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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, 2024

OR

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

For the transition period from _____ to _____

Commission File Number 001-37581

Aclaris Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	46-0571712
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
701 Lee Road, Suite 103 Wayne, PA (Address of principal executive offices)	19087 (Zip Code)

Registrant's telephone number, including area code: (484) 324-7933

N/A

(Former name, former address and former fiscal year, if changed since last report)

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, $0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934:

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 Securities Exchange Act of 1934). Yes ☐ No ☒

The number of outstanding shares of the registrant's common stock, par value $0.00001 per share, as of the close of business on April 30, 2024 was 71,264,786.

ACLARIS THERAPEUTICS, INC.

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Part I. FINANCIAL INFORMATION
Item 1. Financial Statements

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

(In thousands, except share and per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 35,841	$ 39,878
Short-term marketable securities	92,325	79,228
Accounts receivable, net	373	298
Prepaid expenses and other current assets	6,799	9,452
Total current assets	135,338	128,856
Marketable securities	33,199	62,771
Property and equipment, net	1,531	1,620
Other assets	3,997	4,158
Total assets	$ 174,065	$ 197,405
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,810	$ 8,878
Accrued expenses	6,565	19,446
Other current liabilities	2,705	2,628
Total current liabilities	20,080	30,952
Other liabilities	2,971	3,074
Contingent consideration	9,000	6,200
Total liabilities	32,051	40,226
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.00001 par value; 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 71,248,017 and 70,894,889 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	930,114	928,080
Accumulated other comprehensive loss	(364)	(106)
Accumulated deficit	(787,737)	(770,796)
Total stockholders' equity	142,014	157,179
Total liabilities and stockholders' equity	$ 174,065	$ 197,405

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

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Contract research	$ 657	$ 889
Licensing	1,741	1,639
Total revenue	2,398	2,528
Costs and expenses:		
Cost of revenue	809	808
Research and development	9,845	22,587
General and administrative	6,844	8,790
Licensing	1,031	1,061
Revaluation of contingent consideration	2,800	(800)
Total costs and expenses	21,329	32,446
Loss from operations	(18,931)	(29,918)
Other income, net	1,990	1,758
Net loss	$ (16,941)	$ (28,160)
Net loss per share, basic and diluted	$ (0.24)	$ (0.42)
Weighted average common shares outstanding, basic and diluted	71,074,858	66,872,778
Other comprehensive loss:		
Unrealized (loss) gain on marketable securities, net of tax of $0	$ (258)	$ 543
Total other comprehensive (loss) gain	(258)	543
Comprehensive loss	$ (17,199)	$ (27,617)

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

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2023	70,894,889	$ 1	$ 928,080	$ (106)	$ (770,796)	$ 157,179
Issuance of common stock in connection with vesting of restricted stock units	353,128	—	(55)	—	—	(55)
Unrealized loss on marketable securities	—	—	—	(258)	—	(258)
Stock-based compensation expense	—	—	2,089	—	—	2,089
Net loss	—	—	—	—	(16,941)	(16,941)
Balance at March 31, 2024	71,248,017	$ 1	$ 930,114	$ (364)	$ (787,737)	$ 142,014

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2022	66,688,647	$ 1	$ 880,832	$ (897)	$ (682,315)	$ 197,621
Issuance of common stock in connection with vesting of restricted stock units	517,378	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	543	—	543
Stock-based compensation expense	—	—	6,806	—	—	6,806
Net loss	—	—	—	—	(28,160)	(28,160)
Balance at March 31, 2023	67,206,025	$ 1	$ 887,638	$ (354)	$ (710,475)	$ 176,810

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

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (16,941)	$ (28,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	243	198
Stock-based compensation expense	2,089	6,806
Revaluation of contingent consideration	2,800	(800)
Changes in operating assets and liabilities:		
Accounts receivable	(75)	(202)
Prepaid expenses and other assets	2,044	(874)
Accounts payable	1,932	(2,161)
Accrued expenses	(12,907)	(1,160)
Net cash used in operating activities	(20,815)	(26,353)
Cash flows from investing activities:		
Purchases of property and equipment	(135)	(553)
Purchases of marketable securities	—	(28,524)
Proceeds from sales and maturities of marketable securities	16,968	54,875
Net cash provided by investing activities	16,833	25,798
Cash flows from financing activities:		
Payments of employee withholding taxes related to restricted stock unit award vesting	(55)	—
Net cash used in financing activities	(55)	—
Net decrease in cash and cash equivalents	(4,037)	(555)
Cash and cash equivalents at beginning of period	39,878	45,277
Cash and cash equivalents at end of period	$ 35,841	$ 44,722
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	$ —	$ 41

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

ACLARIS THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Business

Overview

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. Aclaris Therapeutics, Inc. and its wholly owned subsidiaries are referred to collectively as the "Company."

The Company is a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. The Company's proprietary KINect drug discovery platform combined with its preclinical development capabilities allows the Company to identify and advance potential drug candidates that it may develop independently or in collaboration with third parties. In addition to identifying and developing its novel drug candidates, the Company is pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize its novel drug candidates. The Company also provides contract research services to third parties enabled by its early-stage research and development expertise.

Liquidity

The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. As of March 31, 2024, the Company had cash, cash equivalents and marketable securities of $161.4 million and an accumulated deficit of $787.7 million. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) ("Confluence") in 2017, the Company had never generated revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, including clinical and preclinical testing of the Company's drug candidates, will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its drug candidates and to generate revenue from identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize its development assets or to raise additional capital to finance its operations. The Company will require additional capital to develop its drug candidates and to support its discovery efforts.

Additional funds may not be available on a timely basis, on commercially acceptable terms, or at all, and such funds, if raised, may not be sufficient to enable the Company to continue to implement its long-term business strategy. The Company's ability to raise additional capital may be adversely impacted by potentially worsening global economic conditions caused by a variety of factors including geopolitical tensions, rising interest rates, and inflationary pressures. If the Company is unable to raise sufficient additional capital or generate revenue from transactions with potential third-party partners for the development and/or commercialization of its drug candidates, it may need to substantially curtail planned operations. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

In accordance with Accounting Standards Codification ("ASC") Subtopic 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that its condensed consolidated financial statements are issued. As of the report date, the Company does not believe that substantial doubt exists about its ability to continue as a going concern. The Company believes its existing cash, cash equivalents and marketable securities are sufficient to fund its operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2024, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, the condensed consolidated statement of stockholders' equity for the three months ended March 31, 2024 and 2023, and the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements contained in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 27, 2024 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position as of March 31, 2024, the results of its operations and comprehensive loss for the three months ended March 31, 2024 and 2023, its changes in stockholders' equity for the three months ended March 31, 2024 and 2023 and its cash flows for the three months ended March 31, 2024 and 2023. The condensed consolidated balance sheet data as of December 31, 2023 was derived from audited financial statements but does not include all disclosures required by generally accepted accounting principles in the United States ("GAAP"). The financial data and other information disclosed in these notes related to the three months ended March 31, 2024 and 2023 are unaudited. The results for the three months ended March 31, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. The unaudited interim financial statements of the Company included herein have been prepared, pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with GAAP. The condensed consolidated financial statements of the Company include the accounts of the operating parent company, Aclaris Therapeutics, Inc., and its wholly owned subsidiaries. All intercompany transactions have been eliminated. Based upon the Company's revenue, the Company believes that gross profit does not provide a meaningful measure of profitability and, therefore, has not included a line item for gross profit on the condensed consolidated statement of operations.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, contingent consideration and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require an update to its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. Actual results could differ from the Company's estimates.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year's financial statement presentation.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2024. There have been no changes to the Company's significant accounting policies from those disclosed in the annual report.

