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, 2025

OR

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

Commission File Number: 001-33038

Alaunos Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

2617 Bissonnet Street, Suite 233
Houston, TX 77005
(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 Capital Stock Market

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

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

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging Growth Company	☐

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

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

As of May 15, 2025 the number of outstanding shares of the registrant's common stock, $0.001 par value, was 1,639,521 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,” "potential," “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 successfully implement our strategic reprioritization or realize any or all of the anticipated benefits once implemented;
- our ability to raise substantial additional capital to continue as a going concern and fund our planned operations in the near term and our strategic reprioritization in the longer term;
- our ability to successfully consummate any strategic transactions, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions;
- estimates regarding our expenses, use of cash, cash runway, timing of future cash needs and anticipated capital requirements;
- our ability to license additional intellectual property to support our strategic reprioritization or out-license our intellectual property 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 collaborations and licenses;
- our expectation of developments and projections relating to competition from other pharmaceutical and biotechnology companies or our industry;
- our plans relating to conducting future *in vitro* testing, *in vivo* efficacy studies, and non-clinical and investigational new drug or IND-enabling activities;
- 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 ability to remain listed on the Nasdaq Capital Market; and
- our intellectual property position, including the strength and enforceability of our intellectual property rights.

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, level of activity, performance or achievements to be materially different from any future results, level of activity, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results, levels of activity or performance of achievements to differ materially from current expectations include, among other things, those described under Part I, 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 Annual Report to “Alaunos,” the “Company,” “we,” “us” or “our” refer to Alaunos Therapeutics, Inc.

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 Alaunos® and hunTR® trademarks as well as the graphic trademark found on our website. Other trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q 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 on Form 10-Q 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, results of operations, cash flows and prospects 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 I, Item 1A of our Annual Report, filed with the SEC on March 31, 2025 and as amended by Amendment No. 1 filed with the SEC on April 30, 2025. Some of the more significant risks include the following:

- Our strategic reprioritization may not be successful, may not yield the desired results and we may be unsuccessful in identifying and implementing any strategic transaction.
- If a strategic transaction is not consummated, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- We may require substantial additional financial resources to continue as a going concern, including through the strategic review process, and if we raise additional funds it may affect the value of your investment in our common stock.
- Our ability to consummate a strategic transaction depends on our ability to retain our current employees and consultants.
- Our stock price has been, and may continue to be, volatile.
- Our decreasing cash reserves has resulted in our shareholder equity falling below $2,500,000 as required by Nasdaq Listing Rule 5550(b)(1), which resulted in our receipt of a delisting notice from Nasdaq. Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock and may impact our ability to consummate certain strategic transactions.
- Since we effectuated a reverse stock split within the past year, should the trading price of our common stock fall again below the Minimum Bid Price requirement, we may be issued a delisting decision.
- We have identified a material weakness and failed to maintain an effective internal control environment, which may result in material misstatements of our financial statements or have a material adverse effect on our business or stock price.
- We may not be able to commercialize, generate significant revenues from, or attain profitability from our small molecule oral obesity program or, should we resume development of, our TCR-T product candidates.
- Our small molecule obesity program is early stage and may encounter issues with manufacturing of the active pharmaceutical ingredient(s) or with the *in vitro* or *in vivo* studies that could preclude clinical trials or be costly to address with respect to time or money.
- For our small molecule oral obesity program or should we resume development of our TCR-T product candidates, any 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 significant 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.
- For our small molecule oral obesity program, or should we resume development of our TCR-T product candidates, if we fail to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer materially.
- The termination of our TCR-T related licenses and research and development agreements could limit our ability to resume our TCR-T clinical trial or begin new clinical trials.
- We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.
- 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.
- The gene transfer vectors from the *Sleeping Beauty* system used to manufacture our TCR-T 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.
- 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.

- If physicians and patients do not accept and use our product candidates, once approved, or if we do not obtain coverage and adequate reimbursement from payors, our ability to generate revenue from sales of our products will be materially and adversely impaired.
- Our small molecule and immuno-oncology product candidates may face competition in the future from generics or biosimilars and/or new technologies and our pending patent applications may not be granted, further limiting our ability to compete with other companies.
- If we 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 materially impaired.
- 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.
- We have and will rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cybersecurity 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 materially and adversely affect our business and reputation.
- 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.
- 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.
- 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.
- Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.
- The exercise of outstanding warrants, and issuance of equity awards may have a dilutive effect on our stock, and negatively and materially impact the price of our common stock.
- 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 significantly harm the market price of 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.

