED IN SECTION 29, ANY ACTION IN REGARD TO THIS AGREEMENT OR ARISING OUT OF ITS TERMS AND CONDITIONS SHALL BE LITIGATED AND/OR INSTITUTED ONLY IN HOUSTON, TEXAS. THE COMPANY AND EMPLOYEE HEREBY EXPRESSLY CONSENT TO THE PERSONAL JURISDICTION OF THE STATE AND FEDERAL COURTS LOCATED IN HOUSTON, TEXAS FOR ANY LAWSUIT FILED ARISING FROM OR RELATED TO THIS AGREEMENT.

**19. Entire Agreement.**

This Agreement contains the entire understanding between the parties hereto with respect to the subject matter hereof and supersedes in all respects any prior or other agreement or understanding, written or oral, between the Company or any affiliate of the Company and Executive with respect to such subject matter.

**20. Withholding.**

The Company shall be entitled to withhold from payment to Executive of any amount of withholding required by law.

**21. Counterparts.**

This Agreement may be executed in two or more counterparts, each of which will be deemed an original.

**22. Remedies.**

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The parties recognize and affirm that in the event of a breach of Sections 8 or 10 of this Agreement, money damages would be inadequate and Company would not have an adequate remedy at law. Accordingly, the parties agree that in the event of a breach or a threatened breach of Sections 8 or 10, Company may, in addition and supplementary to other rights and remedies existing in its favor, apply to any court of law or equity of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce or prevent any violations of the provisions hereof (without posting a bond or other security). In addition, Executive agrees that in the event a court of competent jurisdiction or an arbitrator finds that Executive violated Section 8 or 10, the time periods set forth in those Sections shall be tolled until such breach or violation has been cured. Executive further agrees that Company shall have the right to offset the amount of any damages resulting from a breach by Executive of Section 8 or 10 against any payments due Executive under this Agreement. The parties agree that if one of the parties is found to have breached this Agreement by a court of competent jurisdiction or arbitrator, the breaching party will be required to pay the non-breaching party's attorneys' fees reasonably incurred in prosecuting the non-breaching party's claim of breach.

**23. Non-Waiver.** The failure by either party to insist upon the performance of any one or more terms, covenants or conditions of this Agreement shall not be construed as a waiver or relinquishment of any right granted hereunder or of any future performance of any such term, covenant or condition, and the obligation of either party with respect hereto shall continue in full force and effect, unless such waiver shall be in writing signed by Company (other than Executive) and Executive.

**24. Construction.**

The headings and captions of this Agreement are provided for convenience only and are intended to have no effect in construing or interpreting this Agreement. The language in all parts of this Agreement shall be in all cases construed in accordance to its fair meaning and not strictly for or against the Company or Executive.

**25. Right to Insure.**

The Company shall have the right to secure, in its own name or otherwise, and at its own expense, life, health, accident or other insurance covering Executive, and Executive shall have no right, title or interest in and to such insurance. Executive shall assist the Company in procuring such insurance by submitting to examinations and by signing such applications and other instruments as may be required by the insurance carriers to which application is made for any such insurance.

**26. No Inconsistent Obligations.**

Executive represents and warrants that to her knowledge she has no obligations, legal, in contract, or otherwise, inconsistent with the terms of this Agreement or with her undertaking employment with the Company to perform the duties described herein. Executive will not disclose to the Company, or use, or induce the Company to use, any confidential, proprietary, or trade secret information of others. Executive represents and warrants that to her knowledge she has returned all property and confidential information belonging to all prior employers, if she is obligated to do so.

**27. Binding Agreement.**

This Agreement shall inure to the benefit of and be binding upon Executive, her heirs and

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personal representatives, and the Company, its successors and assigns.

**28. Voluntary Agreement.**

Each party to this Agreement has read and fully understands the terms and provisions hereof, has had an opportunity to review this Agreement with legal counsel, has executed this Agreement based upon such party's own judgment and advice of counsel (if any), and knowingly, voluntarily, and without duress, agrees to all of the terms set forth in this Agreement. The parties have participated jointly in the negotiation and drafting of this Agreement. If an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the parties and no presumption or burden of proof will arise favoring or disfavoring any party because of authorship of any provision of this Agreement. Except as expressly set forth in this Agreement, neither the parties nor their affiliates, advisors and/or their attorneys have made any representation or warranty, express or implied, at law or in equity with respect of the subject matter contained herein. Without limiting the generality of the previous sentence, the Companies, their affiliates, advisors, and/or attorneys have made no representation or warranty to Executive concerning the state or Federal tax consequences to Executive regarding the transactions contemplated by this Agreement.

