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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, 2021

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.)
640 Lee Road, Suite 200 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 29, 2021 was 61,227,333.

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 53,602	$ 22,063
Short-term marketable securities	144,280	32,068
Accounts receivable, net	811	772
Prepaid expenses and other current assets	7,089	2,590
Total current assets	205,782	57,493
Marketable securities	45,735	—
Property and equipment, net	1,170	1,654
Intangible assets	7,067	7,123
Other assets	3,740	4,514
Total assets	$ 263,494	$ 70,784
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,564	$ 5,254
Accrued expenses	7,408	5,906
Current portion of lease liabilities	669	603
Discontinued operations - current liabilities	2,198	3,111
Total current liabilities	17,839	14,874
Other liabilities	2,507	3,179
Long-term debt, net	—	10,653
Contingent consideration	26,200	4,061
Deferred tax liability	367	367
Total liabilities	46,913	33,134
Commitments and contingencies (Note 17)		
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at September 30, 2021 and December 31, 2020; 61,226,750 and 45,109,314 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	—
Additional paid-in capital	789,186	542,286
Accumulated other comprehensive loss	(3)	(94)
Accumulated deficit	(572,603)	(504,542)
Total stockholders' equity	216,581	37,650
Total liabilities and stockholders' equity	$ 263,494	$ 70,784

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,	
	2021	2020	2021	2020
Revenues:				
Contract research	$ 1,415	$ 1,331	$ 4,556	$ 4,373
Other revenue	244	118	704	529
Total revenue	1,659	1,449	5,260	4,902
Costs and expenses:				
Cost of revenue	1,099	1,189	3,564	3,847
Research and development	13,976	6,240	29,711	20,382
General and administrative	5,979	3,859	16,676	15,632
Revaluation of contingent consideration	900	626	22,139	2,393
Total costs and expenses	21,954	11,914	72,090	42,254
Loss from operations	(20,295)	(10,465)	(66,830)	(37,352)
Other expense, net	(851)	(194)	(1,231)	(205)
Loss from continuing operations	(21,146)	(10,659)	(68,061)	(37,557)
Loss from discontinued operations	—	—	—	(285)
Net loss	$ (21,146)	$ (10,659)	$ (68,061)	$ (37,842)
Net loss per share, basic and diluted	$ (0.35)	$ (0.25)	$ (1.23)	$ (0.90)
Weighted average common shares outstanding, basic and diluted	61,219,321	42,802,582	55,215,037	42,187,140
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net of tax of $0	$ 5	$ (24)	$ (5)	$ (1)
Foreign currency translation adjustment	176	(36)	96	22
Total other comprehensive income (loss)	181	(60)	91	21
Comprehensive loss	$ (20,965)	$ (10,719)	$ (67,970)	$ (37,821)

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, 2020	45,109,314	$ —	$ 542,286	$ (94)	$ (504,542)	$ 37,650
Issuance of common stock in connection with exercise of stock options and warrants and vesting of restricted stock units	666,144	—	(2,579)	—	—	(2,579)
Issuance of common stock in connection with public offering, net of offering costs of $7,011	6,306,271	—	103,348	—	—	103,348
Unrealized loss on marketable securities	—	—	—	(35)	—	(35)
Foreign currency translation adjustment	—	—	—	(11)	—	(11)
Stock-based compensation expense	—	—	2,675	—	—	2,675
Net loss	—	—	—	—	(28,754)	(28,754)
Balance at March 31, 2021	52,081,729	$ —	$ 645,730	$ (140)	$ (533,296)	$ 112,294
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	1,024,666	—	1,041	—	—	1,041
Issuance of common stock in connection with public offering, net of offering costs of $8,899	8,098,592	1	134,851	—	—	134,852
Unrealized gain on marketable securities	—	—	—	25	—	25
Foreign currency translation adjustment	—	—	—	(69)	—	(69)
Stock-based compensation expense	—	—	3,833	—	—	3,833
Net loss	—	—	—	—	(18,161)	(18,161)
Balance at June 30, 2021	61,204,987	$ 1	$ 785,455	$ (184)	$ (551,457)	$ 233,815
Issuance of common stock in connection with vesting of restricted stock units	21,763	—	29	—	—	29
Unrealized gain on marketable securities	—	—	—	5	—	5
Foreign currency translation adjustment	—	—	—	176	—	176
Stock-based compensation expense	—	—	3,702	—	—	3,702
Net loss	—	—	—	—	(21,146)	(21,146)
Balance at September 30, 2021	61,226,750	$ 1	$ 789,186	$ (3)	$ (572,603)	$ 216,581