Contingent Consideration

The Company records a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of regulatory and commercial milestones, as well as estimated future sales levels and the discount rates applied to calculate the present value of the potential payments. Significant judgement is involved in determining the appropriateness of these assumptions. These assumptions are considered Level 3 inputs. Revaluation of the contingent consideration liability can result from changes to one or more of these assumptions. The Company evaluates the fair value estimate of the contingent consideration liability on a quarterly basis with changes, if any, recorded as income or expense in the condensed consolidated statement of operations.

The fair value of contingent consideration is estimated using a probability-weighted expected payment model for regulatory milestone payments and a Monte Carlo simulation model for commercial milestone and royalty payments and then applying a risk-adjusted discount rate to calculate the present value of the potential payments. Significant assumptions used in the Company's estimates include the probability of achieving regulatory milestones and commencing commercialization, which are based on an asset's current stage of development and a review of existing clinical data. Probability of success assumptions ranged between 17% and 40% at March 31, 2024. Additionally, estimated future sales levels and the risk-adjusted discount rate applied to the potential payments are also significant assumptions used in calculating the fair value. The discount rate ranged between 7.4% and 8.3% depending on the year of each potential payment.

Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers. Under ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services.

To determine revenue recognition in accordance with ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) performance obligations are satisfied. At contract inception, the Company assesses the goods or services promised within a contract with a customer to identify the performance obligations, and to determine if they are distinct. The Company recognizes the revenue that is allocated to each distinct performance obligation when (or as) that performance obligation is satisfied. The Company only recognizes revenue when collection of the consideration it is entitled to under a contract with a customer is probable.

Contract Research Revenue

The Company earns contract research revenue from the provision of laboratory services. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis and are generally billed on a monthly basis in arrears for services rendered. Revenue related to these contracts is generally recognized as the laboratory services are performed, based upon the rates specified in the contracts. Under ASC Topic 606, the Company elected to apply the "right to invoice" practical expedient when recognizing contract research revenue and as such, recognizes revenue in the amount which it has the right to invoice. ASC Topic 606 also provides an optional exemption, which the Company has elected to apply, from disclosing remaining performance obligations when revenue is recognized from the satisfaction of the performance obligation in accordance with the "right to invoice" practical expedient.

Licensing Revenue

Licenses of Intellectual Property – The Company recognizes revenue received from non-refundable, upfront fees related to the licensing of intellectual property when the intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the license has been transferred to the customer, and the customer is able to use and benefit from the license.

Milestone and Royalty Payments – The Company considers any future potential milestones and sales-based royalties to be variable consideration. The Company recognizes revenue from development, regulatory and anniversary milestone payments as they are achieved. The Company recognizes revenue from commercial milestones and royalty payments as the sales occur.

Discontinued Operations

As of March 31, 2024 and December 31, 2023, the Company had $2.2 million in discontinued operations reported as other current liabilities in the Company's consolidated balance sheet, related to discontinued commercial products.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." This standard requires disclosure of significant segment expenses and other segment items by reportable segment. This ASU becomes effective for annual periods beginning in 2024 and interim periods in 2025. The Company is assessing the impact of this ASU and upon adoption expects that any impact would be limited to additional segment expense disclosures in the footnotes to the Company's consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. This ASU becomes effective January 1, 2025. The Company is currently assessing the impact of this ASU.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the fair value measurements of the Company's financial assets and liabilities which are measured at fair value on a recurring and non-recurring basis, and indicate the level of the fair value hierarchy utilized to determine such fair values:

	March 31, 2024			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 33,536	$ —	$ —	$ 33,536
Marketable securities	—	125,524	—	125,524
Total assets	$ 33,536	$ 125,524	$ —	$ 159,060
Liabilities:				
Contingent consideration	$ —	$ —	$ 9,000	$ 9,000
Total liabilities	$ —	$ —	$ 9,000	$ 9,000

(In thousands)	December 31, 2023 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 32,177	$ —	$ —	$ 32,177
Marketable securities	—	141,999	—	141,999
Total assets	$ 32,177	$ 141,999	$ —	$ 174,176
Liabilities:				
Contingent consideration	$ —	$ —	$ 6,200	$ 6,200
Total liabilities	$ —	$ —	$ 6,200	$ 6,200

As of March 31, 2024 and December 31, 2023, the Company's cash equivalents consisted of money market funds, which were valued based upon Level 1 inputs. The Company's marketable securities as of March 31, 2024 and December 31, 2023 consisted of commercial paper and corporate debt, asset-backed debt, foreign government agency debt and U.S. government and government agency debt securities, which were all valued based upon Level 2 inputs.

In determining the fair value of its Level 2 investments, the Company relies on quoted prices for identical securities in markets that are not active. These quoted prices are obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. During the three months ended March 31, 2024 and 2023, there were no transfers into or out of Level 3.

The overall $2.8 million increase in the fair value of the contingent consideration liability during the three months ended March 31, 2024 was primarily due to changes in estimated sales levels and changes to the probability of success for certain drug candidates.

As of March 31, 2024 and December 31, 2023, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

(In thousands)	March 31, 2024 Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities[1]	$ 52,531	$ 26	$ (186)	$ 52,371
Commercial paper	4,949	—	—	4,949
Asset-backed debt securities[2]	10,537	71	(33)	10,575
Foreign government agency debt securities[3]	4,765	22	—	4,787
U.S. government and government agency debt securities[4]	53,110	—	(268)	52,842
Total marketable securities	$ 125,892	$ 119	$ (487)	$ 125,524

[1] Included in Corporate debt securities is $17.9 million with maturity dates between one and two years.

[2] Included in Asset-backed debt securities is $5.8 million with maturity dates between one and two years.

[3] Included in Foreign government agency debt securities is $4.8 million with a maturity date between one and two years.

[4] Included in U.S. government and government agency debt securities is $4.7 million with maturity dates between one and two years.

(In thousands)	December 31, 2023 Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities[1]	$ 52,362	$ 65	$ (142)	$ 52,285
Commercial paper	12,345	2	(1)	12,346
Asset-backed debt securities[2]	10,953	42	(30)	10,965
Foreign government agency debt securities[3]	4,698	43	—	4,741
U.S. government and government agency debt securities[4]	61,750	8	(96)	61,662
Total marketable securities	$ 142,108	$ 160	$ (269)	$ 141,999

[1] Included in Corporate debt securities is $28.0 million with maturity dates between one and two years.

[2] Included in Asset-backed debt securities is $6.2 million with maturity dates between one and three years.

[3] Included in Foreign government agency debt securities is $4.7 million with a maturity date between one and two years.

[4] Included in U.S. government and government agency debt securities is $23.9 million with maturity dates between one and two years.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	March 31, 2024	December 31, 2023
Computer equipment	$ 1,206	$ 1,253
Lab equipment	3,153	3,154
Furniture and fixtures	694	558
Leasehold improvements	817	817
Property and equipment, gross	5,870	5,782
Accumulated depreciation	(4,339)	(4,162)
Property and equipment, net	$ 1,531	$ 1,620

Depreciation expense was $0.2 million for each of the three months ended March 31, 2024 and 2023.

5. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	March 31, 2024	December 31, 2023
Employee compensation expenses	$ 1,694	$ 3,910
Research and development expenses	1,232	6,661
Licensing expenses	794	5,478
Restructuring expenses (Note 12)	2,588	3,112
Other expenses	257	285
Total accrued expenses	$ 6,565	$ 19,446

6. Stockholders' Equity

Preferred Stock

As of March 31, 2024 and December 31, 2023, the Company's amended and restated certificate of incorporation (the "Charter") authorized the Company to issue 10,000,000 shares of undesignated preferred stock. There were no shares of preferred stock outstanding as of March 31, 2024 or December 31, 2023.

Common Stock

As of March 31, 2024 and December 31, 2023, the Company's Charter authorized the Company to issue 200,000,000 shares of $0.00001 par value common stock. There were 71,248,017 and 70,894,889 shares of common stock issued and outstanding as of March 31, 2024 and December 31, 2023, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to any preferential dividend rights of any series of preferred stock that may be outstanding. No dividends have been declared through March 31, 2024.

7. Stock-Based Awards

2015 Equity Incentive Plan

In September 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (the "2015 Plan"), and the Company's stockholders approved the 2015 Plan. The 2015 Plan became effective in connection with the Company's initial public offering in October 2015. Beginning at the time the 2015 Plan became effective, no further grants may be made under the Company's 2012 Equity Compensation Plan, as amended and restated (the "2012 Plan"). The 2015 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, performance stock awards, cash-based awards, and other stock-based awards. The number of shares initially reserved for issuance under the 2015 Plan was 1,643,872 shares of common stock. The number of shares of common stock that may be issued under the 2015 Plan will automatically increase on January 1 of each year ending on January 1, 2025, in an amount equal to the lesser of (i) 4.0% of the shares of the Company's common stock outstanding on December 31st of the preceding calendar year or (ii) an amount determined by the Company's board of directors. The shares of common stock underlying any awards that expire, are otherwise terminated, settled in cash, or repurchased by the Company under the 2015 Plan and the 2012 Plan will be added back to the shares of common stock available for issuance under the 2015 Plan. As of January 1, 2024, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 2,835,795 shares. As of March 31, 2024, 4,020,777 shares remained available for grant under the 2015 Plan. The Company had 6,233,088 stock options and 3,139,539 RSUs outstanding as of March 31, 2024 under the 2015 Plan.

2017 Inducement Plan

In July 2017, the Company's board of directors adopted the 2017 Inducement Plan (the "2017 Inducement Plan"). The 2017 Inducement Plan is a non-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Company had 353,100 stock options outstanding as of March 31, 2024 under the 2017 Inducement Plan. All shares of common stock that were eligible for issuance under the 2017 Inducement Plan after October 1, 2018, including any shares underlying any awards that expire or are otherwise terminated, reacquired to satisfy tax withholding obligations, settled in cash or repurchased by the Company in the future that would have been eligible for re-issuance under the 2017 Inducement Plan, were retired.

2012 Equity Compensation Plan

In August 2012, the Company's board of directors adopted the 2012 Plan and the Company's stockholders approved the 2012 Plan. Upon the 2015 Plan becoming effective, no further grants can be made under the 2012 Plan. The Company had 380,792 stock options outstanding as of March 31, 2024 under the 2012 Plan.

Stock Option Valuation

The weighted average assumptions the Company used to estimate the fair value of stock options granted during the three months ended March 31, 2024 and 2023 were as follows:

	Three Months Ended March 31,	
	2024	2023
Risk-free interest rate	3.81 %	3.46 %
Expected term (in years)	6.0	6.3
Expected volatility	81.81 %	77.73 %
Expected dividend yield	0 %	0 %

The Company recognizes compensation expense for awards over their vesting period. Compensation expense for awards includes the impact of forfeitures in the period when they occur.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2024:

(In thousands, except share and per share data and years)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	6,419,455	$ 15.94	7.1	$ 14
Granted	1,842,300	1.20		
Forfeited and cancelled	(1,294,775)	14.54		
Outstanding as of March 31, 2024	6,966,980	$ 12.32	7.0	$ 96
Options vested and expected to vest as of March 31, 2024	6,966,980	$ 12.32	7.0	$ 96
Options exercisable as of March 31, 2024	3,695,196	$ 16.24	5.1	$ 24

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2024 was $0.86 per share.

Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 2024:

(In thousands, except share and per share data)	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	1,521,940	$ 15.72	
Granted	2,444,350	1.20	
Vested	(399,716)	14.93	$ 482
Forfeited and cancelled	(427,035)	13.65	
Outstanding as of March 31, 2024	3,139,539	$ 4.81	

Stock-Based Compensation

Stock-based compensation expense included in total costs and expenses on the condensed consolidated statement of operations included the following:

(In thousands)	Three Months Ended March 31, 2024	2023
Cost of revenue	$ 252	$ 299
Research and development	(29)	2,602
General and administrative	1,866	3,905
Total stock-based compensation expense	$ 2,089	$ 6,806

As of March 31, 2024, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $16.6 million and $13.6 million, respectively, which is expected to be recognized over weighted average periods of 2.5 years and 2.3 years, respectively.

8. Net Loss per Share

Basic and diluted net loss per share is summarized in the following table:

(In thousands, except for share and per share data)	Three Months Ended March 31, 2024	2023
Numerator:		
Net loss	$ (16,941)	$ (28,160)
Denominator:		
Weighted average shares of common stock outstanding, basic and diluted	71,074,858	66,872,778
Net loss per share, basic and diluted	$ (0.24)	$ (0.42)

The Company's potentially dilutive securities, which included stock options and RSUs, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential shares of common stock excluded from the calculation of diluted net loss per share for the three months ended March 31, 2024 and 2023. All share amounts presented in the table below represent the total number outstanding as of March 31, 2024 and 2023.

	March 31, 2024	2023
Options to purchase common stock	6,966,980	6,865,524
Restricted stock unit awards	3,139,539	1,740,081
Total potential shares of common stock	10,106,519	8,605,605

9. Leases

Operating Leases

Agreements for Office and Laboratory Space

The Company had a sublease agreement pursuant to which it subleased 33,019 square feet of office space for its headquarters in Wayne, Pennsylvania, which expired on October 31, 2023.

In May 2023, the Company entered into a new lease agreement pursuant to which it leases 11,564 square feet of office space for its headquarters in Wayne, Pennsylvania. The lease commenced on November 1, 2023 and has a term that runs through February 2029.

In February 2019, the Company entered into a sublease agreement for 20,433 square feet of office and laboratory space in St. Louis, Missouri. The lease commenced in June 2019 and has a term that runs through June 2029. In January 2023, the Company amended the sublease agreement to add an additional 6,261 square feet of office and laboratory space effective February 2023, which term runs concurrently with the existing term.

Supplemental balance sheet information related to operating leases is as follows:

(In thousands)	March 31, 2024	December 31, 2023
Operating Leases:		
Gross cost	$ 5,094	$ 5,094
Accumulated amortization	(1,378)	(1,235)
Other assets	$ 3,716	$ 3,859
Current portion of lease liabilities	$ 503	$ 426
Other liabilities	2,971	3,074
Total operating lease liabilities	$ 3,474	$ 3,500

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled $0.1 million and $0.3 million for the three months ended March 31, 2024 and 2023, respectively.

10. Agreements Related to Intellectual Property

License Agreement – Sun Pharmaceutical Industries, Inc.

