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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 September 30, 2023

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 October 31, 2023 was 70,836,194.

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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 39,040	$ 45,277
Short-term marketable securities	64,012	172,294
Accounts receivable, net	346	484
Prepaid expenses and other current assets	19,670	13,495
Total current assets	123,068	231,550
Marketable securities	83,944	12,242
Property and equipment, net	1,764	1,099
Intangible assets	6,917	6,973
Other assets	2,661	2,732
Total Assets	$ 218,354	$ 254,596
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,648	$ 10,351
Accrued expenses	15,160	8,701
Current portion of lease liabilities	310	684
Discontinued operations	2,202	2,202
Total current liabilities	27,320	21,938
Other liabilities	1,834	1,570
Contingent consideration	32,500	33,100
Deferred tax liability	367	367
Total liabilities	62,021	56,975
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.00001 par value; 200,000,000 and 100,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 70,818,954 and 66,688,647 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	926,766	880,832
Accumulated other comprehensive loss	(1,129)	(897)
Accumulated deficit	(769,305)	(682,315)
Total stockholders' equity	156,333	197,621
Total liabilities and stockholders' equity	$ 218,354	$ 254,596

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Contract research	$ 705	$ 1,090	$ 2,469	$ 3,529
Licensing	8,577	17,898	11,210	18,378
Other	—	30	—	92
Total revenue	9,282	19,018	13,679	21,999
Costs and expenses:				
Cost of revenue	848	923	2,698	3,146
Research and development	23,876	23,656	71,738	56,741
General and administrative	7,091	5,813	24,198	17,987
Licensing	7,344	7,300	8,955	7,300
Revaluation of contingent consideration	1,700	2,200	(600)	(2,400)
Total costs and expenses	40,859	39,892	106,989	82,774
Loss from operations	(31,577)	(20,874)	(93,310)	(60,775)
Other income, net	2,316	922	6,320	1,502
Net loss	$ (29,261)	$ (19,952)	$ (86,990)	$ (59,273)
Net loss per share, basic and diluted	$ (0.41)	$ (0.30)	$ (1.25)	$ (0.92)
Weighted average common shares outstanding, basic and diluted	70,807,934	66,675,337	69,452,495	64,718,008
Other comprehensive loss:				
Unrealized loss on marketable securities, net of tax of $0	$ (18)	$ (139)	$ (232)	$ (1,241)
Total other comprehensive loss	(18)	(139)	(232)	(1,241)
Comprehensive loss	$ (29,279)	$ (20,091)	$ (87,222)	$ (60,514)

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, 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
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	163,677	—	30	—	—	30
Issuance of common stock under at-the-market sales agreement, net of offering costs of $826	3,400,000	—	26,714	—	—	26,714
Unrealized loss on marketable securities	—	—	—	(757)	—	(757)
Stock-based compensation expense	—	—	6,522	—	—	6,522
Net loss	—	—	—	—	(29,569)	(29,569)
Balance at June 30, 2023	70,769,702	$ 1	$ 920,904	$ (1,111)	$ (740,044)	$ 179,750
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	49,252	—	(86)	—	—	(86)
Unrealized loss on marketable securities	—	—	—	(18)	—	(18)
Stock-based compensation expense	—	—	5,948	—	—	5,948
Net loss	—	—	—	—	(29,261)	(29,261)
Balance at September 30, 2023	70,818,954	$ 1	$ 926,766	$ (1,129)	$ (769,305)	$ 156,333

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2021	61,228,446	$ 1	$ 792,971	$ (224)	$ (595,407)	$ 197,341
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	509,037	—	49	—	—	49
Unrealized loss on marketable securities	—	—	—	(748)	—	(748)
Stock-based compensation expense	—	—	2,346	—	—	2,346
Net loss	—	—	—	—	(18,789)	(18,789)
Balance at March 31, 2022	61,737,483	$ 1	$ 795,366	$ (972)	$ (614,196)	$ 180,199
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	91,388	—	88	—	—	88
Issuance of common stock under at-the-market sales agreement, net of offering costs of $2,341	4,838,709	—	72,659	—	—	72,659
Unrealized loss on marketable securities	—	—	—	(354)	—	(354)
Stock-based compensation expense	—	—	3,692	—	—	3,692
Net loss	—	—	—	—	(20,532)	(20,532)
Balance at June 30, 2022	66,667,580	$ 1	$ 871,805	$ (1,326)	$ (634,728)	$ 235,752
Issuance of common stock in connection with vesting of restricted stock units	12,061	—	(11)	—	—	(11)
Unrealized loss on marketable securities	—	—	—	(139)	—	(139)
Stock-based compensation expense	—	—	4,188	—	—	4,188
Net loss	—	—	—	—	(19,952)	(19,952)
Balance at September 30, 2022	66,679,641	$ 1	$ 875,982	$ (1,465)	$ (654,680)	$ 219,838

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)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (86,990)	$ (59,273)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	635	607
Stock-based compensation expense	19,276	10,226
Revaluation of contingent consideration	(600)	(2,400)
Changes in operating assets and liabilities:		
Accounts receivable	138	26
Prepaid expenses and other assets	(9,293)	3,408
Accounts payable	(1,079)	(2,319)
Accrued expenses	6,349	1,273
Net cash used in operating activities	(71,564)	(48,452)
Cash flows from investing activities:		
Purchases of property and equipment	(868)	(500)
Purchases of marketable securities	(135,675)	(118,729)
Proceeds from sales and maturities of marketable securities	175,213	129,155
Net cash provided by investing activities	38,670	9,926
Cash flows from financing activities:		
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	26,714	72,744
Payments of employee withholding taxes related to restricted stock unit award vesting	(102)	(34)
Proceeds from exercise of employee stock options and the issuance of stock	45	120
Net cash provided by financing activities	26,657	72,830
Net (decrease) increase in cash and cash equivalents	(6,237)	34,304
Cash and cash equivalents at beginning of period	45,277	27,349
Cash and cash equivalents at end of period	$ 39,040	$ 61,653
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	$ 376	$ 4

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. In 2017, Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) ("Confluence") was acquired by Aclaris Therapeutics, Inc. and became a wholly owned subsidiary thereof. 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. In addition to 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.