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2019	41,485,638	$ —	$ 523,505	$ (66)	$ (453,527)	$ 69,912
Issuance of common stock in connection with vesting of restricted stock units	346,582	—	(121)	—	—	(121)
Fair value of warrants issued	—	—	378	—	—	378
Unrealized gain on marketable securities	—	—	—	60	—	60
Foreign currency translation adjustment	—	—	—	53	—	53
Stock-based compensation expense	—	—	3,453	—	—	3,453
Net loss	—	—	—	—	(15,586)	(15,586)
Balance at March 31, 2020	41,832,220	$ —	$ 527,215	$ 47	$ (469,113)	$ 58,149
Issuance of common stock in connection with vesting of restricted stock units	858,894	—	(463)	—	—	(463)
Unrealized loss on marketable securities	—	—	—	(37)	—	(37)
Foreign currency translation adjustment	—	—	—	5	—	5
Stock-based compensation expense	—	—	3,309	—	—	3,309
Net loss	—	—	—	—	(11,597)	(11,597)
Balance at June 30, 2020	42,691,114	$ —	$ 530,061	$ 15	$ (480,710)	$ 49,366
Issuance of common stock in connection with vesting of restricted stock units	103,689	—	(95)	—	—	(95)
Issuance of common stock in connection with equity purchase agreement	121,584	—	263	—	—	263
Unrealized loss on marketable securities	—	—	—	(24)	—	(24)
Foreign currency translation adjustment	—	—	—	(35)	—	(35)
Stock-based compensation expense	—	—	1,941	—	—	1,941
Net loss	—	—	—	—	(10,659)	(10,659)
Balance at September 30, 2020	42,916,387	$ —	$ 532,170	$ (44)	$ (491,369)	$ 40,757

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,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (68,061)	$ (37,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	726	1,773
Stock-based compensation expense	10,209	8,703
Revaluation of contingent consideration	22,139	2,393
Loss on extinguishment of debt	752	—
Changes in operating assets and liabilities:		
Accounts receivable	(39)	4,783
Prepaid expenses and other assets	(8)	1,303
Accounts payable	1,293	(5,448)
Accrued expenses	(2,070)	(5,441)
Net cash used in operating activities	(35,059)	(29,776)
Cash flows from investing activities:		
Purchases of property and equipment	(108)	(445)
Purchases of marketable securities	(199,862)	(39,898)
Proceeds from sales and maturities of marketable securities	41,514	49,035
Net cash provided by (used in) investing activities	(158,456)	8,692
Cash flows from financing activities:		
Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	238,200	—
Proceeds from debt financing (including warrants), net of issuance costs	—	10,913
Repayment of debt	(11,483)	—
Restricted stock unit employee tax withholdings	(3,122)	—
Finance lease payments	—	(128)
Deferred issuance costs	—	(242)
Proceeds from exercise of employee stock options and the issuance of stock	1,459	—
Net cash provided by financing activities	225,054	10,543
Net increase (decrease) in cash, cash equivalents and restricted cash	31,539	(10,541)
Cash, cash equivalents and restricted cash at beginning of period	22,063	35,937
Cash, cash equivalents and restricted cash at end of period	$ 53,602	$ 25,396
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of warrants issued in connection with debt financing	$ —	$ 378
Fair value of common stock issued in connection with an equity purchase agreement	$ —	$ 263

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 July 2015, Aclaris Therapeutics International Limited ("ATIL") was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. In August 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., ATIL and Confluence 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, 2021, the Company had cash, cash equivalents and marketable securities of $243.6 million and an accumulated deficit of $572.6 million. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, the Company had never generated revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, including clinical and preclinical testing of the Company's drug candidates, will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its drug candidates and to generate revenue from identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize its development assets or to raise additional capital to finance its operations. The Company will require additional capital to complete the clinical development of zunsemetinib (ATI-450) and ATI-1777, 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 and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that its condensed consolidated financial statements are issued. As of the report date, the Company does not believe that substantial doubt exists about its ability to continue as a going concern. The Company believes its existing cash, cash equivalents and marketable securities are sufficient to fund its operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2021, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statement of stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020 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 25, 2021 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, 2021, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, its changes in stockholders' equity for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020. The condensed consolidated balance sheet data as of December 31, 2020 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, 2021 and 2020 are unaudited. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, 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, 2020 included in the Company's annual report on Form 10-K filed with the SEC on February 25, 2021.