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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, 2025	December 31, 2024
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 319	$ 1,091
Receivables	2	5
Prepaid expenses and other current assets, current	746	1,659
Total current assets	1,067	2,755
Prepaid expenses and other assets, non current	1,053	—
Total assets	$ 2,120	$ 2,755
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 831	$ 516
Accrued expenses	231	176
Total current liabilities	1,062	692
Total liabilities	$ 1,062	$ 692
Commitments and contingencies (Note 5)		
Stockholders' equity		
Common stock $0.001 par value; 5,000,000 shares authorized, 1,601,252 shares issued and outstanding at March 31, 2025 and at December 31, 2024	2	2
Additional paid-in capital	922,575	922,507
Accumulated deficit	(921,519)	(920,446)
Total stockholders' equity	1,058	2,063
Total liabilities and stockholders' equity	$ 2,120	$ 2,755

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,	
	2025	2024
Revenue	$ 2	$ 1
Operating expenses:		
Research and development	347	126
General and administrative	747	1,617
Total operating expenses	1,094	1,743
Loss from operations	(1,092)	(1,742)
Other income:		
Other income, net	19	60
Other income, net	19	60
Net loss	$ (1,073)	$ (1,682)
Basic and diluted earnings per share	$ (0.67)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	1,601,252	1,601,252

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, 2025

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2025	1,601,252	$ 2	$ 922,507	$ (920,446)	$ 2,063
Stock-based compensation	—	—	68	—	68
Net loss	—	—	—	(1,073)	(1,073)
Balance at March 31, 2025	1,601,252	$ 2	$ 922,575	$ (921,519)	$ 1,058

For the Three Months Ended March 31, 2024

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2024	1,601,252	$ 2	$ 922,072	$ (915,767)	$ 6,307
Stock-based compensation	—	—	172	—	172
Net loss	—	—	—	(1,682)	(1,682)
Balance at March 31, 2024	1,601,252	$ 2	$ 922,244	$ (917,449)	$ 4,797

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

Alaunos Therapeutics, Inc.

CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (1,073)	$ (1,682)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	2
Stock-based compensation	68	172
Changes in operating assets and liabilities:		
Receivables	3	—
Prepaid expenses and other current assets	(140)	307
Accounts payable	315	(19)
Accrued expenses	55	(697)
Net cash flows from operating activities	(772)	(1,917)
Net decrease in cash, cash equivalents and restricted cash	(772)	(1,917)
Cash, cash equivalents and restricted cash, beginning of period	1,091	6,062
Cash and cash equivalents, end of period	$ 319	$ 4,145
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ —

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

1. Organization

Overview

Alaunos Therapeutics, Inc., which is referred to herein as "Alaunos," or the "Company," is a pre-clinical obesity and metabolic disorder and clinical-stage oncology-focused cell therapy company with a current focus on developing small molecules that are expected to be efficacious against obesity and other metabolic disorders and was historically involved in the development of adoptive TCR therapies, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. The Company is currently working to develop novel small molecule-based obesity therapeutics.

The Company's operations to date have consisted primarily of conducting research and development and raising capital to fund those efforts.

As of March 31, 2025, there were 1,601,252 shares of common stock outstanding and an additional 71,792 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.

Liquidity and Going Concern

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, 2025, the Company had approximately $0.3 million of cash and cash equivalents. The Company's accumulated deficit at March 31, 2025 was approximately $921.5 million. Given its current development plans and cash management efforts, the Company anticipates cash resources will be sufficient to fund operations into the second quarter of 2025. 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 reflect all adjustments (which are normal and recurring) that are necessary for a fair presentation of the financial position of the Company and its results of operations and cash flows for the periods presented. The unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2024, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the SEC on March 31, 2025, or the Annual Report.

The results disclosed in the statements of operations for the three months ended March 31, 2025 are not necessarily indicative of the results to be expected for the full fiscal year 2025.

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.

Reverse Stock Splits

As previously disclosed, in January 2024, the Company completed a reverse stock split of the Company's common stock at a ratio of 1-for-15 (the "First Reverse Split"). In connection therewith, Company decreased the number of authorized shares of common stock from 520,000,000 to 34,666,667. In July 2024, the Company completed an additional a reverse stock split of the Company's common stock at a ratio of 1-for-10 (the "Second Reverse Split") (together with the First Reverse Split, the "Reverse Splits"). In connection with the Second Reverse Split, the Company further decreased the number of authorized shares of common stock from 34,666,667 to 5,000,000.

No fractional shares were issued in connection with the Reverse Splits. Stockholders of record who would otherwise have been entitled to receive fractional shares as a result of the Reverse Splits received a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing sales price per share of the common stock on the effective date of the Reverse Splits..

All share and per share data in the accompanying condensed financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the Reverse Splits as if it had occurred at the beginning of the earliest period presented.