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 September 30, 2023, the Company had cash, cash equivalents and marketable securities of $187.0 million and an accumulated deficit of $769.3 million. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence, 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 complete the clinical development of zunsemetinib (ATI-450), ATI-1777, ATI-2138 and ATI-2231, to develop its preclinical compounds, 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 potential worsening global economic conditions caused by a variety of factors including geopolitical tensions, rising interest rates, the closure of financial institutions 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 has 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 September 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statement of stockholders' equity for the three and nine months ended September 30, 2023 and 2022, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 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 23, 2023 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 September 30, 2023, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, its changes in stockholders' equity for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine months ended September 30, 2023 and 2022. The condensed consolidated balance sheet data as of December 31, 2022 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 and nine months ended September 30, 2023 and 2022 are unaudited. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, 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, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on February 23, 2023.

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.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds all cash, cash equivalents and marketable securities balances at three accredited financial institutions, the majority of which are in amounts that exceed or are not subject to federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply drug product, including all underlying components, for its research and development activities, including preclinical and clinical testing. These activities could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients or other components.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on February 23, 2023. There have been no changes to the Company's significant accounting policies from those disclosed in the annual report.

Contingent Consideration

The Company initially recorded a contingent consideration liability at fair value on the date of acquisition related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of development, 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 was 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 41% at September 30, 2023. 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 9.3% and 10.4% 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

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

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

In September 2019, the Company announced the completion of a strategic review and its decision to refocus its resources on its immuno-inflammatory development programs and to actively seek partners for its commercial products.

As of September 30, 2023 and December 31, 2022, the Company had $2.2 million in accrued expenses reported as discontinued operations in the Company's consolidated balance sheet.

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:

	September 30, 2023			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 35,593	$ —	$ —	$ 35,593
Marketable securities	—	147,956	—	147,956
Total assets	$ 35,593	$ 147,956	$ —	$ 183,549
Liabilities:				
Contingent consideration	$ —	$ —	$ 32,500	$ 32,500
Total liabilities	$ —	$ —	$ 32,500	$ 32,500

(In thousands)	December 31, 2022 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 38,516	$ —	$ —	$ 38,516
Marketable securities	—	184,536	—	184,536
Total assets	$ 38,516	$ 184,536	$ —	$ 223,052
Liabilities:				
Contingent consideration	$ —	$ —	$ 33,100	$ 33,100
Total liabilities	$ —	$ —	$ 33,100	$ 33,100

As of September 30, 2023, the Company's cash equivalents consisted of a money market fund and treasury bills, which were valued based upon Level 1 inputs. As of December 31, 2022, the Company's cash equivalents consisted of a money market fund, which was valued based upon Level 1 inputs. The Company's marketable securities as of September 30, 2023 consisted of commercial paper, treasury bills, 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. The Company's marketable securities as of December 31, 2022 consisted of commercial paper and corporate debt, asset-backed 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 and nine months ended September 30, 2023 and 2022, there were no transfers into or out of Level 3.

The overall $0.6 million decrease in the fair value of the contingent consideration liability during the nine months ended September 30, 2023 was primarily due to the removal of estimated sales levels from zunsemetinib (ATI-450) for moderate to severe hidradenitis suppurativa following the Company's decision to cease pursuing this indication, as well as higher discount rates resulting from higher risk-free rates and changes in credit spreads being applied to potential payments relative to prior periods. This decrease was partially offset by an increase in the probability of success of ATI-2138, as well as the passage of time.

As of September 30, 2023 and December 31, 2022, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

(In thousands)	September 30, 2023 Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities[1]	$ 52,169	$ —	$ (463)	$ 51,706
Commercial paper	14,663	—	(31)	14,632
Treasury bills	4,936	1	—	4,937
Asset-backed debt securities[2]	11,349	8	(21)	11,336
Foreign government agency debt securities[3]	4,659	—	(18)	4,641
U.S. government and government agency debt securities[4]	61,315	—	(611)	60,704
Total marketable securities	$ 149,091	$ 9	$ (1,144)	$ 147,956

[1] Included in Corporate debt securities is $27.5 million with maturity dates between one and two years.

[2] Included in Asset-backed debt securities is $11.3 million with maturity dates between two and four years.

[3] Included in Foreign government agency debt securities is $4.6 million with a maturity date between one and two years.

[4] Included in U.S. government and government agency debt securities is $40.5 million with maturity dates between one and two years.

(In thousands)	December 31, 2022 Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities[1]	$ 40,626	$ —	$ (251)	$ 40,375
Commercial paper	79,598	—	—	79,598
Asset-backed debt securities[2]	14,641	4	(123)	14,522
U.S. government and government agency debt securities[3]	50,571	—	(530)	50,041
Total marketable securities	$ 185,436	$ 4	$ (904)	$ 184,536

(1) Included in Corporate debt securities is $4.8 million with maturity dates between one and five years.

(2) Included in Asset-backed debt securities is $2.4 million with maturity dates between one and five years.

(3) Included in U.S. government and government agency debt securities is $5.0 million with maturity dates between one and five years.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
Computer equipment	$ 1,444	$ 1,381
Lab equipment	3,152	2,010
Furniture and fixtures	649	620
Leasehold improvements	1,123	1,123
Property and equipment, gross	6,368	5,134
Accumulated depreciation	(4,604)	(4,035)
Property and equipment, net	$ 1,764	$ 1,099

Depreciation expense was $0.2 million for each of the three months ended September 30, 2023 and 2022, and $0.6 million for each of the nine months ended September 30, 2023 and 2022.

5. Intangible Assets

Intangible assets consisted of the following:

(In thousands, except years)	Remaining Life (years)	Gross Cost September 30, 2023	Gross Cost December 31, 2022	Accumulated Amortization September 30, 2023	Accumulated Amortization December 31, 2022
Other intangible assets	3.8	$ 751	$ 751	$ 463	$ 407
In-process research and development	n/a	6,629	6,629	—	—
Total intangible assets		$ 7,380	$ 7,380	$ 463	$ 407

Amortization expense was $19 thousand for each of the three months ended September 30, 2023 and 2022, and $56 thousand for each of the nine months ended September 30, 2023 and 2022.