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, ATIL and Confluence. 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, research and development expenses, contingent consideration and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. The COVID-19 pandemic has resulted in a global slowdown in economic activity. 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 financial statement presentation.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2020 included in the Company's annual report on Form 10-K filed with the SEC on February 25, 2021. Except as set forth below, 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 4% and 40%. 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 5.9% and 7.8% depending on the year of each potential payment.

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, 2021			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 50,631	$ —	$ —	$ 50,631
Marketable securities	—	190,015	—	190,015
Total assets	$ 50,631	$ 190,015	$ —	$ 240,646
Liabilities:				
Contingent consideration	$ —	$ —	$ 26,200	$ 26,200
Total liabilities	$ —	$ —	$ 26,200	$ 26,200

(In thousands)	December 31, 2020 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 14,955	$ 1,500	$ —	$ 16,455
Marketable securities	—	32,068	—	32,068
Total assets	$ 14,955	$ 33,568	$ —	$ 48,523
Liabilities:				
Contingent consideration	$ —	$ —	$ 4,061	$ 4,061
Total liabilities	$ —	$ —	$ 4,061	$ 4,061

As of September 30, 2021 and December 31, 2020, the Company's cash equivalents consisted of a money market fund, which was valued based upon Level 1 inputs. The Company's cash equivalents as of December 31, 2020 also included commercial paper, which was valued based upon Level 2 inputs. The Company's marketable securities as of September 30, 2021 and December 31, 2020 consisted of commercial paper and asset-backed and U.S. government agency debt securities, which were valued based upon Level 2 inputs. The Company's marketable securities as of September 30, 2021 also included corporate debt securities and foreign government agency debt securities, which were valued based upon Level 2 inputs.

In determining the fair value of its Level 2 investments, the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were 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. Quarterly, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of the quoted prices provided. The Company evaluates whether adjustments to third-party pricing are necessary and, historically, the Company has not made adjustments to quoted prices obtained from the third-party pricing service. During the nine months ended September 30, 2021 and 2020, there were no transfers between Level 1, Level 2 and Level 3.

The increase in contingent consideration of $22.1 million during the nine months ended September 30, 2021 resulted from updates to the Company's probability of achieving regulatory milestones and commencing commercialization and estimated future sales level assumptions as a result of the completion of a Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis and the inclusion of estimated future sales of zunsemetinib for the potential treatment of psoriatic arthritis and moderate to severe hidradenitis suppurativa, which are additional planned indications for zunsemetinib, as well as a result of the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis.

As of September 30, 2021 and December 31, 2020, the fair value of the Company's available for sale marketable securities by type of security was as follows:

(In thousands)	September 30, 2021 Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 36,725	$ 3	(10)	$ 36,718
Commercial paper	81,828	—	—	81,828
Asset-backed debt securities	37,229	3	(7)	37,225
Foreign government agency debt securities	4,112	—	(2)	4,110
U.S. government agency debt securities	30,124	10	—	30,134
Total marketable securities	$ 190,018	$ 16	$ (19)	$ 190,015

(In thousands)	December 31, 2020 Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Commercial paper	$ 20,483	$ —	$ —	$ 20,483
Asset-backed debt securities	4,036	1	—	4,037
U.S. government agency debt securities	7,547	1	—	7,548
Total marketable securities	$ 32,066	$ 2	$ —	$ 32,068

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
Computer equipment	$ 1,253	$ 1,197
Lab equipment	1,389	1,340
Furniture and fixtures	620	617
Leasehold improvements	1,123	1,123
Property and equipment, gross	4,385	4,277
Accumulated depreciation	(3,215)	(2,623)
Property and equipment, net	$ 1,170	$ 1,654

Depreciation expense was $0.2 million and $0.3 million for the three months ended September 30, 2021 and 2020, respectively, and $0.6 million and $0.9 million for the nine months ended September 30, 2021 and 2020, respectively.