Nasdaq Stockholders' Equity Deficiency Notice

On April 7, 2025, the Company received a notice (the "Notice") from the Listing Qualifications staff of Nasdaq notifying the Company that the Company's stockholders equity as reported in its Annual Report on Form 10-K for the period ended December 31, 2024 (the "2024 10-K"), did not satisfy the continued listing requirements under Nasdaq Listing Rule 5550(b)(1) for the Nasdaq Capital Market, which requires that a listed company's stockholder equity be at least $2.5 million. In its 2024 Form 10-K, the Company reported stockholders' equity of $2.1 million, and, as a result, does not currently satisfy Nasdaq Listing Rule 5550(b)(1).

The Notice has no immediate effect on the Company's listing on the Nasdaq Capital Market. In accordance with Nasdaq rules, the Company has 45 calendar days from the date of the notification to submit a plan to regain compliance with Nasdaq Listing Rule 5550(b)(1). The Company intends to submit a compliance plan within 45 days of the date of the notification to Nasdaq and is evaluating available options to resolve the deficiency and regain compliance. If the Company's compliance plan is accepted, the Company may be granted up to 180 calendar days from April 7, 2025, to evidence compliance.

2. Financings

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, 2025 and 2024, there were no sales of the Company's common stock under the Equity Distribution Agreement.

3. Summary of Significant Accounting Policies

Certain of our accounting estimates are important to the portrayal of our financial condition, since they require management to make difficult, complex or subjective judgments, some of which may relate to matters that are inherently certain. Estimates are susceptible to material changes as a result of changes in facts and circumstances. Management believes that clinical trial expenses and other research and development expenses, collaboration agreements, fair value measurements of stock-based compensation, and income taxes are its most critical accounting estimates. Our accounting policies are discussed in detail in Note 3 – Summary of Significant Accounting Policies in our Annual Report on Form 10-K for the year ended December 31, 2024. There have been no material changes in those policies since the filing of our 2024 Annual Report.

4. Net earnings per share

Basic earnings 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 earnings 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 earnings per share is antidilutive. The effect of computing diluted net loss per common share was antidilutive for any potentially issuable shares of common stock and, as such, have been excluded from the calculation. Such potentially dilutive shares of common stock consisted of the following as of March 31, 2025 and 2024:

	March 31,	
	2025	2024
Common stock options	45,237	25,145
Warrants	26,555	145,239
	71,792	170,384

5. Commitments and Contingencies

License Agreements

Exclusive License Agreement with Precigen

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 parties' previous license agreement in full. Under the A&R License Agreement, the Company still had 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. On October 4, 2024, pursuant to Section 10.2 of the License Agreement, the Company duly notified Precigen of its full termination of all rights under the License Agreement.

The decision to terminate the A&R License Agreement was made after a thorough review of our strategic priorities and business objectives, including recognizing that the non-viral *Sleeping Beauty* gene transfer platform patent will expire in 2026. The Company continues to prosecute certain of the intellectual property underlying the TCRs targeting driver mutations such as KRAS, TP53 and EGFR, and the hunTR TCR discovery platform used in the discovery of our proprietary TCR library. The Company continues to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions.

License Agreement 2015 and 2019 Research and Development Agreement —The University of Texas MD Anderson Cancer Center

In 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.

In 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.

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. At various times, the Company amended the 2015 R&D Agreement to extend the term until December 31, 2026 and in 2019 entered into the 2019 R&D Agreement, pursuant to which the Company agreed to collaborate with respect to the TCR program. The Company did not incur clinical costs from MD Anderson related to the these agreements for the three months ended March 31, 2025.

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 22,222 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 $1.50 per share, expires on December 31, 2026, and vests upon the occurrence of certain clinical milestones. As of March 31, 2025, the milestones have not been met.

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

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

Under the terms of the agreement, the Company may be required to make additional payments to the Licensors upon achievement of certain milestones in varying amounts which, on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. During the three months ended March 31, 2025 and 2024, 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.

During the three months ended March 31, 2025, the Company did not earn collaboration revenue and earned $2 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement. During the three months ended March 31, 2024, the Company did not earn collaboration revenue and earned $1 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement.

Insurance Contract

During the first quarter of 2025, the Company entered into an insurance arrangement whereby an insurance contract for certain risks which was previously paid in full began to be in force for a period of six years. Accordingly, the Company began amortizing the prepaid expense related to the contract. The Company has classified the prepaid contract between its current portion and long term portion. $746 is included in prepaid expenses and other current assets and $1,053 is included in prepaid expense and other assets in the accompanying condensed consolidated balance sheet as of March 31, 2025.

6. Stock-Based Compensation

The following table presents share-based compensation expense on all employee and non-employee awards included in the accompanying condensed statements of operations as follows:

	For the Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Research and development	$ 2	$ 11
General and administrative	66	161
Stock-based compensation expense	$ 68	$ 172

The Company granted an aggregate of 12,000 stock options during the three months ended March 31, 2025, with a weighted-average grant date fair value of $1.25 per share, and granted an aggregate of 40,000 stock options during the three months ended March 31, 2024, with a weighted-average grant date fair value of $1.50 per share.