As of September 30, 2023, estimated future amortization expense was as follows:

(In thousands)	Year Ending December 31,
2023	$ 19
2024	75
2025	75
2026	75
2027	44
Total	$ 288

6. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
Employee compensation expenses	$ 4,968	$ 5,295
Research and development expenses	2,985	2,689
Licensing expenses	6,647	500
Other	560	217
Total accrued expenses	$ 15,160	$ 8,701

7. Stockholders' Equity

Preferred Stock

As of September 30, 2023 and December 31, 2022, 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 September 30, 2023 or December 31, 2022.

Common Stock

On June 1, 2023, at the 2023 Annual Meeting of Stockholders, the Company's stockholders approved an amendment to the Charter to increase the authorized number of shares of common stock from 100,000,000 shares to 200,000,000 shares. On June 1, 2023, the Company filed a Certificate of Amendment to the Charter with the Secretary of State of the State of Delaware, which became effective upon filing.

As of September 30, 2023 and December 31, 2022, the Company's Charter authorized the Company to issue 200,000,000 and 100,000,000 shares, respectively, of $0.00001 par value common stock. There were 70,818,954 and 66,688,647 shares of common stock issued and outstanding as of September 30, 2023 and December 31, 2022, 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 September 30, 2023.

Sales of Common Stock Pursuant to At-The-Market Facility

In April 2023, the Company sold 3.4 million shares of its common stock for aggregate gross proceeds of $27.5 million, pursuant to a sales agreement with SVB Securities LLC and Cantor Fitzgerald & Co., as sales agents, dated

February 23, 2023. The Company paid selling commissions of $0.8 million in connection with the sale.

In April 2022, the Company sold 4.8 million shares of its common stock for aggregate gross proceeds of $75.0 million, pursuant to a sales agreement with SVB Securities LLC and Cantor Fitzgerald & Co., as sales agents, dated May 20, 2021. The Company paid selling commissions and other fees of $2.3 million in connection with the sale.

8. 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, 2023, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 2,667,545 shares. As of September 30, 2023, 2,890,919 shares remained available for grant under the 2015 Plan. The Company had 6,295,647 stock options and 1,707,190 RSUs outstanding as of September 30, 2023 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 370,600 stock options outstanding as of September 30, 2023 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

Upon the 2015 Plan becoming effective, no further grants can be made under the 2012 Plan. The Company had 456,208 stock options outstanding as of September 30, 2023 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 nine months ended September 30, 2023 and 2022 were as follows:

	Nine Months Ended September 30,	
	2023	2022
Risk-free interest rate	3.53 %	2.07 %
Expected term (in years)	6.2	6.2
Expected volatility	77.73 %	77.95 %
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 nine months ended September 30, 2023:

(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, 2022	5,167,164	$ 16.04	7.2	$ 15,288
Granted	2,218,550	15.71		
Exercised	(34,269)	1.30		$ 319
Forfeited and cancelled	(228,990)	15.71		
Outstanding as of September 30, 2023	7,122,455	$ 16.02	7.1	$ 3,680
Options vested and expected to vest as of September 30, 2023	7,122,455	$ 16.02	7.1	$ 3,680
Options exercisable as of September 30, 2023	3,190,762	$ 16.70	4.7	$ 3,323

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2023 was $11.04 per share.

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2023:

(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, 2022	1,520,730	$ 14.02	
Granted	980,700	15.32	
Vested	(706,167)	11.61	$ 8,141
Forfeited and cancelled	(88,073)	15.68	
Outstanding as of September 30, 2023	1,707,190	$ 15.68	

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2023	2022	2023	2022
Cost of revenue	$ 347	$ 307	$ 1,119	$ 837
Research and development	3,072	1,400	9,168	2,228
General and administrative	2,529	2,481	8,989	7,161
Total stock-based compensation expense	$ 5,948	$ 4,188	$ 19,276	$ 10,226

As of September 30, 2023, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $35.6 million and $21.7 million, respectively, which is expected to be recognized over weighted average periods of 2.9 years and 2.8 years, respectively.

9. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except for share and per share data)	2023	2022	2023	2022
Numerator:				
Net loss	$ (29,261)	$ (19,952)	$ (86,990)	$ (59,273)
Denominator:				
Weighted average shares of common stock outstanding, basic and diluted	70,807,934	66,675,337	69,452,495	64,718,008
Net loss per share, basic and diluted	$ (0.41)	$ (0.30)	$ (1.25)	$ (0.92)

The Company's potentially dilutive securities, which include 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 nine months ended September 30, 2023 and 2022. All share amounts presented in the table below represent the total number outstanding as of September 30, 2023 and 2022.

	September 30,	
	2023	2022
Options to purchase common stock	7,122,455	5,187,664
Restricted stock unit awards	1,707,190	1,585,184
Total potential shares of common stock	8,829,645	6,772,848

10. 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. The sublease expired on October 31, 2023. In December 2020, the Company entered into a sub-sublease agreement under which it sub-subleased 8,115 square feet to a third party. The sub-sublease was terminated in December 2022. 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 March 2029.

In February 2019, the Company entered into a sublease agreement pursuant to which it subleases 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)	September 30, 2023	December 31, 2022
Operating Leases:		
Gross cost	$ 5,804	$ 5,240
Accumulated amortization	(3,220)	(2,560)
Other assets	$ 2,584	$ 2,680
Current portion of lease liabilities	$ 310	$ 684
Other liabilities	1,834	1,570
Total operating lease liabilities	$ 2,144	$ 2,254

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled $0.2 million and $0.3 million for the three months ended September 30, 2023 and 2022, respectively, and $0.7 million and $0.8 million for the nine months ended September 30, 2023 and 2022, respectively.

11. Agreements Related to Intellectual Property

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 ATI-1777 in Greater China. Pediatrix has agreed to pay the Company an upfront payment, development, regulatory and commercial milestone payments, and a tiered royalty ranging from a low-to-high single digit percentage of net sales of ATI-1777 by Pediatrix in Greater China. A portion of consideration received from Pediatrix is payable to the former Confluence equity holders as described below.

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 agreed to pay the Company an upfront payment, regulatory and commercial milestone payments, anniversary payments, 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.