**29. Dispute Resolution.**

(a) In the event that the Parties are unable to resolve any controversy or claim arising out of or in connection with this Agreement or breach thereof, any Party may refer the dispute to binding arbitration, which, except as expressly provided hereafter, will be the exclusive forum for resolving such claims. Such arbitration will be administered by the American Arbitration Association (the "AAA") and governed by Texas law. The arbitration will be conducted by a single arbitrator selected by Employee and the Company according to the rules of the AAA. In the event that the Parties fail to agree on the selection of the arbitrator within 30 days after either the Employee's or the Company's request for arbitration, the arbitrator will be chosen by the AAA. The arbitration proceeding will commence on a mutually agreeable date within 90 days after the request for arbitration. The forum for the arbitration will be agreed on by the Parties, or in the absence of any agreement, will be in a venue located in Houston, Texas.

(b) The arbitrator will have authority to award attorneys' fees and costs to any Party.

(c) The arbitrator will have no power or authority to make awards or orders granting relief that would not be available to a Party in a court of law. The arbitrator's award is limited by and must comply with this Agreement and applicable federal, state, and local laws. The decision of the arbitrator will be final and binding on the Parties.

(d) Notwithstanding the foregoing, no claim or controversy for injunctive or equitable relief contemplated by or allowed under applicable law pursuant to Section 10 will be subject to arbitration, but will instead be subject to determination as provided in Sections 18.

**30. Section 409A.**

This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**"), and the Treasury regulations and other interpretive guidance issued thereunder (collectively, "**Section 409A**"), or to be treated as exempt therefrom, and shall be construed and administered in accordance with such intent. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service, as a short-term deferral, or as any other compensation that is otherwise

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exempt from Section 409A shall be excluded from Section 409A to the maximum extent possible. Any payments to be made under this Agreement upon a termination of Executive's employment that are subject to Section 409A and are intended to be paid only upon a termination of employment shall only be made if such termination of employment constitutes a "separation from service" under Section 409A. Notwithstanding any provision in this Agreement to the contrary, if any payment or benefit provided for herein would be subject to additional taxes and interest under Section 409A if Executive's receipt of such payment or benefit is not delayed until the earlier of (i) the date of Executive's death or (ii) the date that is six months after the Date of Termination of Executive's employment hereunder (such date, the "**Section 409A Payment Date**"), then such payment or benefit shall not be provided to Executive (or Executive's estate, if applicable) until the Section 409A Payment Date. Any such payment shall be immediately deposited in a segregated account pending its distribution to Executive on the Section 409A Payment Date. Each payment under this Agreement is intended to be a "separate payment" and not one of a series of payments for purposes of Section 409A. Notwithstanding the foregoing, the Company does not guarantee any particular tax effect, and Executive shall be solely responsible and liable for the satisfaction of all taxes, penalties and interest that may be imposed on or for the account of Executive in connection with the Agreement (including any taxes, penalties and interest under Section 409A), and neither the Company, nor any of its affiliates, shall have any obligation to indemnify or otherwise hold Executive (or any beneficiary) harmless from any or all of such taxes, penalties or interest.

\* \* \* \* \*

**IN WITNESS WHEREOF**, the parties hereto have executed this Agreement, effective as of the Effective Date.

**COMPANY, ZIOPHARM ONCOLOGY:**

/s/ Kevin S. Boyle, Sr.

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

**EXECUTIVE:**

/s/ Melinda K. Lackey

Melinda K. Lackey

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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: May 10, 2023

/s/ Kevin S. Boyle, Sr.

Kevin S. Boyle, Sr.

Chief Executive Officer and Director

*Principal Executive Officer and*

*Principal Financial Officer*

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**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 March 31, 2023, 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*  
May 10, 2023

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