For the three months ended March 31, 2025 and 2024, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

	For the Three Months Ended March 31,	
	2025	2024
Risk-free interest rate	4.05%	4.09%
Expected life in years	6.06	5.27
Expected volatility	113.26%	114.65%
Expected dividend yield	—%	—%

Stock option activity under the Company's stock option plans for the three months ended March 31, 2025 was as follows:

(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted- Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2024	33,237	$ 153.79	7.15	$ —
Granted	12,000	1.46		
Exercised	-	-		
Cancelled	-	-		
Outstanding, March 31, 2025	45,237	$ 113.39	7.81	$ —
Options exercisable, March 31, 2025	27,077	$ 175.80	6.63	$ —
Options available for future grant, March 31, 2025	130,745			

At March 31, 2025, total unrecognized compensation costs related to unvested stock options outstanding amounted to $0.2 million. The cost is expected to be recognized over a weighted-average period of 1.47 years.

7. Warrants

The following is a summary of the Company's warrant activity for the three months ended March 31, 2025:

(in thousands, except share and per share data)	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term (Years)
Outstanding, December 31, 2024	26,552	$ 28.50	2.75
Granted	-	-	
Exercised	-	-	
Forfeited	-	-	
Outstanding, March 31, 2025	26,552	$ 28.50	2.5

8. Segment Information

The Chief Operating Decision Maker ("CODM") for the Company is the Chief Executive Officer (the "CEO"). The Company's CEO reviews operating results on an aggregate basis and manages the Company's operations as a whole for the purpose of evaluating financial performance and allocating resources. This decision-making process reflects the way in which financial information is regularly reviewed and used by the CODM to evaluate performance, set operational targets, forecast future financial results, and allocate resources. Accordingly, the Company has determined that it has a single reportable and operating segment related to biopharmaceutical research and development.

The Company's CODM assesses financial performance and allocates resources based on operating results which are also reported on the accompanying condensed statements of operations. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM utilizes consolidated operating results by comparing actual results against budgeted amounts. As part of this process, consolidated net loss is a critical performance measure used to evaluate the Company's operating performance and guide strategic decisions and resource allocations, including additional investments in research and development.

9. Subsequent Events.

Subscription Agreement

On April 11, 2025, the Company entered into a Subscription Agreement (the "Agreement"), by and among the Company and Watermill Asset Management, pursuant to which the Company agreed to issue and sell, in a private offering to the Purchaser shares of Series A-1 Convertible Preferred Stock of the Company, par value of $0.001 per share (the "Series A-1 Preferred Stock"), at a price per share of $1,000 (the "Preferred Offering") for an aggregate purchase price of $500,000. The Preferred Offering also relates to the offering of the shares of the Company's common stock (the "Common Stock") issuable upon the conversion of or otherwise pursuant to the terms of the Series A-1 Preferred Stock). The Preferred Offering closed on April 11, 2025.

Series A-1 Preferred Stock

On April 11, 2025, the Company filed with the Secretary of State of the State of Delaware the Certificate of Designation of Series A-1 Convertible Preferred Stock of the Company and designated 1,000 shares of Series A-1 Preferred Stock.

Under the terms of the Certificate of Designation, each share of Series A-1 Preferred Stock has a stated value of $1,000 per share and, when issued, the Series A-1 Preferred Stock will be fully paid and non-assessable. The holders of Series A-1 Preferred Stock will be entitled to receive dividends at a rate of 10% per annum, payable in shares of Series A-1 Preferred Stock. In addition, the holders of Series A-1 Preferred Stock, to the extent any other dividends or distributions are declared for holders of the Common Stock, the holders of Series A-1 Preferred Stock will be entitled to participate in such dividends or distributions on an as-converted basis. The holders of Series A-1 Preferred Stock are entitled to vote alongside holders of Common Stock on an as-converted basis on a 1:1 ratio as Common Stock, voting together as a single class, with respect to any and all matters presented to the stockholders of the Company for their action. Each holder of Series A-1 Preferred Stock shall be entitled to a number of votes equal to the number of shares of Common Stock into which such holder's shares of Series A-1 Preferred Stock are convertible pursuant to the Certificate of Designation as of the record date of such vote or written consent (or as otherwise required by applicable law).

Each holder of Series A-1 Preferred Stock has the right to convert all or any portion of the outstanding Series A-1 Preferred Stock held by such holder along with the aggregate accrued or accumulated and unpaid dividends thereon, at any time at such holder's option, into shares of Common Stock in accordance with the terms of the Certificate of Designation. The initial fixed "Conversion Price" shall be $2.76 per share for Series A-1 Preferred Stock, subject to proportional adjustments in accordance with the Certificate of Designation.