The Company recorded licensing revenue under this agreement of $8.3 million and $10.7 million during the three and nine months ended September 30, 2023, respectively. Of these amounts, $7.3 million and $9.0 million were payable to third parties during the three and nine months ended September 30, 2023, respectively, and recorded as licensing expense.

The Company recorded licensing revenue under this agreement of $17.6 million for each of the three and nine months ended September 30, 2022. Of this amount, $7.3 million was payable to third parties and recorded as licensing expense.

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. EPI Health agreed to pay the Company a high single-digit royalty calculated as a percentage of net sales on a country-by-country basis until the date that the patent rights related to RHOFADE have expired or, if later, ten years from the date of the first commercial sale of RHOFADE in such country. EPI Health also agreed to pay the Company potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales of products covered by the asset purchase agreement, and 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the disposition in any territory outside of the United States, subject to specified exceptions.

On July 17, 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. Under the sale agreement, the Company's asset purchase agreement with EPI Health was not assumed by the buyer, and as a result, the buyer is not obligated to continue to pay the Company royalties or milestones on future sales of RHOFADE, nor is the buyer obligated to cure the outstanding amounts in default by EPI Health. The sale was approved by the bankruptcy court on September 12, 2023. As a result of the bankruptcy proceedings, the Company recorded an allowance for doubtful accounts resulting in $0.3 million of bad debt expense for the three months ended September 30, 2023, and $1.3 million of bad debt expense for the nine months ended September 30, 2023, representing all amounts that were due and outstanding by EPI Health.

Agreement and Plan of Merger – Confluence

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 September 30, 2023 and December 31, 2022, the balance of the Company's contingent consideration liability was $32.5 million and $33.1 million, respectively (see Note 3).

12. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three and nine months ended September 30, 2023 and 2022. 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.

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. The contract research segment earns 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. 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 and nine months ended September 30, 2023 and 2022 are summarized in the tables below:

(In thousands) Three Months Ended September 30, 2023	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 8,577	$ 4,817	$ (4,112)	$ 9,282
Cost of revenue	—	4,726	(3,878)	848
Research and development	24,110	—	(234)	23,876
General and administrative	—	1,174	5,917	7,091
Licensing	7,344	—	—	7,344
Revaluation of contingent consideration	1,700	—	—	1,700
Loss from operations	$ (24,577)	$ (1,083)	$ (5,917)	$ (31,577)

(In thousands) Three Months Ended September 30, 2022	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 17,928	$ 4,299	$ (3,209)	$ 19,018
Cost of revenue	—	3,925	(3,002)	923
Research and development	23,863	—	(207)	23,656
General and administrative	—	875	4,938	5,813
Licensing	7,300	—	—	7,300
Revaluation of contingent consideration	2,200	—	—	2,200
Loss from operations	$ (15,435)	$ (501)	$ (4,938)	$ (20,874)

(In thousands) Nine Months Ended September 30, 2023	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 11,210	$ 14,591	$ (12,122)	$ 13,679
Cost of revenue	—	14,068	(11,370)	2,698
Research and development	72,490	—	(752)	71,738
General and administrative	—	3,490	20,708	24,198
Licensing	8,955	—	—	8,955
Revaluation of contingent consideration	(600)	—	—	(600)
Loss from operations	$ (69,635)	$ (2,967)	$ (20,708)	$ (93,310)

(In thousands) Nine Months Ended September 30, 2022	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 18,469	$ 12,795	$ (9,265)	$ 21,999
Cost of revenue	—	11,823	(8,677)	3,146
Research and development	57,329	—	(588)	56,741
General and administrative	—	2,570	15,417	17,987
Licensing	7,300	—	—	7,300
Revaluation of contingent consideration	(2,400)	—	—	(2,400)
Loss from operations	$ (43,760)	$ (1,598)	$ (15,417)	$ (60,775)

Intersegment Revenue

Revenue for the contract research segment included $4.1 million and $3.2 million for services performed on behalf of the therapeutics segment for the three months ended September 30, 2023 and 2022, respectively, and $12.1 million and $9.3 million for the nine months ended September 30, 2023 and 2022, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

14. Legal Proceedings

Securities Class Action

On July 30, 2019, plaintiff Linda Rosi ("Rosi") filed a putative class action complaint captioned *Rosi v. Aclaris Therapeutics, Inc., et al.* in the U.S. District Court for the Southern District of New York against the Company and certain of its executive officers. On September 5, 2019, an additional plaintiff, Robert Fulcher ("Fulcher"), filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc., et al.* in the same court against the same defendants. On November 6, 2019, the court consolidated the Rosi and Fulcher actions (together, the "Consolidated Securities Action") and appointed Fulcher "lead plaintiff" for the putative class. The parties signed and filed a settlement agreement in July 2021. The court granted final approval of the settlement on December 9, 2021. As of December 31, 2021, the Company's financial obligation under the settlement was $2.7 million, which was within the limits of its insurance coverage. The settlement was paid in January 2022.

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, 2022, which are included in our Annual Report on Form 10-K filed with the SEC on February 23, 2023.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. In addition to 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.

Development Programs

Zunsemetinib, an Investigational Oral MK2 Inhibitor

We are developing zunsemetinib, an investigational oral, novel, small molecule selective MK2 inhibitor, as a potential treatment for rheumatoid arthritis and psoriatic arthritis. MK2 is a key regulator of pro-inflammatory mediators including TNFα, IL1β, IL6, IL8, IL17 and other essential pathogenic signals in chronic immuno-inflammatory diseases, as well as in oncology. As an oral drug candidate, we are developing zunsemetinib as a potential alternative to injectable anti-TNF/IL1/IL6/IL17 biologics and JAK inhibitors for treating certain immuno-inflammatory diseases. Zunsemetinib has been adopted as the nonproprietary name for ATI-450.

Moderate to Severe Rheumatoid Arthritis

In December 2021, we initiated a Phase 2b randomized, multicenter, double-blind, parallel group, placebo-controlled, dose-ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-202). This trial consists of a 12-week treatment period and a 30-day follow-up period and has completed enrollment of 251 subjects in the United States and in multiple countries in Europe. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We expect topline data in November 2023.