5. Intangible Assets

Intangible assets consisted of the following:

(In thousands, except years)	Remaining Life (years)	Gross Cost		Accumulated Amortization	
		September 30, 2021	December 31, 2020	September 30, 2021	December 31, 2020
Other intangible assets	5.8	$ 751	$ 751	$ 313	$ 257
In-process research and development	n/a	6,629	6,629	—	—
Total intangible assets		$ 7,380	$ 7,380	$ 313	$ 257

As of September 30, 2021, estimated future amortization expense was as follows:

(In thousands)	Year Ending December 31,
2021	$ 18
2022	75
2023	75
2024	75
2025	75
Thereafter	120
Total	$ 438

6. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
Employee compensation expenses	$ 2,845	$ 3,971
Research and development expenses	882	761
Litigation settlements (see Note 17)	3,075	—
Other	606	1,174
Total accrued expenses	$ 7,408	$ 5,906

7. Debt

Loan and Security Agreement – Silicon Valley Bank

In March 2020, the Company entered into a Loan and Security Agreement with Silicon Valley Bank ("SVB"). The Loan and Security Agreement provided for $11.0 million in term loans, of which the Company borrowed the entire amount on March 30, 2020. In connection with the Loan and Security Agreement, the Company issued to SVB a warrant to purchase up to 460,251 shares of common stock (the "Warrant") (see Note 8). The proceeds of the Loan and Security Agreement were allocated to the term loan and Warrant using a relative fair value approach.

In July 2021, the Company repaid in full the $11.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees as of the payoff date, for a total payment of $11.7 million. Following this repayment, all of the Company's obligations under the Loan and Security Agreement are deemed to be terminated, except as set forth in the agreement.

8. Stockholders' Equity

Preferred Stock

As of September 30, 2021 and December 31, 2020, the Company's amended and restated certificate of incorporation 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, 2021 or December 31, 2020.

Common Stock

As of September 30, 2021 and December 31, 2020, the Company's amended and restated certificate of incorporation authorized the Company to issue 100,000,000 shares of $0.00001 par value common stock.

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, 2021.

Warrants

The Warrant issued to SVB in March 2020 had an initial exercise price of $0.956 per share, subject to adjustment as provided in the Warrant. The Warrant became immediately exercisable in full upon the funding of the term loan facility. The Company assigned a fair value of $0.4 million to the Warrant using a Black-Scholes valuation methodology, and also concluded that the Warrant was indexed to its own stock and therefore classified the Warrant as an equity instrument. In January 2021, SVB net exercised the Warrant in full, and the Company issued to SVB 388,119 shares of common stock.

Equity Purchase Agreement with Lincoln Park Capital Fund, LLC

In August 2020, the Company entered into an equity purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company could sell to Lincoln Park, at its discretion, up to $15.0 million of shares of its common stock over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 121,584 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of the Company's common stock on the effective date of the Purchase Agreement resulting in an aggregate fair value of $0.3 million. Through December 31, 2020, the Company sold 2,111,170 shares of its common stock to Lincoln Park under the Purchase Agreement for net proceeds of $7.7 million. The Company terminated the Purchase Agreement in January 2021 in connection with the public offering of common stock described below. The Company did not sell any additional shares prior to terminating the Purchase Agreement.

January 2021 Public Offering

In January 2021, the Company closed a public offering in which it sold 6,306,271 shares of common stock at a price to the public of $17.50 per share, for aggregate gross proceeds of $110.4 million. The Company paid underwriting discounts and commissions of $6.6 million, and also incurred expenses of $0.4 million in connection with the offering. As a result, the net offering proceeds received by the Company, after deducting underwriting discounts, commissions and offering expenses, were $103.3 million.

June 2021 Public Offering

In June 2021, the Company closed a public offering in which it sold 8,098,592 shares of common stock at a price to the public of $17.75 per share, for aggregate gross proceeds of $143.8 million. The Company paid underwriting discounts and commissions of $8.6 million, and also incurred expenses of $0.3 million in connection with the offering. As a result, the net offering proceeds received by the Company, after deducting underwriting discounts, commissions and offering expenses, were $134.9 million.

9. 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, 2021, the number of shares of common stock that may be issued under the 2015 Plan was increased by 1,804,372 shares. As of September 30, 2021, 2,795,696 shares remained available for grant under the 2015 Plan. The Company had 2,843,205 stock options and 1,458,483 RSUs outstanding as of September 30, 2021 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 416,375 stock options and 7,480 RSUs outstanding as of September 30, 2021 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 granted stock options to purchase a total of 1,140,524 shares under the 2012 Plan, of which 484,145 were outstanding as of September 30, 2021. Stock options granted under the 2012 Plan expire after ten years.