Director Compensation

On April 13, 2025, the Board of Directors of the Company elected to receive compensation in equity rather than in cash for their cumulative deferred board service fees. The total deferred board service fees amounted to $139,000, accrued from the third quarter of 2024 through the first quarter of 2025. In exchange for these deferred fees, the Company issued 38,269 shares of common stock, each with a par value of $0.001, having an aggregate fair value of $111,750. Additionally, the Company granted 10,904 fully vested stock options at an exercise price of $2.92 per share, with an aggregate fair value of $27,250.

Director Resignation

On April 15, 2025, Dr. Hofmeister resigned as a member of the Board of Directors of the Company with immediate effect. Dr. Hofmeister's resignation was not the result of any disagreement on any matter relating to the Company's operations, policies or practices.

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 31, 2025, 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.

All share amounts presented in this Item 7 give effect to the 1-for-15 reverse stock split and the 1-for-10 second reverse stock split of our outstanding shares of common stock that occurred on January 31, 2024 and July 17, 2024, respectively.

Overview

On October 10, 2024, we announced our continued progress and evaluation of our internally developed small molecule oral obesity program. The aim of this program is to develop a drug for obesity with a differentiated profile relative to currently marketed and in development oral and injectable products. We have also operated as 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. On August 14, 2023, we announced a strategic reprioritization of our business and wind down of our TCR-T Library Phase 1/2 Trial. In connection with the reprioritization, we have reduced our workforce during the third and fourth quarters of 2023, and we continue working to reduce costs in order to extend our cash runway. We continue to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. We engaged Cantor Fitzgerald & Co., or Cantor, to act as strategic advisor for this process.

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, 2025, we had a net loss of $1.6 million, and as of March 31, 2025, we have incurred approximately $921.5 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses for the foreseeable future.

2024 Developments

Obesity Program

On October 10, 2024, we announced our continued progress and evaluation of our internally developed small molecule oral obesity program. The aim of this program is to develop an oral drug for obesity and other metabolic disorders with a differentiated profile relative to currently marketed and in development oral and injectable products. We believe our small molecule product candidates are distinct in that they do not rely on hormonal manipulation, which is common with many obesity treatments. We aim to develop an oral obesity compound that addresses many of the shortcomings of injectable GLP-1 receptor agonists including preserving lean muscle mass. We engaged a contract development and manufacturing organization or CMDO to manufacture active pharmaceutical ingredients for our small molecule product candidates and initiated *in vitro* testing of our candidates in the fourth quarter 2024.

The ongoing *in vitro* study aims to evaluate the impact of ALN1001 and its derivatives on lipid deposition and gene expression. This study evaluates if genes related to thermogenic activity, lipid metabolism, and energy regulation are activated or deactivated by treatment, to determine if these compounds positively affect fat and energy metabolism. The results of this study, which are expected second quarter of 2025, will provide critical insights into the development strategy for ALN1001 and its derivatives for obesity, metabolic disorders, and inflammation. Drug development candidates most effective in increasing metabolic activity and reducing fat accumulation may be advanced to evaluation of the compounds in rodent models of obesity.

As is standard in the industry, if the aforementioned *in vitro* study is successful, we plan to conduct a proof-of-concept diet-induced obesity or DIO mouse study to validate our mechanism of action by the third quarter of 2025 before proceeding to Investigational New Drug or IND Application enabling studies. Our ability to execute on this plan is dependent on study results and our ability to raise additional capital or partner these assets with other companies or research institutions.

TCR-T Library Phase 1/2 Trial

Eight patients were treated and evaluated in our TCR-T Library Phase 1/2 Trial from 2022-2023. Patients with pancreatic (3), colorectal (4) and non-small cell lung cancer (1) were treated, with certain pancreatic and colorectal patients also having lung metastases. Overall, the trial showed our T-cells were generally well-tolerated in all evaluable participants with no dose-limiting toxicities (DLTs) and no immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. All cytokine release syndrome (CRS) events were within grades 1-3 and were self-limiting or resolved with standard clinical management and, in some cases, a single dose of tocilizumab. One patient with non-small cell lung cancer (NSCLC) achieved an objective partial response with six months progression-free survival. Six other patients achieved a best overall response of stable disease. The total overall response rate was 13% and disease control rate was 87% in evaluable patients with advanced, metastatic, refractory solid tumors (see Figure A). This trial established proof-of-concept that Sleeping Beauty TCR-T cells can result in objective clinical responses and recognize established tumors *in vivo*. Despite the encouraging TCR-T Library Phase 1/2 Trial data, based on the substantial cost to continue development and the current financing environment, we announced in August 2023 that we would not pursue any further development of our clinical programs.

hunTR® Platform

We have discovered multiple proprietary TCRs targeting driver mutations through our hunTR TCR discovery platform. In addition to TCRs that recognize KRAS and TP53 mutations similar to those licensed from the NCI, we identified additional TCRs that bind to other driver mutations and TCRs that are restricted to additional HLAs. We believe that the hunTR library has the potential to allow for the treatment of a large patient population.