Moderate to Severe Psoriatic Arthritis

In June 2022, we initiated a Phase 2a, randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of zunsemetinib (50 mg twice

daily) in subjects with moderate to severe psoriatic arthritis (ATI-450-PsA-201). This trial consists of a 12-week treatment period and a 30-day follow-up period and seeks to enroll approximately 70 subjects in the United States and in Poland. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We expect topline data in the first half of 2024.

Moderate to Severe Hidradenitis Suppurativa

In December 2021, we initiated a Phase 2a, randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50 mg twice daily) in subjects with moderate to severe hidradenitis suppurativa (ATI-450-HS-201). In March 2023, we announced that the study did not meet its primary or secondary efficacy endpoints. We do not plan to further pursue this indication.

ATI-1777, an Investigational Topical "Soft" JAK 1/3 Inhibitor

We are developing ATI-1777, an investigational topical "soft" JAK 1/3 inhibitor, as a potential treatment for mild to severe atopic dermatitis. "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.

In May 2022, we initiated a Phase 2b, multicenter, randomized, double-blind, vehicle-controlled, parallel-group trial to determine the efficacy, safety, tolerability, and pharmacokinetics of ATI-1777 in subjects with moderate to severe atopic dermatitis (ATI-1777-AD-202). In April 2023, we expanded the patient population to include patients with mild disease. In this trial, we are exploring multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777. This trial consists of a 4-week treatment period and a 2-week follow-up period and has completed enrollment of 250 patients, including adults and children as young as 12 years old, across the United States. The primary endpoint is the percentage change from baseline in EASI score at week 4. We expect topline data around the end of 2023.

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

We are developing ATI-2138, an investigational oral covalent ITK/JAK3 inhibitor, as a potential treatment for T cell-mediated autoimmune diseases. The ITK/JAK3 compound interrupts T cell signaling through the combined inhibition of ITK/JAK3 pathways in lymphocytes.

In October 2022, we submitted an IND for ATI-2138 for the treatment of ulcerative colitis, which was allowed by the FDA in November 2022. In December 2022, we initiated a two-week Phase 1 placebo-controlled, randomized, multiple ascending dose (MAD) trial to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ATI-2138 in healthy volunteers (ATI-2138-PKPD-102). The study enrolled 60 healthy subjects across 6 dosing cohorts ranging from 10 to 80 mg of total daily doses, with eight active and two placebo controlled per arm. Preliminary data from the trial demonstrated that ATI-2138 was generally well tolerated at all doses tested in the trial and had dose proportional pharmacokinetics. 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.

Based on the positive results of this study, we will progress this program into a Phase 2a proof of concept study in patients with ulcerative colitis. We anticipate initiation of this Phase 2a trial in early 2024.

We are also exploring the potential of conducting a second proof of concept trial of ATI-2138 in an additional T cell-mediated autoimmune disease.

ATI-2231, an Investigational Oral MK2 Inhibitor

We are exploring the use of ATI-2231, an investigational oral MK2 inhibitor designed to have a long half-life, as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer. We are also currently exploring options to use ATI-2231 as a potential treatment for

immuno-inflammatory diseases.

We are supporting Washington University in a first-in-human investigator-initiated Phase 1a trial of ATI-2231 in patients with advanced solid tumor malignancies. We expect clinical development activities to be initiated in the second half of 2023.

Discovery Programs

We conduct small molecule drug discovery and preclinical development research, including through KINect®, our proprietary drug discovery platform. We leverage our early research and development capabilities and KINect to identify potential drug candidates that we may develop independently or in collaboration with third parties.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our drug candidates and to operate without infringing the proprietary rights of others. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such developments, evaluating and taking appropriate courses of action. Our policy is to protect our proprietary position by, among other methods, filing patent applications on inventions that are important to the development and conduct of our business with the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts.

With respect to our MK2 signaling pathway inhibitor development program, we own numerous issued patents and pending applications to novel MK2 pathway inhibitors, including our lead candidate zunsemetinib, and various methods of use that expire, or would expire, between 2031 and 2041, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own two issued U.S. patents and issued patents and pending applications in the European Union and other foreign countries directed to zunsemetinib and analogs thereof and certain methods of using the same. The U.S. patents expire in 2034 and any claims that may issue from the pending applications expire in 2034, subject to any applicable adjustment or extension. We own one allowed U.S. application and numerous pending patent applications in the European Union and other foreign countries directed to methods of treating inflammatory conditions, such as rheumatoid arthritis and psoriatic arthritis, by orally administering zunsemetinib, which, if issued, would each expire in 2041, subject to any applicable adjustment or extension. Further, we own one U.S. patent and numerous pending patent applications in the U.S., European Union and other foreign countries directed to certain methods of manufacturing zunsemetinib and crystal forms of zunsemetinib, which, if issued, would each expire in 2041, subject to any applicable adjustment or extension. We also own pending patent applications in the U.S., European Union and other foreign countries directed to ATI-2231, and methods of use, which, if issued, would expire in 2040, subject to any applicable adjustment or extension.

With respect to our “soft” JAK inhibitor development program, we own numerous issued patents and pending applications in the U.S. and foreign countries to novel “soft” JAK inhibitors and various methods of use that expire, or would expire, between 2038 and 2042, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own issued patents in the U.S. and other foreign countries, as well as pending applications in the U.S. and foreign countries directed to various novel inhibitors of JAK1 and/or JAK3, including ATI-1777, and methods of using the same, which, if issued, would expire in 2038, subject to any applicable adjustment or extension. We also own pending applications in the U.S. and foreign countries directed to crystal forms of ATI-1777 and directed to methods of using ATI-1777 and topical formulations, which, if issued, would expire in 2041 and 2042, respectively, subject to any applicable adjustment or extension.

With respect to our ITK inhibitor development program, we own numerous issued U.S. patents and pending applications in the U.S. and foreign countries directed to novel inhibitors of ITK and methods of use that expire, or would expire, between 2035 and 2039, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own one U.S. patent and pending U.S., European Union and other foreign country applications directed to ATI-2138 and analogs thereof and methods of using the same, which, if issued, would expire in 2039, subject to any applicable adjustment or extension.