In December 2023, the Company entered into an exclusive patent license agreement with Sun Pharmaceutical Industries, Inc. (“Sun Pharma”). Under the license agreement, the Company granted Sun Pharma exclusive rights under certain patents that the Company exclusively licenses from a third party. The patents relate to the use of deuruxolitinib, Sun Pharma’s Janus kinase (“JAK”) inhibitor, or other isotopic forms of ruxolitinib, to treat alopecia areata or androgenetic alopecia. Under the license agreement, Sun Pharma has paid the Company an upfront payment, and has agreed to pay the Company regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a mid single-digit tiered royalty calculated as a percentage of Sun Pharma’s net sales. The Company has separate contractual obligations under which the Company has agreed to pay to third parties a portion of the consideration it may receive under the license agreement.

Upon execution of the agreement, the Company received an upfront payment of $15.0 million from Sun Pharma, a portion of which was payable to third parties.

License Agreement – Pediatrix Therapeutics, Inc.

In November 2022, the Company entered into a license agreement with Pediatrix Therapeutics, Inc. (“Pediatrix”), under which the Company granted Pediatrix the exclusive rights to develop, manufacture and commercialize lepzacitinib in Greater China. Pediatrix has paid the Company an upfront payment, and has agreed to pay the Company development, regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a tiered royalty ranging from a low-to-high single digit percentage of net sales of lepzacitinib by Pediatrix in Greater China. A portion of consideration received from Pediatrix is payable to the former Confluence equity holders as described below under the caption “Agreement and Plan of Merger - Confluence.”

License Agreement – Eli Lilly and Company

In August 2022, the Company entered into a non-exclusive patent license agreement with Eli Lilly and Company ("Lilly"). Under the license agreement, the Company granted Lilly non-exclusive rights under certain patents and patent applications that the Company exclusively licenses from a third party. The patents and patent applications relate to the use of baricitinib, Lilly's JAK inhibitor, to treat alopecia areata. Under the license agreement, Lilly has paid the Company an upfront payment, and regulatory and certain commercial milestone payments, and has agreed to pay the Company anniversary payments and other commercial milestone payments upon the achievement of specified milestones as set forth in the agreement, and a low single-digit royalty calculated as a percentage of Lilly's net sales of baricitinib for the treatment of alopecia areata. The Company has separate contractual obligations under which the Company has agreed to pay to third parties an amount equal to any regulatory and commercial milestone payments it receives under the Lilly license agreement, as well as a portion of the upfront consideration and a portion of the royalties it may receive under the license agreement.

During the three months ended March 31, 2024 and 2023, the Company recorded licensing revenue under this agreement of $1.7 million and $1.6 million, respectively, from Lilly, a portion of which was payable to third parties.

Asset Purchase Agreement – EPI Health, LLC

In October 2019, the Company sold RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") to EPI Health, LLC ("EPI Health") pursuant to an asset purchase agreement. In July 2023, EPI Health filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code. Through the bankruptcy process, EPI Health and its parent company, Novan, Inc., sold the RHOFADE assets to a third party, which excluded the Company's asset purchase agreement with EPI Health and the outstanding amounts due. The sale was approved by the bankruptcy court in September 2023. As a result of the bankruptcy proceedings, all amounts that are due and outstanding by EPI Health have been fully reserved for as of March 31, 2024.

Agreement and Plan of Merger – Confluence

In August 2017, the Company entered into an Agreement and Plan of Merger, pursuant to which it acquired Confluence (the "Confluence Agreement"). Under the Confluence Agreement, the Company has agreed to pay the former Confluence equity holders aggregate remaining contingent consideration of up to $75.0 million based upon the achievement of specified regulatory and commercial milestones set forth in the Confluence Agreement. In addition, the Company has agreed to pay the former Confluence equity holders future royalty payments calculated as a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. In addition to the payments described above, if the Company sells, licenses or transfers any of the intellectual property acquired from Confluence pursuant to the Confluence Agreement to a third party, the Company will be obligated to pay the former Confluence equity holders a portion of any consideration received from such sale, license or transfer in specified circumstances.

As of March 31, 2024 and December 31, 2023, the balance of the Company's contingent consideration liability was $9.0 million and $6.2 million, respectively (see Note 3).

11. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three months ended March 31, 2024 and 2023. The Company concluded that it is more likely than not that its deferred tax assets will not be realized which resulted in recording a full valuation allowance during those periods.

12. Restructuring Charges

In December 2023, the Company's board of directors approved a reduction of the Company's workforce by approximately 46%, which the Company expects to be substantially completed by June 2024. This action was taken in order to streamline operations, reduce costs and preserve capital. As a result, the Company terminated certain employees ("terminated employees") and gave notice to additional employees ("noticed employees") who were asked to provide transition services through termination dates ranging between one to thirteen months from the date notice was given. The terminated employees were entitled to receive cash severance payments and other benefits. The noticed employees are entitled to receive cash severance payments and other benefits, which are contingent upon providing additional services to the Company.

During the year ended December 31, 2023, the Company recorded a restructuring charge for the one-time termination benefit for impacted employees with retention periods less than the sixty-day minimum retention period, which was triggered immediately upon either terminating or giving notice to the impacted employees. During the three months ended March 31, 2024, the Company recognized severance expense of $2.5 million and made cash payments of $3.0 million related to severance to terminated employees.

13. Segment Information

The Company has two reportable segments, therapeutics and contract research. The therapeutics segment is focused on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases and earns revenue through licensing of the Company's intellectual property. The contract research segment earns revenue from the provision of laboratory services. All intersegment revenue has been eliminated in the Company's consolidated statement of operations. All customers and revenue pertaining to the Company's segments are based in the United States. Corporate and other includes general and administrative expenses as well as eliminations of intercompany transactions. The Company does not report balance sheet information by segment since it is not reviewed by the chief operating decision maker, and all of the Company's tangible assets are held in the United States.

The Company's results of operations by segment for the three months ended March 31, 2024 and 2023 are summarized in the tables below:

(In thousands) Three Months Ended March 31, 2024	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue from external customers	$ 1,741	$ 657	$ —	$ 2,398
Intercompany revenue	—	3,666	(3,666)	—
Cost of revenue	—	4,024	(3,432)	592
Research and development	8,760	—	(233)	8,527
General and administrative	—	1,108	4,742	5,850
Licensing	1,031	—	—	1,031
Revaluation of contingent consideration	2,800	—	—	2,800
Restructuring expense	1,318	217	994	2,529
Loss from operations	$ (12,168)	$ (1,026)	$ (5,737)	$ (18,931)

(In thousands) Three Months Ended March 31, 2023	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue from external customers	$ 1,638	$ 890	$ —	$ 2,528
Intercompany revenue	—	4,011	(4,011)	—
Cost of revenue	—	4,547	(3,739)	808
Research and development	22,859	—	(272)	22,587
General and administrative	—	1,062	7,728	8,790
Licensing	1,061	—	—	1,061
Revaluation of contingent consideration	(800)	—	—	(800)
Loss from operations	$ (21,482)	$ (708)	$ (7,728)	$ (29,918)

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

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "may," "might," "can," "will," "to be," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "likely," "continue," "ongoing" or similar expressions, or the negative of such words, are intended to identify "forward-looking statements." We have based these forward-looking statements on our current expectations and projections about future events. Because such statements include risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those below in this Quarterly Report on Form 10-Q and those in our Annual Report on Form 10-K, in each case under the caption "Risk Factors," and in our other filings with the Securities and Exchange Commission, or SEC. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes for the year ended December 31, 2023, which are included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. Our proprietary KINect drug discovery platform combined with our preclinical development capabilities allows us to identify and advance potential drug candidates that we may develop independently or in collaboration with third parties. In addition to identifying and developing our novel drug candidates, we are pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our novel drug candidates. We also provide contract research services to third parties enabled by our early-stage research and development expertise. In January 2024, we announced that we are undertaking a strategic review of our business.