Strategic Alternatives

We continue to explore strategic alternatives, which may include but are not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions.

Nasdaq Shareholders Equity Deficiency Notice

On April 7, 2025, the Company received a notice (the "Notice") from the Listing Qualifications staff of Nasdaq notifying the Company that the Company's stockholders equity as reported in its Annual Report on Form 10-K for the period ended December 31, 2024 (the "2024 10-K"), did not satisfy the continued listing requirements under Nasdaq Listing Rule 5550(b)(1) for the Nasdaq Capital Market, which requires that a listed company's stockholder equity be at least $2.5 million. In its 2024 10-K, the Company reported stockholders' equity of $2.1 million, and, as a result, does not currently satisfy Nasdaq Listing Rule 5550(b)(1).

The Notice has no immediate effect on the Company's listing on the Nasdaq Capital Market. In accordance with Nasdaq rules, the Company has 45 calendar days from the date of the notification to submit a plan to regain compliance with Nasdaq Listing Rule 5550(b)(1) to Nasdaq. The Company intends to submit a compliance plan within 45 days of the date of the notification and will evaluate available options to resolve the deficiency and regain compliance. If the Company's compliance plan is accepted, the Company may be granted up to 180 calendar days from April 7, 2025 to evidence compliance.

Results of Operations

Three Months Ended March 31, 2025 Compared to Three Months Ended March 31, 2024

Royalty Revenue

Collaboration revenue during the three months ended March 31, 2025 and 2024 was as follows:

	For the three months ended March 31,			
	2025	2024	Change	
($ in thousands)				
Revenue	$ 2	$ 1	$ 1	100%

Collaboration revenue during the three months ended March 31, 2025 was $2 thousand and was $1 for the three months ended March 31, 2024.

Research and Development Expenses

Research and development expenses during the three months ended March 31, 2025 and 2024 was as follows:

($ in thousands)	For the three months ended March 31, 2025	2024	Change	
Research and development expenses	$ 347	$ 126	$ 221	175%

Research and development expenses for the three months ended March 31, 2025 increased by $0.2 million when compared to the three months ended March 31, 2024, primarily due to an increase of $0.2 million in regulatory writing as part of our wind-down clinical activities and consulting fees incurred in pursuit of our obesity program.

For the three months ended March 31, 2024, 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, which we are currently in the process of winding down. For the three months ended March 31, 2025, our clinical stage projects mainly consisted of developing and manufacturing of our active pharmaceutical ingredients. We continue to incur costs associated with the process of winding down the TCR studies.

General and Administrative Expenses

General and administrative expenses during the three months ended March 31, 2025 and 2024 was as follows:

($ in thousands)	For the three months ended March 31, 2025	2024	Change	
General and administrative expenses	$ 747	$ 1,617	$ (870)	(54)%

General and administrative expenses for the three months ended March 31, 2025 decreased by $0.9 million as compared to three months ended March 31, 2024, primarily due to a $0.1 million decrease in employee-related expenses due to lower salaries and employee related costs, a $0.4 decrease in consulting expenses and a $0.4 decrease in insurance cost, filing fees and a combination of reduced travel costs and bank fees due to our downsized operations.

Other Income

Other income during the three months ended March 31, 2025 and 2024 was as follows:

($ in thousands)	For the three months ended March 31, 2025	2024	Change	
Other income, net	19	60	(41)	(68)%

Other income, net, for the three months ended March 31, 2025 decreased be $0.04 million as compared to the three months ended March 31, 2024, primarily due to reduced interest income from our cash reserves, as our cash balances were lower in the current quarter as compared to prior quarters.

Liquidity and Capital Resources

Liquidity

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 and preferred equity securities, term debt and collaborations.

On August 14, 2023, we announced a strategic reprioritization of our business and wind down of our TCR-T Library Phase 1/2 Trial. In connection with the reprioritization, we have reduced our workforce, and we continue working to reduce costs in order to extend our cash runway. We continue to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. We have engaged Cantor to act as strategic advisor for this process.

Given our current development plans and cash management efforts, we anticipate that our cash resources will be sufficient to fund operations into the second quarter of 2025. 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.