Financial Overview

Since our inception, we have incurred significant net losses. Our net loss was $87.0 million for the nine months ended September 30, 2023 and $86.9 million for the year ended December 31, 2022. As of September 30, 2023, we had an accumulated deficit of $769.3 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. We also expect to add additional personnel, as needed, to support our operational plans and strategic direction. 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, the closure of financial institutions and the Russia-Ukraine war, 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

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.

Asset Purchase Agreement with EPI Health

In 2019, we entered into an asset purchase agreement with EPI Health, LLC, or EPI Health, pursuant to which we sold the worldwide rights to RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which included the assignment of certain licenses for related intellectual property assets (such transaction, the "Disposition").

Pursuant to the asset purchase agreement, EPI Health paid us closing consideration of $35.2 million. In addition, EPI Health agreed to pay us (i) potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales of products covered by the agreement, (ii) a specified high single-digit royalty calculated as a percentage of net sales, on a product-by-product and country-by-country basis, until the date that the patent rights related to a particular product, such as RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country and (iii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the Disposition in any territory outside of the United States, subject to specified exceptions. In addition, EPI Health agreed to assume our obligation to pay specified royalties and milestone payments under certain agreements with third parties.

On July 17, 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. Under the sale agreement, our asset purchase agreement with EPI Health was not assumed by the buyer, and as a result, the buyer is not obligated to continue to pay us royalties or milestones on future sales of RHOFADE, nor is the buyer obligated to cure the outstanding amounts in default by EPI Health. The sale was approved by the bankruptcy court on September 12, 2023. As a result of the bankruptcy proceedings, we recorded an allowance for doubtful accounts resulting in $0.3 million of bad debt expense for the three months ended September 30, 2023, and $1.3 million of bad debt expense for the nine months ended September 30, 2023, representing all amounts that were due and outstanding by EPI Health.

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 agreed to pay us an upfront payment, regulatory and commercial milestone payments, anniversary payments, 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 and nine months ended September 30, 2023, we recorded $8.3 million and $10.7 million in royalties, commercial milestones and anniversary milestones, respectively, from Lilly, a portion of which is payable to third parties. During each of the three and nine months ended September 30, 2022, we recorded $17.6 million in upfront payment and regulatory milestones, respectively, from Lilly, 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 ATI-1777 in Greater China. Pediatrix has agreed to pay us an upfront payment, development, regulatory and commercial milestone payments, and a tiered royalty ranging from a low-to-high single digit percentage of net sales of ATI-1777 by Pediatrix in Greater China. A portion of consideration received from Pediatrix is payable to the former Confluence equity holders as described above.

Upon execution of the agreement, we received an upfront payment of $5.0 million from Pediatrix, a portion of

which was paid to the former Confluence equity holders as described above.

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.

Other

Other revenue consists of amounts earned from the sub-sublease of our office space, which was terminated during the year ended December 31, 2022.

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 clinical development of zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and moderate to severe psoriatic arthritis, ATI-1777 as a potential treatment for mild to severe atopic dermatitis and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases, and as we continue the development of our preclinical compounds and discover and develop additional drug candidates. 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 impact on the recruitment, enrollment, conduct and timing of our clinical trials due to macroeconomic conditions;
- 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, travel expenses and bad debt expense.

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.

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, 2022 included in our Annual Report on Form 10-K filed with the SEC on February 23, 2023.

Contingent Consideration

We initially recorded a contingent consideration liability at fair value on the date of acquisition related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of development, 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 was 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 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 41% on September 30, 2023. 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 9.3% and 10.4% depending on the year of each potential payment.

During the nine months ended September 30, 2023, we removed estimated sales from zunsemetinib for moderate to severe hidradenitis suppurativa following our decision to cease pursuing that indication. As a result of this, as well as due to higher discount rates resulting from higher risk-free rates and changes in credit spreads being applied to potential payments relative to prior periods, we recorded an overall decrease in contingent consideration of $0.6 million. This decrease was partially offset by an increase in the probability of success of ATI-2138, as well as the passage of time.

During the nine months ended September 30, 2022, we did not modify any significant assumptions; however, due to higher discount rates resulting from higher risk-free rates and wider credit spreads being applied to potential payments relative to prior periods, we recorded an overall decrease in contingent consideration of $2.4 million. This decrease was partially offset by increases as a result of the impact of the passage of time.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2023 and 2022

(In thousands)	Three Months Ended September 30, 2023	2022	Change	Nine Months Ended September 30, 2023	2022	Change
Revenues:						
Contract research	$ 705	$ 1,090	**$ (385)**	$ 2,469	$ 3,529	**$ (1,060)**
Licensing	8,577	17,898	**(9,321)**	11,210	18,378	**(7,168)**
Other	—	30	**(30)**	—	92	**(92)**
Total revenue	9,282	19,018	**(9,736)**	13,679	21,999	**(8,320)**
Costs and expenses:						
Cost of revenue	848	923	**(75)**	2,698	3,146	**(448)**
Research and development	23,876	23,656	**220**	71,738	56,741	**14,997**
General and administrative	7,091	5,813	**1,278**	24,198	17,987	**6,211**
Licensing	7,344	7,300	**44**	8,955	7,300	**1,655**
Revaluation of contingent consideration	1,700	2,200	**(500)**	(600)	(2,400)	**1,800**
Total costs and expenses	40,859	39,892	**967**	106,989	82,774	**24,215**
Loss from operations	(31,577)	(20,874)	**(10,703)**	(93,310)	(60,775)	**(32,535)**
Other income, net	2,316	922	**1,394**	6,320	1,502	**4,818**
Net loss	$ (29,261)	$ (19,952)	$ **(9,309)**	$ (86,990)	$ (59,273)	$ **(27,717)**

Revenue

Contract research

Contract research revenue was $0.7 million and $1.1 million for the three months ended September 30, 2023 and 2022, 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.

Contract research revenue was $2.5 million and $3.5 million for the nine months ended September 30, 2023 and 2022, respectively, and was comprised of fees earned from the provision of laboratory services. The decrease was primarily driven by lower overall hours billed.

Licensing

Licensing revenue was $8.6 million and $17.9 million for the three months ended September 30, 2023 and 2022, respectively. The decrease was primarily driven by a one-time upfront payment under the Lilly license agreement during the three months ended September 30, 2022.