ATI-2138, an Investigational Oral Covalent ITK/JAK3 Inhibitor

ATI-2138 is an investigational oral covalent inhibitor of interleukin-2-inducible T cell kinase, or ITK, and Janus kinase, or JAK, 3 for the potential treatment of T cell-mediated autoimmune diseases. The ITK/JAK3 compound interrupts T cell signaling through the combined inhibition of ITK/JAK3 pathways in lymphocytes.

In September 2023, we announced positive results from our two-week Phase 1 placebo-controlled, randomized, multiple ascending dose, or MAD, trial of ATI-2138 (ATI-2138-PKPD-102). ATI-2138-PKPD-201 was designed to investigate the safety, tolerability, pharmacokinetics, or PK, and pharmacodynamics of ATI-2138 in healthy volunteers. The trial enrolled 60 healthy volunteers across 6 dosing cohorts ranging from 10 to 80 mg of total daily doses, with eight volunteers receiving ATI-2138 and two volunteers receiving placebo in each arm. Data from the trial demonstrated that ATI-2138 was generally well tolerated at all doses tested and had dose proportional PK. Additionally, ATI-2138 demonstrated a dose-dependent inhibition of both ITK and JAK3 exploratory pharmacodynamic biomarkers, with near maximal inhibition achieved at the 30 mg total daily dose. No serious adverse events were reported.

We plan to progress ATI-2138 into a Phase 2a trial in subjects with moderate to severe atopic dermatitis.

Lepzacitinib, an Investigational Topical "Soft" JAK 1/3 Inhibitor

Lepzacitinib, also referred to as ATI-1777, is an investigational topical "soft" JAK 1/3 inhibitor for the potential treatment of atopic dermatitis and other dermatologic conditions. "Soft" JAK inhibitors are designed to be topically applied and active in the skin, but rapidly metabolized and inactivated when they enter the bloodstream, which may result in low systemic exposure. Lepzacitinib has been adopted as the nonproprietary name for ATI-1777.

In January 2024, we announced positive top-line results from our Phase 2b multicenter, randomized, double-blind, vehicle-controlled, parallel-group trial of lepzacitinib in patients with mild to severe atopic dermatitis (ATI-1777-AD-202). ATI-1777-AD-202 was designed to evaluate the efficacy, safety, tolerability and PK of multiple concentrations (0.5%, 1% and 2%) of twice daily, or BID, treatment with lepzacitinib and a single concentration (2%) of once daily, or QD, treatment with lepzacitinib. The trial randomized 250 patients with mild, moderate or severe atopic dermatitis, including adults and children as young as 12 years old, across 30 clinical trial sites in the United States. The trial met the primary efficacy endpoint, the percent change from baseline in the Eczema Area and Severity Index, or EASI, score at week 4, with statistical significance for patients treated with lepzacitinib 2% BID compared to patients treated with vehicle (69.7% versus 58.7% in the pooled vehicle group, p=0.035). In addition, a PK analysis showed minimal levels of exposure to lepzacitinib. The mean steady state trough drug levels at week 4 were 0.319 ng/mL, representing 0.7% of IC50 for JAK 1/3 inhibition in whole blood. In total, 97% of lepzacitinib plasma samples from dosed patients had concentrations below 1/10th of the IC50, and six samples (from five lepzacitinib treated patients) of 570 samples analyzed had concentrations above 1/4 of the IC50. No meaningful safety findings were observed and lepzacitinib was well tolerated.

We are currently seeking a global development and commercialization partner for this program (excluding Greater China). In 2022, we granted Pediatrix Therapeutics, Inc. exclusive rights to develop and commercialize lepzacitinib in Greater China.

Zunsemetinib, an Investigational Oral MK2 Inhibitor

Zunsemetinib, or ATI-450, is an investigational oral, novel, small molecule selective MK2 inhibitor for the potential treatment of metastatic breast cancer, or MBC, and pancreatic ductal adenocarcinoma, or PDAC. We plan to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib in patients with MBC and PDAC. We expect these trials to be primarily funded by grants awarded to Washington University.

Discovery Programs and KINect Drug Discovery Platform

We conduct small molecule drug discovery and preclinical development research through KINect, our proprietary drug discovery platform. Our KINect platform enables us to identify potential drug candidates through a unique combination of our proprietary chemical library of kinase inhibitors, our novel approaches to inhibitor modalities, our expertise in structure-based drug design, and our custom kinase assays.

Our focus has been on difficult to drug kinase targets that exhibit some level of clinical, genetic and/or pharmacological disease validation. Our approach involves the following mechanisms: (1) reversible and irreversible covalent inhibitors, (2) molecular glue/complex targeted inhibitors and (3) targeted protein degraders. These novel approaches are currently being utilized to prosecute additional validated, difficult to drug kinase targets with the goal of demonstrating potential platform utility.

We are actively progressing several discovery programs focused on delivering the next wave of drug candidates from our KINect platform. Our discovery efforts center on targeting kinases that play pivotal roles in various inflammatory, autoimmune, and oncology pathways. For example, we are progressing to development candidate selection a second generation ITK selective inhibitor for autoimmune indications. We intend to evaluate both internal and external development options, including strategic partnerships, for these assets.

Discontinued Programs

We were previously developing zunsemetinib as a potential treatment for various immuno-inflammatory diseases, including hidradenitis suppurativa, psoriatic arthritis, and rheumatoid arthritis. Following the results of the Phase 2 trials for these programs, we discontinued further development of our MK2 inhibitor programs in immuno-inflammatory diseases in 2023.

Financial Overview

Since our inception, we have incurred significant net losses. Our net loss was $16.9 million for the three months ended March 31, 2024 and $88.5 million for the year ended December 31, 2023. As of March 31, 2024, we had an accumulated deficit of $787.7 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical and clinical development. In addition, our drug candidates, even if they are approved by regulatory agencies for marketing, may not achieve commercial success. We may also not be successful in pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates. Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. As a result, we will need substantial additional funding to support our continuing operations.

We have historically financed our operations primarily with sales of equity securities and incurring indebtedness in the form of loans from commercial lenders. In the near term, we expect to finance our operations through these and other capital sources, including potential partnerships with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on commercially acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when needed, we may have to significantly delay, scale back or discontinue the development of one or more of our drug candidates.

Impact of Macroeconomic Conditions on Our Business

Unfavorable conditions in the economy both in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including rising inflation, the U.S. Federal Reserve raising interest rates and geopolitical conflicts, have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

Acquisition and License Agreements

License Agreement with Sun Pharmaceutical Industries, Inc.

In December 2023, we entered into an exclusive patent license agreement with Sun Pharmaceutical Industries, Inc., or Sun Pharma. Under the license agreement, we granted Sun Pharma exclusive rights under certain patents that we exclusively license from a third party. The patents relate to the use of deuruxolitinib, Sun Pharma's JAK inhibitor, or other isotopic forms of ruxolitinib, to treat alopecia areata or androgenetic alopecia. Under the license agreement, Sun Pharma has paid us an upfront payment, and has agreed to pay us regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a mid single-digit tiered royalty calculated as a percentage of Sun Pharma's net sales. We have separate contractual obligations under which we have agreed to pay to third parties a portion of the consideration we may receive under the license agreement.