We anticipate that losses will continue for the foreseeable future. As of March 31, 2025, our accumulated deficit was approximately $921.5 million. Our working capital as of March 31, 2024 was $0.1 million, consisting of $1.1 million in current assets and $1.0 million in current liabilities. 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.

As of March 31, 2025, we had approximately $0.3 million of cash and cash equivalents. Our streamlined and cost efficiency efforts, in light of our 2023 announced strategic reprioritization , we anticipate our cash resources will be sufficient to fund our operations into the second quarter of 2025. In order to continue our operations beyond our forecasted runway, including, if necessary, to continue to explore strategic alternatives, 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, we may be unable to persist as a going concern for sufficient time to identify or execute on any strategic alternatives.

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.

Sales of Series A-1 Preferred Stock

On April 11, 2025, the Company entered into a Subscription Agreement (the “Agreement”), by and between the Company and Watermill Asset Management, pursuant to which the Company agreed to issue and sell, in a private offering to the Purchaser shares of Series A-1 Convertible Preferred Stock of the Company, par value of $0.001 per share (the “Series A-1 Preferred Stock”), at a price per share of $1,000 (the “Preferred Offering”) for an aggregate purchase price of $500,000. The Preferred Offering also relates to the offering of the shares of the Company's common stock (the "Common Stock") issuable upon the conversion of or otherwise pursuant to the terms of the Series A-1 Preferred Stock). The Preferred Offering closed on April 11, 2025.

Cash Flows

The following table summarizes our net decrease in cash and cash equivalents for the three months ended March 31, 2025 and 2024:

	For the three months ended March 31,	
($ in thousands)	**2025**	**2024**
Net cash flows from:		
Operating activities	$ (772)	$ (1,917)
Investing activities	—	—
Financing activities	—	—
Net decrease in cash and cash equivalents	$ (772)	$ (1,917)

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, amortization, impairment charges, stock-based compensation and reduction in right-of-use assets; 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 flows from operating activities for the three months ended March 31, 2025 was $0.8 million, as compared to net cash used in operating activities of $1.9 million for the three months ended March 31, 2024. The decrease in net cash used in operating activities was primarily related to changes in our net loss.

The net cash flows from operating activities for the three months ended March 31, 2025 was primarily due to our net loss of $1.01 million, adjusted for $0.01 million of non-cash items such as depreciation and stock-based compensation and a $0.01 million increase in accrued expenses, an increase in accounts payable of $0.3 million, a decrease to prepaid expenses and other current assets of $0.01 million.

Capital Resources

Operating Leases

As of March 31, 2025, we have no lease commitments, other than a short-term lease.

Royalty and License Fees

On May 28, 2019, the Company entered into a Patent License with the NCI for exclusive worldwide rights to develop and commercialize certain engineered T-cell therapies targeting mutated KRAS, TP53, and EGFR neoantigens, as well as related manufacturing technologies. The agreement included minimum annual royalties, milestone payments upon achieving clinical, regulatory, and sales benchmarks, and royalties on product sales. The Company terminated the agreement effective December 26, 2023, after developing proprietary alternatives internally.

In June 2022, Solasia Pharma K. K., or Solasia, announced that darinaparsin had been approved for relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the year ended December 31, 2024, the Company did not earn collaboration revenue and earned $10 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement. During the three months ended March 31, 2025 and 2024, the Company did not earn collaboration revenue and earned $2 thousand and $1 thousand, respectively, in royalty revenues on net sales under the Solasia License and Collaboration Agreement.

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, 2025. 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 that evaluation, our principal executive officer and principal financial officer has concluded that as of March 31, 2025, our disclosure controls and procedures were not effective.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) of the Exchange Act) that occurred during the three months ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities from time to time. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our business, financial condition, results of operations, cash flows and prospects. 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.

We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, be reasonably likely to have a material adverse effect on our business, financial condition, results of operations, cash flows or prospects.

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 2024 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

****Changes to United States tariff and import/export regulations may have an adverse effect on our business, financial condition and results of operations.***

The United States has enacted and continues to enact significant new tariffs, and President Trump has directed various federal agencies to further evaluate key aspects of U.S. trade policy. There has been and are ongoing discussions and commentaries regarding potential significant changes to U.S. trade policies, treaties and tariffs. There exists significant uncertainty about the future relationship between the U.S. and other countries with respect to such trade policies, treaties and tariffs. These developments, or the perception that any of them could occur, may have a material adverse effect on global and domestic economic conditions, whether or not there will be a recession, and the stability of global and domestic financial markets, and may significantly reduce global trade and, in particular, trade between the impacted nations and the U.S. These actions and policies may adversely affect the ability of the Company to fund our operations, affect our ability to develop products and work with partner companies and generally carry on our respective businesses. Although it is not yet possible to assess their impact, any of these factors could depress economic activity and restrict access to suppliers or customers, hinder our ability to obtain funding from the government through grants and from investors, and have a material adverse effect on our overall business, financial condition and results of operations.