Licensing revenue was $11.2 million and $18.4 million for the nine months ended September 30, 2023 and 2022, respectively. The decrease was primarily driven by a one-time upfront payment under the Lilly license agreement during the nine months ended September 30, 2022.

Other

Other revenue was $30 thousand for the three months ended September 30, 2022, and $92 thousand for the nine months ended September 30, 2022, which was comprised of rent received from the sub-sublease of our office space. The sub-sublease was terminated in December 2022.

Costs and Expenses

Cost of Revenue

Cost of revenue was $0.8 million and $0.9 million for the three months ended September 30, 2023 and 2022, respectively, 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 decreased in the three months ended September 30, 2023 compared to the corresponding prior year period due to lower variable costs resulting from a decrease in hours billed.

Cost of revenue was $2.7 million and $3.1 million for the nine months ended September 30, 2023 and 2022, respectively, 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 decreased in the nine months ended September 30, 2023 compared to the corresponding prior year period due to lower variable costs resulting from a decrease in hours billed.

Research and Development

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Zunsemetinib	$ 6,921	$ 10,182	**$ (3,261)**	$ 22,371	$ 21,500	**$ 871**
ATI-1777	2,556	3,354	**(798)**	7,848	9,220	**(1,372)**
ATI-2138	3,220	1,793	**1,427**	9,851	4,060	**5,791**
ATI-2231	745	1,308	**(563)**	1,265	4,397	**(3,132)**
Discovery	1,994	1,141	**853**	4,976	3,411	**1,565**
Other research and development	957	418	**539**	2,341	1,084	**1,257**
Personnel	4,411	4,060	**351**	13,918	10,841	**3,077**
Stock-based compensation	3,072	1,400	**1,672**	9,168	2,228	**6,940**
Total research and development expenses	$ 23,876	$ 23,656	**$ 220**	$ 71,738	$ 56,741	**$ 14,997**

Zunsemetinib

The decrease in expenses for zunsemetinib during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 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.

The increase in expenses for zunsemetinib during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to higher costs associated with drug candidate manufacturing and costs associated with clinical development activities for a Phase 2b trial in subjects with rheumatoid arthritis, which initiated in December 2021, and several ancillary clinical trials. The increase was partially offset by 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.

ATI-1777

The decrease in expenses for ATI-1777 during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 was primarily due to lower costs associated with drug candidate manufacturing and other preclinical development activities. The decrease was partially offset by an increase in costs associated with a Phase 2b clinical trial in subjects with atopic dermatitis.

ATI-2138

The increase in expenses for ATI-2138 during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 was primarily due to an increase in clinical development expenses associated with a Phase 1 MAD trial, as well as an increase in preclinical development activities and ancillary studies.

ATI-2231

The decrease in expenses for ATI-2231 during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 was primarily due to preclinical development activities, IND-enabling studies and drug manufacturing in the prior period as we progressed the program toward IND submission in 2023.

Discovery

The increase in expenses related to discovery during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 was due to continued investment in our discovery-stage programs as we progressed programs toward candidate selection.

Personnel and stock-based compensation

The increase in personnel and stock-based compensation expenses in the aggregate during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was primarily due to an increase in costs associated with higher average headcount and equity awards granted in 2023.

The increase in personnel and stock-based compensation expenses in the aggregate during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily due to an increase in costs associated with higher average headcount, compensation adjustments and equity awards granted in 2023, and lower costs during the nine months ended September 30, 2022 due to forfeiture credits.

General and Administrative

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In thousands)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Personnel	$ 1,893	$ 1,283	**$ 610**	$ 5,766	$ 4,221	**$ 1,545**
Professional and legal fees	1,042	877	**165**	4,207	3,167	**1,040**
Facility and support services	738	601	**137**	2,213	1,692	**521**
Other general and administrative	596	571	**25**	1,709	1,746	**(37)**
Stock-based compensation	2,529	2,481	**48**	8,989	7,161	**1,828**
Bad debt	293	—	**293**	1,314	—	**1,314**
Total general and administrative expenses	$ 7,091	$ 5,813	**$ 1,278**	$ 24,198	$ 17,987	**$ 6,211**

Personnel and stock-based compensation

Personnel and stock-based compensation expenses in the aggregate increased during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 primarily due to higher average headcount, compensation adjustments, and equity awards granted in 2023.

Professional and legal fees

Professional and legal fees, including accounting, investor relations and corporate communication costs, increased during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022. The increase during the three months ended September 30, 2023 compared to the three months ended

September 30, 2022 was primarily driven by an increase in accounting related expenses. The increase during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily driven by an increase in patent and accounting related expenses.

Facility and support services

Facility and support services, including general office expenses, information technology costs and other expenses, increased during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 primarily as a result of an increase in rent expense due to leasing additional office and laboratory space and an increase in information technology costs during the three and nine months ended September 30, 2023.

Bad debt

Bad debt expenses were related to our determination that amounts due to us as of September 30, 2023 pursuant to the asset purchase agreement with EPI Health are uncertain as a result of the bankruptcy filing by EPI Health, which was initiated in July 2023.

Licensing

Licensing expenses during the three and nine months ended September 30, 2023 and 2022 were related to amounts payable to third parties pertaining to the Lilly agreement.

Revaluation of Contingent Consideration

The loss on revaluation of contingent consideration decreased during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 and was mainly due to the modification of a valuation model assumption during the three months ended September 30, 2022.

The gain on revaluation of contingent consideration decreased during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 and was mainly driven by changes in discount rates, including risk-free rates and credit spreads, on potential future payments, as well as an increase in the probability of success of ATI-2138 during the nine months ended September 30, 2023. This decrease was partially offset by the removal of estimated future sales levels of zunsemetinib for moderate to severe hidradenitis suppurativa following our decision to cease pursuing this indication during the nine months ended September 30, 2023.

Other Income, net

Other income, net increased during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022, 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 also receive royalties and milestone payments under existing license and acquisition agreements with third parties. 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 September 30, 2023, we had cash, cash equivalents and marketable securities of $187.0 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.

Equity Financing

Sale of Common Stock under At-the-Market-Facility

In April 2023, we sold 3.4 million shares of our common stock for aggregate gross proceeds of $27.5 million, pursuant to a sales agreement with SVB Securities LLC and Cantor Fitzgerald & Co., as sales agents, dated February 23, 2023. We paid selling commissions of $0.8 million in connection with the sale.