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, 2021 and 2020 were as follows:

	Nine Months Ended September 30,	
	2021	2020
Risk-free interest rate	0.90 %	0.87 %
Expected term (in years)	6.2	6.1
Expected volatility	76.60 %	85.19 %
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, 2021:

(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, 2020	2,871,498	$ 15.16	6.8	$ 4,890
Granted	1,013,600	23.73		
Exercised	(115,548)	12.63		$ 1,373
Forfeited and cancelled	(25,825)	22.77		
Outstanding as of September 30, 2021	3,743,725	$ 17.51	7.0	$ 18,150
Options vested and expected to vest as of September 30, 2021	3,743,725	$ 17.51	7.0	$ 18,150
Options exercisable as of September 30, 2021	2,177,823	$ 17.85	5.6	$ 10,517

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2021 was $15.86 per share.

Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2021:

(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, 2020	2,244,157	$ 3.83	
Granted	629,348	23.72	
Vested	(1,339,625)	3.18	$ 31,486
Forfeited and cancelled	(67,917)	10.06	
Outstanding as of September 30, 2021	1,465,963	$ 12.67	

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)	2021	2020	2021	2020
Cost of revenue	$ 206	$ 216	$ 787	$ 728
Research and development	939	437	2,969	2,192
General and administrative	2,557	1,288	6,453	5,783
Total stock-based compensation expense	$ 3,702	$ 1,941	$ 10,209	$ 8,703

As of September 30, 2021, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $14.7 million and $15.0 million, respectively, each of which is expected to be recognized over a weighted average period of 3.0 years.

10. 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)	2021	2020	2021	2020
Numerator:				
Net loss	$ (21,146)	$ (10,659)	$ (68,061)	$ (37,842)
Denominator:				
Weighted average shares of common stock outstanding, basic and diluted	61,219,321	42,802,582	55,215,037	42,187,140
Net loss per share, basic and diluted	$ (0.35)	$ (0.25)	$ (1.23)	$ (0.90)

The Company's potentially dilutive securities, which included stock options, RSUs and warrants, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential shares of common stock excluded from the calculation

of diluted net loss per share for the three and nine months ended September 30, 2021 and 2020. All share amounts presented in the table below represent the total number outstanding as of September 30, 2021 and 2020.

	September 30,	
	2021	2020
Options to purchase common stock	3,743,725	3,100,763
Restricted stock unit awards	1,465,963	2,308,357
Warrants	—	460,251
Total potential shares of common stock	5,209,688	5,869,371

11. Leases

Operating Leases

Agreements for Office Space

The Company has a sublease agreement with Auxilium Pharmaceuticals, LLC (the "Sublandlord") pursuant to which it subleases 33,019 square feet of office space for its headquarters in Wayne, Pennsylvania. The sublease has a term that runs through October 2023. If for any reason the lease between Chesterbrook Partners, LP ("Landlord") and Sublandlord is terminated or expires prior to October 2023, the Company's sublease will automatically terminate. In December 2020, the Company entered into a sub-sublease agreement under which it sub-subleased 8,115 square feet. The sub-sublease term runs concurrently with the original sublease agreement.

In February 2019, the Company entered into a sublease agreement with a third party for 20,433 square feet of office and laboratory space in St. Louis, Missouri. The lease commenced in June 2019 and has a term that runs through June 2029.

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

(In thousands)	September 30, 2021	December 31, 2020
Operating Leases:		
Gross cost	$ 5,240	$ 5,240
Accumulated amortization	(1,625)	(1,111)
Other assets	$ 3,615	$ 4,129
Current portion of lease liabilities	$ 669	$ 603
Other liabilities	2,383	2,894
Total operating lease liabilities	$ 3,052	$ 3,497

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled $0.3 million for each of the three months ended September 30, 2021 and 2020 and $0.8 million for each of the nine months ended September 30, 2021 and 2020.

Finance Leases

Laboratory Equipment

The Company leased laboratory equipment which it used in its laboratory space in St. Louis, Missouri under two finance lease financing arrangements which the Company entered into in August 2017 and October 2017, for which terms ended in October 2020 and December 2020, respectively.

12. Related Party Transactions

Mallinckrodt plc

In April 2018, Bryan Reasons was appointed to the Company's board of directors. Subsequently, in March 2019, Mr. Reasons became the Chief Financial Officer of Mallinckrodt plc. Prior to Mr. Reasons joining Mallinckrodt plc, the Company entered into a master services agreement with a subsidiary of Mallinckrodt plc, pursuant to which Confluence provides laboratory services to the subsidiary ("Mallinckrodt") in the ordinary course of business. Mr. Reasons was not involved in the negotiation or execution of the agreement, but may be deemed to have an interest in the ongoing transactions based on his employment as an executive officer of Mallinckrodt plc. During the nine months ended September 30, 2021 and 2020, the Company invoiced Mallinckrodt for $24 thousand and $0.3 million, respectively, under the master services agreement. As of September 30, 2021 and December 31, 2020, the Company had $0 and $24 thousand, respectively, of outstanding accounts receivable balances from Mallinckrodt. Mr. Reasons had no financial interest in these transactions.