** If Nasdaq does not approve our plan for compliance with Nasdaq List Rule 5550(b)(1) following the April 7, 2025 notice that our stockholders' equity has fallen below the required $2,500,000, we may be delisted from the Nasdaq Capital Market exchange.*

On April 7, 2025, the Company received the Notice from the Listing Qualifications staff of Nasdaq notifying us that our stockholders equity as reported in our 2024 10-K, did not satisfy the continued listing requirements under Nasdaq Listing Rule 5550(b)(1) for the Nasdaq Capital Market (the "Nasdaq SE Rule"), which requires that a listed company's stockholder equity be at least $2,500,000. In our 2024 10-K, we reported stockholders' equity of $2,063,000, and, as a result, do not currently satisfy Nasdaq Listing Rule 5550(b)(1). While the Notice has no immediate effect on our Nasdaq listing, in order to regain compliance, we are required to present a our plan within 45 calendar days or by May 22, 2025 to Nasdaq staff. If our compliance plan is accepted at that time, we may be granted up to 180 calendar days from April 7, 2025, to evidence compliance.

We may not be able to timely present a plan for compliance within the 45 days. Even if we do present a compliance plan within the prescribed deadline, Nasdaq staff may find it insufficient to evidence compliance with the Nasdaq SE Rule. If they do not find it sufficient, we may be delisted. If the Nasdaq staff do find our plan to sufficiently demonstrate compliance with the Nasdaq SE Rule, we may be granted up to 180 calendar days to implement the plan and regain compliance. Nasdaq may provide us insufficient time to implement our compliance plan or at the end of the compliance period, we may not be able to demonstrate compliance for any number of reasons. If any of these events occur, we could be delisted.

OTHER RISKS RELATED TO OUR COMPANY

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 significantly harm the market price of our common stock.

As of March 31, 2025, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 3.45% 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.

Artificial intelligence used by us and our partners and vendors may have negative effects on our company.

Artificial intelligence or AI use in many industries has rapidly expanded. While we do not utilize any specific AI technologies internal to Alaunos, we may work with vendors or service providers that do utilize AI technologies with or without our knowledge. Areas in which our business that could be negatively impacted include novel cybersecurity threats such as malicious code or phishing attempts. AI could also perpetrate fraud or misappropriation of company funds. From a regulatory standpoint, we could be liable for noncompliance related to data compromise or perceived or actual noncompliance with data privacy or protection or AI requirements to various agencies or jurisdictions. There are also potential risks around ethical, social, and reputational risks should AI cause us to infringe on privacy rights or violate intellectual property rights. AI is also known for "deep fakes" or false information being spread electronically and attributed to innocent companies and their management or directors. Such accusations could negatively impact human rights, privacy, employment, or other social concerns, which may result in claims, lawsuits, brand or reputational harm, and increased regulatory scrutiny, any of which could harm our business, financial condition, and operating results. Operational risks potentially caused by AI technologies include unanticipated disruptions to systems, potential loss or corruption of data, implementation delays, and cost overruns that could stem from underlying defects in the AI tools used. Finally, competition risk may result from rapid adoption of AI that could provide unforeseen advantages to our competitors and lead to the erosion of our market share by potentially leading to the emergence of new products and categories, the rapid maturation of categories, cannibalization of categories, changing price points and product replacement and upgrade cycles.

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

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Alaunos Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed February 1, 2024).
3.2	Certificate of Designation of Series A-1 Convertible Preferred Stock of Alaunos Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 14, 2025).
3.3	Amended and Restated Bylaws of the Registrant, dated as of September 21, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed September 22, 2020).
31.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a) or 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH+	Inline XBRL Taxonomy Extension Schema Document
104+	Cover Page Interactive Data File—the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments
+	Filed herewith.
++	This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALAUNOS THERAPEUTICS, INC.

By:

/s/ Dale Curtis Hogue, Jr.
Dale Curtis Hogue, Jr.
Interim Chief Executive Officer
(On Behalf of the Registrant and as Principal Executive Officer and Principal Financial Officer)
Dated: May 15, 2025

By:

/s/ Ferdinand Groenewald
Ferdinand Groenewald
Vice President, Finance
(Principal Accounting Officer)
Dated: May 15, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Dale Curtis Hogue, Jr.., 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 15, 2025

/s/ Dale Curtis Hogue, Jr..
Dale Curtis Hogue, Jr.
Interim Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Alaunos Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dale Curtis Hogue, Jr.., Interim Chief Executive Officer and Director (and 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/ Dale Curtis Hogue, Jr.
Dale Curtis Hogue, Jr.
Interim Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer
May 15, 2025