In April 2022, we sold 4.8 million shares of our common stock for aggregate gross proceeds of $75.0 million, pursuant to a sales agreement with SVB Securities LLC and Cantor Fitzgerald & Co., as sales agents, dated May 20, 2021. We paid selling commissions and other fees of $2.3 million in connection with the sale.

Cash Flows

Cash and cash equivalents were $39.0 million as of September 30, 2023 compared to $45.3 million as of December 31, 2022. We also had $148.0 million in short- and long-term marketable securities as of September 30, 2023 compared to $184.5 million as of December 31, 2022.

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

	Nine Months Ended September 30,	
(In thousands)	**2023**	**2022**
Cash and cash equivalents beginning balance	$ 45,277	$ 27,349
Net cash used in operating activities	(71,564)	(48,452)
Net cash provided by investing activities	38,670	9,926
Net cash provided by financing activities	26,657	72,830
Cash and cash equivalents ending balance	$ 39,040	$ 61,653

Operating Activities

Cash flow related to operating activities was the result of:

	Nine Months Ended September 30,	
(In thousands)	**2023**	**2022**
Net loss	$ (86,990)	$ (59,273)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	19,311	8,433
Change in accounts payable and accrued expenses	5,270	(1,046)
Change in accounts receivable	138	26
Change in prepaid expenses and other assets	(9,293)	3,408
Net cash used in operating activities	$ (71,564)	$ (48,452)

Net cash used in operating activities increased for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 primarily as a result of higher net losses after adjusting for non-cash items.

The increase in non-cash adjustments to reconcile net loss to net cash used in operating activities was mainly driven by an increase in stock-based compensation expense during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due to higher employee headcount and equity awards granted in 2023, as well as forfeiture credits recognized during the nine months ended September 30, 2022, and licensing expenses pertaining to the Lilly agreement payable to third parties. This increase was partially offset by a decrease in the gain on revaluation of contingent consideration during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 mainly driven by changes in discount rates, including risk-free rates and credit spreads, on potential future payments, as well as an increase in the probability of success of ATI-2138 during the nine months ended September 30, 2023. This decrease was partially offset by the removal of estimated future sales levels of zunsemetinib for moderate to severe hidradenitis suppurativa following our decision to cease pursuing this indication during the nine months ended September 30, 2023.

Investing Activities

Cash flow related to investing activities was the result of:

	Nine Months Ended September 30,	
(In thousands)	**2023**	**2022**
Purchases of property and equipment	$ (868)	$ (500)
Purchases of marketable securities	(135,675)	(118,729)
Proceeds from sales and maturities of marketable securities	175,213	129,155
Net cash provided by investing activities	$ 38,670	$ 9,926

The increase in net cash provided by investing activities for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 resulted primarily from higher sales and maturities of marketable securities during the nine months ended September 30, 2023, which were used to fund our operations, partially offset by higher purchases of marketable securities during the nine months ended September 30, 2023.

Financing Activities

Cash flow related to financing activities was the result of:

	Nine Months Ended September 30,	
(In thousands)	**2023**	**2022**
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	$ 26,714	$ 72,744
Payments of employee withholding taxes related to restricted stock unit award vesting	(102)	(34)
Proceeds from exercise of employee stock options and the issuance of stock	45	120
Net cash provided by financing activities	$ 26,657	$ 72,830

Net cash provided by financing activities decreased for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 primarily due to larger proceeds in 2022 from sales under our at-the-market sales agreement.

Funding Requirements

We anticipate we will incur net losses in the near term as we continue the clinical development of zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and moderate to severe psoriatic arthritis, ATI-1777 as a potential treatment for mild to severe atopic dermatitis and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases, continue the development of our preclinical compounds, and continue to discover and develop additional 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, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. We expect to add additional personnel to support our operational plans and strategic direction. Our future funding requirements will be heavily determined by the resources needed to support the development of our drug candidates.

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 complete the clinical development of zunsemetinib, ATI-1777 and ATI-2138, to develop our preclinical compounds, 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, the closure of financial institutions 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;
- the impact on the timing of our preclinical studies, the recruitment, enrollment, conduct and timing of our clinical trials and our business due to macroeconomic conditions, including the Russia-Ukraine war;
- 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 occupied space for our headquarters in Wayne, Pennsylvania under a sublease agreement, which expired as of October 31, 2023. We also occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through June 2029. In February 2023, we added an additional 6,261 square feet of office and laboratory space in St. Louis, Missouri.

Our aggregate remaining lease payment obligations for these two spaces was $2.8 million as of September 30, 2023.

As of November 1, 2023, we occupy 11,564 square feet of office space for our headquarters in Wayne, Pennsylvania under a lease agreement which has a term that runs through March 2029. Total lease payment obligations for the life of the lease are $2.0 million.

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. 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, treasury bills, foreign government agency debt securities, and U.S. government 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 nine months ended September 30, 2023.

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 chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2023, 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 provide reasonable assurance 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 provide reasonable assurance 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, 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 September 30, 2023, our chief executive officer and chief 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 September 30, 2023 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 including intellectual property and product liability litigation. 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, 2022, filed with the SEC on February 23, 2023.

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.

On August 17, 2023, Maxine Gowen, a member of our Board of Directors, adopted a Rule 10b5-1 trading plan intended to satisfy the affirmative defense conditions of Rule10b5-1(c)(1) under the Exchange Act. Sales may commence under the plan on November 16, 2023 and the plan terminates on December 31, 2024, subject to earlier termination in accordance with its terms. The aggregate number of securities to be sold under the plan is 44,801 shares of common stock.

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).
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.

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: November 6, 2023

By: /s/ Douglas Manion
Douglas Manion
President and Chief Executive Officer
(On behalf of the Registrant)

Date: November 6, 2023

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, Douglas Manion, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2023 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: November 6, 2023

/s/ Douglas Manion
Douglas Manion
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 September 30, 2023 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: November 6, 2023

/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), Douglas Manion, 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 September 30, 2023, 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 6th day of November 2023.

/s/ Douglas Manion	/s/ Kevin Balthaser
Douglas Manion	Kevin Balthaser
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.