Upon execution of the agreement, we received an upfront payment of $15.0 million from Sun Pharma, a portion of which was payable to third parties.

License Agreement with Pediatrix Therapeutics, Inc.

In November 2022, we entered into a license agreement with Pediatrix Therapeutics, Inc., or Pediatrix, under which we granted Pediatrix the exclusive rights to develop, manufacture and commercialize lepzacitinib in Greater China. Pediatrix has paid us an upfront payment, and has agreed to pay us development, regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a tiered royalty ranging from a low-to-high single digit percentage of net sales of lepzacitinib by Pediatrix in Greater China. A portion of consideration received from Pediatrix is payable to the former Confluence equity holders as described below under the caption "Agreement and Plan of Merger with Confluence."

License Agreement with Eli Lilly and Company

In August 2022, we entered into a non-exclusive patent license agreement with Eli Lilly and Company, or Lilly. Under the license agreement, we granted Lilly non-exclusive rights under certain patents and patent applications that we exclusively license from a third party. The patents and patent applications relate to the use of baricitinib, Lilly's JAK inhibitor, to treat alopecia areata. Under the license agreement, Lilly has paid us an upfront payment and regulatory and certain commercial milestone payments, and has agreed to pay us anniversary payments and other commercial milestone payments upon the achievement of specified milestones as set forth in the agreement, and a low single-digit royalty calculated as a percentage of Lilly's net sales of baricitinib for the treatment of alopecia areata. We have separate contractual obligations under which we have agreed to pay to third parties an amount equal to any regulatory and commercial milestone payments we receive under the Lilly license agreement, as well as a portion of the upfront consideration and a portion of the royalties we may receive under the license agreement.

During the three months ended March 31, 2024 and 2023, we recorded licensing revenue under this agreement of $1.7 million and $1.6 million from Lilly, respectively, a portion of which was payable to third parties.

Asset Purchase Agreement with EPI Health

In October 2019, we sold RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, to EPI Health, LLC, or EPI Health, pursuant to an asset purchase agreement. In July 2023, EPI Health filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code. Through the bankruptcy process, EPI Health and its parent company, Novan, Inc., sold the RHOFADE assets to a third party, which excluded our asset purchase agreement with EPI Health and the outstanding amounts due. The sale was approved by the bankruptcy court in September 2023. As a result of the bankruptcy proceedings, all amounts that are due and outstanding by EPI Health have been fully reserved for as of March 31, 2024.

Agreement and Plan of Merger with Confluence

In 2017, we entered into an Agreement and Plan of Merger, or the Confluence Agreement, with Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence, Aclaris Life Sciences, Inc., our wholly owned subsidiary, or Merger Sub, and Fortis Advisors LLC, as representative of the equity holders of Confluence. Pursuant to the terms of the Confluence Agreement, Merger Sub merged with and into Confluence, with Confluence surviving as our wholly owned subsidiary.

Under the Confluence Agreement, we have agreed to pay the former Confluence equity holders aggregate remaining contingent consideration of up to $75.0 million based upon the achievement of specified regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders future royalty payments calculated as a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. In addition to the payments described above, if we sell, license or transfer any of the intellectual property acquired from Confluence pursuant to the Confluence Agreement to a third party, we will be obligated to pay the former Confluence equity holders a portion of any consideration received from such sale, license, or transfer in specified circumstances.

Restructuring

In December 2023, our Board of Directors approved a reduction of our workforce by approximately 46%, which we expect to be substantially completed by June 2024. This action was taken in order to streamline operations, reduce costs and preserve capital. As a result, we terminated certain employees, or terminated employees, and gave notice to additional employees, or noticed employees, who were asked to provide transition services through termination dates ranging between one to thirteen months from the date notice was given. The terminated employees were entitled to receive cash severance payments and other benefits. The noticed employees are entitled to receive cash severance payments and other benefits, which are contingent upon providing additional services to us.

During the three months ended March 31, 2024, we recognized severance expense of $2.5 million and made cash payments of $3.0 million related to severance to terminated employees.

Components of Our Results of Operations

Revenue

Contract Research

We earn revenue from the provision of laboratory services. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis and are generally billed on a monthly basis in arrears for services rendered.

Licensing

Licensing revenue primarily consists of upfront consideration, royalties and milestone payments earned pursuant to license and acquisition agreements with third parties, as described above.

Cost and Expenses

Cost of Revenue

Cost of revenue consists of the costs incurred in connection with the provision of contract research services. Cost of revenue primarily includes:

- employee-related expenses, which include salaries, benefits, and stock-based compensation;
- outsourced professional scientific services;
- depreciation of laboratory equipment;
- facility-related costs; and
- laboratory materials and supplies used to support the services provided.

Research and Development

Research and development expenses consist of expenses incurred in connection with the discovery and development of our drug candidates. These expenses primarily include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as clinical trial sites and consultants that conduct our clinical trials and preclinical studies, and investigator-initiated trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing active pharmaceutical ingredients and preclinical and clinical trial materials, including domestic technology transfer expenses;
- quality assurance and quality control costs;
- outsourced professional scientific development services;
- medical affairs expenses related to our drug candidates;

- employee-related expenses, which include salaries, benefits, and stock-based compensation;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies; and
- laboratory materials and supplies used to support our research activities.

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to continue to incur research and development expenses in the near term as we continue the development of our drug candidates and pursue our discovery programs. We expense research and development costs as incurred. Our direct research and development expenses primarily consist of external costs including fees paid to CROs, consultants, clinical trial sites, regulatory agencies and third parties that manufacture our preclinical and clinical trial materials and are tracked on a program-by-program basis. We do not allocate personnel costs or other indirect expenses to specific research and development programs.

The successful development of our drug candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our drug candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable subjects;
- the number of subjects that ultimately participate in the trials;
- the number of doses subjects receive;
- the duration of subject follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the preparation of regulatory filings for our drug candidates. We may obtain unexpected results from our clinical trials or other development activities. We may elect to discontinue, delay, or modify the development, including clinical trials, of some drug candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative

General and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for personnel in executive, administrative, finance and legal functions. General and administrative expenses also include facility-related costs, patent filing and prosecution costs, professional fees for legal, auditing and tax services, investor relations costs, business development costs, insurance costs, and travel expenses.

Licensing

Licensing expenses consist of third-party contractual obligations incurred under license and acquisition agreements with third parties, as described above.

Revaluation of Contingent Consideration

Revaluation of contingent consideration consists of changes in the fair value of our contingent consideration liability between reporting dates, as described below.

Other Income, Net

Other income, net primarily consists of interest earned on our cash, cash equivalents and marketable securities.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and judgments on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. There have been no material changes to our significant accounting policies and use of estimates as disclosed in the footnotes to our audited consolidated financial statements for the year ended December 31, 2023 included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Contingent Consideration

We record a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of regulatory and commercial milestones, as well as estimated future sales levels and the discount rates applied to calculate the present value of the potential payments. Significant judgement is involved in determining the appropriateness of these assumptions. These assumptions are considered Level 3 inputs. Revaluation of our contingent consideration liability can result from changes to one or more of these assumptions. These assumptions are highly dependent on the outcome and timing of the development of certain of our drug candidates. We evaluate the fair value estimate of our contingent consideration liability on a quarterly basis with changes, if any, recorded as income or expense in our consolidated statement of operations. Any such changes could have a material impact on our financial results.

The fair value of contingent consideration is estimated using a probability-weighted expected payment model for regulatory milestone payments and a Monte Carlo simulation model for commercial milestone and royalty payments and then applying a risk-adjusted discount rate to calculate the present value of the potential payments. Significant assumptions used in our estimates include the probability of achieving regulatory milestones and commencing commercialization, which are based on an asset's current stage of development and a review of existing clinical data. Probability of success assumptions ranged between 17% and 40% at March 31, 2024. Additionally, estimated future sales levels and the risk-adjusted discount rate applied to the potential payments are also significant assumptions used in calculating the fair value. The discount rate ranged between 7.4% and 8.3% depending on the year of each potential payment.

During the three months ended March 31, 2024 we recorded a charge to the contingent consideration liability, which was primarily due to changes in estimated sales levels and changes to the probability of success for certain drug candidates.

Results of Operations

Comparison of Three Months Ended March 31, 2024 and 2023

(In thousands)	Three Months Ended March 31, 2024	2023	Change
Revenues:			
Contract research	$ 657	$ 889	**$ (232)**
Licensing	1,741	1,639	**102**
Total revenue	2,398	2,528	**(130)**
Costs and expenses:			
Cost of revenue	809	808	**1**
Research and development	9,845	22,587	**(12,742)**
General and administrative	6,844	8,790	**(1,946)**
Licensing	1,031	1,061	**(30)**
Revaluation of contingent consideration	2,800	(800)	**3,600**
Total costs and expenses	21,329	32,446	**(11,117)**
Loss from operations	(18,931)	(29,918)	**10,987**
Other income, net	1,990	1,758	**232**
Net loss	$ (16,941)	$ (28,160)	**$ 11,219**

Revenue

Contract research

Contract research revenue was $0.7 million and $0.9 million for the three months ended March 31, 2024 and 2023, respectively, and was comprised of fees earned from the provision of laboratory services. The decrease was driven by lower overall hours billed and a lower average billing rate.

Licensing

Licensing revenue was $1.7 million and $1.6 million for the three months ended March 31, 2024 and 2023, respectively. The increase was primarily driven by an increase in royalties under the Lilly license agreement during the three months ended March 31, 2024, offset by the achievement of a commercial milestone during the three months ended March 31, 2023.

Costs and Expenses

Cost of Revenue

Cost of revenue was $0.8 million for each of the three months ended March 31, 2024 and 2023, and in each case, related to providing laboratory services. Changes in cost of revenue generally correlate to changes in contract research revenue. Cost of revenue included a decrease in expense due to lower variable costs resulting from a decrease in hours billed, which was offset by an increase in termination benefits, as a result of our restructuring that was announced in December 2023.

Research and Development

The following table summarizes our research and development expenses by drug candidate or, for unallocated expenses, by type:

(In thousands)	Three Months Ended March 31, 2024	2023	Change
Zunsemetinib	$ 2,023	$ 6,839	**$ (4,816)**
Lepzacitinib	1,073	3,123	**(2,050)**
ATI-2138	63	3,225	**(3,162)**
Discovery	1,540	1,381	**159**
Other research and development	473	498	**(25)**
Personnel	4,702	4,919	**(217)**
Stock-based compensation	(29)	2,602	**(2,631)**
Total research and development expenses	$ 9,845	$ 22,587	**$ (12,742)**

Zunsemetinib

The decrease in expenses for zunsemetinib during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily due to a decrease in costs associated with clinical development activities for a Phase 2a trial in subjects with hidradenitis suppurativa, which initiated in December 2021 and was completed in early March 2023, and a Phase 2b trial in subjects with rheumatoid arthritis, which initiated in December 2021 and was completed in November 2023. Drug candidate manufacturing costs also decreased accordingly.

Lepzacitinib

The decrease in expenses for lepzacitinib during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily due to lower costs associated with preclinical development activities and costs associated with a Phase 2b clinical trial in subjects with atopic dermatitis, which initiated in May 2022 and was completed in January 2024.

ATI-2138

The decrease in expenses for ATI-2138 during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily due to a decrease in clinical development expenses associated with a Phase 1 MAD trial which was completed in September 2023, as well as a decrease in preclinical development activities and ancillary studies.

Discovery

The increase in expenses related to discovery during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was due to continued investment in our discovery-stage programs as we progressed programs toward candidate selection.

Personnel and stock-based compensation

The decrease in personnel and stock-based compensation expenses in the aggregate during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily due to lower headcount and higher forfeiture credits, offset by an increase in termination benefits, as a result of our restructuring.

General and Administrative

The following table summarizes our general and administrative expenses:

(In thousands)	Three Months Ended March 31, 2024	2023	Change
Personnel	$ 2,555	$ 1,980	**$ 575**
Professional and legal fees	1,253	1,721	**(468)**
Facility and support services	633	618	**15**
Other general and administrative	537	566	**(29)**
Stock-based compensation	1,866	3,905	**(2,039)**
Total general and administrative expenses	$ 6,844	$ 8,790	**$ (1,946)**

Personnel and stock-based compensation

The decrease in personnel and stock-based compensation expenses in the aggregate during the three months ended March 31, 2024 compared to the three months ended March 31, 2023, was primarily due to higher forfeiture credits, offset by an increase in termination benefits, as a result of our restructuring.

Professional and legal fees

Professional and legal fees, including accounting, investor relations and corporate communication costs, decreased during the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The decrease was primarily driven by a decrease in patent expenses.

Licensing

The decrease in licensing expenses during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was due to the achievement of a commercial milestone during the three months ended March 31, 2023, offset by an increase in royalties during the three months ended March 31, 2024, earned under the Lilly license agreement.

Revaluation of Contingent Consideration

The increase in the fair value of our contingent consideration liability during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 was primarily due to changes in estimated sales levels and changes to the probability of success for certain drug candidates.

Other Income, net

Other income, net increased during the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily due to higher interest income on investment portfolio balances.

Liquidity and Capital Resources

Overview

Since our inception, we have incurred net losses and negative cash flows from our operations. Prior to our acquisition of Confluence, we did not generate any revenue. We have financed our operations over the last several years primarily through sales of our equity securities and incurring indebtedness in the form of loans from commercial lenders. We may engage in additional debt and equity financing transactions in order to raise funds. We may receive royalties and milestone payments under third-party licensing and acquisition agreements. In addition, to the extent we are able to consummate transactions with potential third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, we may receive upfront payments, milestone payments or royalties from such arrangements that would increase our liquidity.

As of March 31, 2024, we had cash, cash equivalents and marketable securities of $161.4 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards liquidity and capital preservation.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity, other than our contingent obligations under the Confluence Agreement, which is summarized above under "Overview—Acquisition and License Agreements," and our lease obligations.

Cash Flows

Cash and cash equivalents were $35.8 million as of March 31, 2024 compared to $39.9 million as of December 31, 2023. We also had $125.6 million in short- and long-term marketable securities as of March 31, 2024 compared to $142.0 million as of December 31, 2023.

The sources and uses of cash that contributed to the change in cash and cash equivalents were:

	Three Months Ended March 31,	
(In thousands)	2024	2023
Cash and cash equivalents beginning balance	$ 39,878	$ 45,277
Net cash used in operating activities	(20,815)	(26,353)
Net cash provided by investing activities	16,833	25,798
Net cash used in financing activities	(55)	—
Cash and cash equivalents ending balance	$ 35,841	$ 44,722

Operating Activities

Cash flow related to operating activities was the result of:

	Three Months Ended March 31,	
(In thousands)	2024	2023
Net loss	$ (16,941)	$ (28,160)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	5,132	6,204
Change in accounts payable and accrued expenses	(10,975)	(3,321)
Change in accounts receivable	(75)	(202)
Change in prepaid expenses and other assets	2,044	(874)
Net cash used in operating activities	$ (20,815)	$ (26,353)

Net cash used in operating activities decreased for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily as a result of lower net losses after adjusting for non-cash items. This change was partially offset by a reduction in accounts payable and accrued expenses, which was due to the timing of payments to vendors as well as third parties in connection with amounts earned under licensing agreements.

Investing Activities

Cash flow related to investing activities was the result of:

	Three Months Ended March 31,	
(In thousands)	**2024**	**2023**
Purchases of property and equipment	$ (135)	$ (553)
Purchases of marketable securities	—	(28,524)
Proceeds from sales and maturities of marketable securities	16,968	54,875
Net cash provided by investing activities	$ 16,833	$ 25,798

The decrease in net cash provided by investing activities for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 resulted primarily from lower sales and maturities of marketable securities during the three months ended March 31, 2024, partially offset by lower purchases of marketable securities during the three months ended March 31, 2024.

Financing Activities

Cash flow related to financing activities was the result of:

	Three Months Ended March 31,	
(In thousands)	**2024**	**2023**
Payments of employee withholding taxes related to restricted stock unit award vesting	$ (55)	$ —
Net cash used in financing activities	$ (55)	$ —

Net cash used in financing activities during the three months ended March 31, 2024 consisted of payments of employee withholding taxes related to restricted stock unit award vesting.

Funding Requirements

We anticipate we will incur net losses in the near term as we continue to discover and develop drug candidates. We may not be able to generate revenue from these programs if, among other things, our clinical trials are not successful, the FDA does not approve our drug candidates currently in clinical trials when we expect, or at all, or we are not able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, research and development expenses, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the development of our drug candidates, without taking into account any potential business development activities resulting from our ongoing strategic review of our business.

As a publicly traded company, we incur and will continue to incur significant legal, accounting, and other similar expenses. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and the Nasdaq Stock Market LLC, requires public companies to implement specified corporate governance practices that could increase our compliance costs.

We believe our existing cash, cash equivalents and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of our condensed consolidated financial statements that appear in Item 1 of this Quarterly Report on Form 10-Q based on our current operating assumptions. We will require additional capital to develop our drug candidates and to support our discovery efforts. Additional funds may not be available on a timely basis, on commercially acceptable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Our ability to raise additional capital may be adversely impacted by potentially worsening global economic conditions caused by a variety of factors including geopolitical tensions, rising interest rates, and inflationary pressures. If we are unable to raise sufficient additional capital or generate revenue from transactions with potential third-party partners for the development and/or commercialization of our drug candidates, we may need to substantially curtail our planned operations.

We may raise additional capital through the sale of equity or debt securities. In such an event, our stockholders' ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a holder of our common stock.

Because of the numerous risks and uncertainties associated with research and development of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our funding requirements in the near term will depend on many factors, including:

- the number and development requirements of the drug candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our drug candidates;
- the costs, timing, and outcome of regulatory review of our drug candidates;
- the extent to which we in-license or acquire additional drug candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates; and
- our ability to earn revenue as a result of licenses to, or partnerships or other arrangements with, third parties.

Leases

We occupy space for our headquarters in Wayne, Pennsylvania under a lease agreement which has a term through February 2029. We also occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through June 2029.

Our aggregate remaining lease payment obligation for these two spaces was $4.5 million as of March 31, 2024.

Agreement and Plan of Merger – Confluence

Under the Confluence Agreement, we have agreed to pay the former Confluence equity holders aggregate remaining contingent consideration of up to $75.0 million based upon the achievement of specified regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders future royalty payments calculated as a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. In addition to the payments described above, if we sell, license or transfer any of the intellectual property acquired from Confluence pursuant to the Confluence Agreement to a third party, we will be obligated to pay the former Confluence equity holders a portion of any consideration received from such sale, license, or transfer in specified circumstances.

R&D Obligations

We enter into contracts in the normal course of business with CROs, contract manufacturing organizations and other service providers for clinical trials, preclinical studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Segment Information

We have two reportable segments, therapeutics, and contract research. The therapeutics segment is focused on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases and earns revenue through licensing our intellectual property. The contract research segment earns revenue from the provision of laboratory services.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our cash equivalents and marketable securities consist of money market funds, asset-backed debt securities, commercial paper, corporate debt securities, foreign government agency debt securities, U.S. government debt securities and U.S. government agency debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the short-term nature and low-risk profile of our investment portfolio, we do not expect that an immediate 10% change in market interest rates would have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in exchange rates. Our primary exposure to currency risk is foreign government agency debt securities. We do not enter into any derivative financial instruments to manage our exposure to foreign currency risk. Due to the conservative nature of our investment portfolio and other financial instruments, we do not believe an immediate 10% change in currency rates would have a material effect on the fair market value of our portfolio.

Inflation Risk

Inflation generally affects us by increasing our cost of labor. Although inflation has increased generally in the United States in recent months, we do not believe that inflation has had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2024.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*

Under the supervision of and with the participation of our management, including our principal executive officer, and our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2024, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are 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 recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. 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 financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and 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, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any other pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024.

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

None.

Item 5. Other Information

Adoption, Modification and Termination of Rule 10b5-1 Plans and Certain Other Trading Arrangements.

During the quarter ended March 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408 of Regulation S-K).

Item 6. Exhibits

Exhibit No.	Document
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on August 7, 2023).
3.3	Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on June 24, 2020).
10.1+	Second Amended and Restated Employment Agreement, effective as of February 1, 2024, by and between the Registrant and Joseph Monahan (incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
10.2+	Separation Agreement, Waiver, and Release, dated as of February 4, 2024, by and between the Registrant and Douglas Manion (incorporated herein by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).

10.3+	Letter Agreement, dated as of January 31, 2024, by and between the Registrant and Neal Walker (incorporated herein by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101.INS	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 Extension 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 (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\+ Indicates management contract or compensatory plan.

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.

ACLARIS THERAPEUTICS, INC.

Date: May 7, 2024

By: /s/ Neal Walker
Neal Walker
Interim President and Chief Executive Officer
(On behalf of the Registrant)

Date: May 7, 2024

By: /s/ Kevin Balthaser
Kevin Balthaser
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neal Walker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of Aclaris Therapeutics, Inc. (the "registrant");

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 7, 2024

/s/ Neal Walker
Neal Walker
Interim President & Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin Balthaser, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of Aclaris Therapeutics, Inc. (the "registrant");

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 7, 2024

/s/ Kevin Balthaser
Kevin Balthaser
Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Neal Walker, Interim President and Chief Executive Officer of Aclaris Therapeutics, Inc. (the "Company"), and Kevin Balthaser, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 7th day of May 2024.

/s/ Neal Walker	/s/ Kevin Balthaser
Neal Walker	Kevin Balthaser
Interim President & Chief Executive Officer	Chief Financial Officer
(principal executive officer)	(principal financial officer and principal accounting officer)

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aclaris Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.