13. Agreements Related to Intellectual Property

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. The Company recorded royalty income under the asset purchase agreement of $0.6 million and $0.5 million during the nine months ended September 30, 2021 and 2020, respectively. Royalty income is included in other revenue on the condensed consolidated statements of operations and comprehensive loss. EPI Health has 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.

Agreement and Plan of Merger – Confluence

In August 2017, the Company entered into an Agreement and Plan of Merger, pursuant to which it acquired Confluence (the "Confluence Agreement"). In November 2018, a development milestone specified in the Confluence Agreement was achieved, as a result of which the Company paid the former Confluence equity holders $2.5 million in cash and issued 253,208 shares of its common stock with a fair value of $2.2 million. Under the Confluence Agreement, the Company also 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 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, 2021 and December 31, 2020, the balance of the Company's contingent consideration liability was $26.2 million and $4.1 million, respectively (see Note 3).

14. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during each of the three and nine months ended September 30, 2021 and 2020. 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.

15. Discontinued Operations

The following table presents information related to liabilities reported as discontinued operations in the Company's condensed consolidated balance sheet:

(In thousands)	September 30, 2021	December 31, 2020
Accounts payable	$ —	$ 1,175
Accrued expenses	2,198	1,936
Discontinued operations - current liabilities	$ 2,198	$ 3,111

16. 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, 2021 and 2020 are summarized in the tables below:

(In thousands) Three Months Ended September 30, 2021	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 244	$ 3,335	$ (1,920)	$ 1,659
Cost of revenue	—	2,912	(1,813)	1,099
Research and development	14,083	—	(107)	13,976
General and administrative	—	837	5,142	5,979
Revaluation of contingent consideration	900	—	—	900
Loss from operations	$ (14,739)	$ (414)	$ (5,142)	$ (20,295)

(In thousands) Three Months Ended September 30, 2020	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 118	$ 3,015	$ (1,684)	$ 1,449
Cost of revenue	—	2,765	(1,576)	1,189
Research and development	6,347	—	(107)	6,240
General and administrative	—	672	3,187	3,859
Revaluation of contingent consideration	626	—	—	626
Loss from operations	$ (6,855)	$ (422)	$ (3,188)	$ (10,465)

(In thousands) Nine Months Ended September 30, 2021	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 704	$ 10,016	$ (5,460)	$ 5,260
Cost of revenue	—	8,705	(5,141)	3,564
Research and development	30,030	—	(319)	29,711
General and administrative	—	2,344	14,332	16,676
Revaluation of contingent consideration	22,139	—	—	22,139
Loss from operations	$ (51,465)	$ (1,033)	$ (14,332)	$ (66,830)

(In thousands) Nine Months Ended September 30, 2020	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 529	$ 10,079	$ (5,706)	$ 4,902
Cost of revenue	—	9,233	(5,386)	3,847
Research and development	20,702	—	(320)	20,382
General and administrative	—	2,112	13,520	15,632
Revaluation of contingent consideration	2,393	—	—	2,393
Loss from operations	$ (22,566)	$ (1,266)	$ (13,520)	$ (37,352)
Loss from discontinued operations	$ (284)	$ —	$ (1)	$ (285)

Intersegment Revenue

Revenue for the contract research segment included $1.9 million and $1.7 million for services performed on behalf of the therapeutics segment for the three months ended September 30, 2021 and 2020, respectively and $5.5 million and $5.7 million for the nine months ended September 30, 2021 and 2020, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

17. 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. The complaint alleges that the defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired the Company's securities between May 8, 2018 and June 20, 2019.

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.

On January 24, 2020, Fulcher filed a consolidated amended complaint in the Consolidated Securities Action, naming two additional executive officers as defendants, extending the putative class period to August 12, 2019, and adding allegations concerning, among other things, alleged statements and omissions throughout the putative class period concerning ESKATA's risks, tolerability and effectiveness. The defendants filed a motion to dismiss the consolidated amended complaint on April 17, 2020. Following briefing and oral argument on February 25, 2021, the motion was granted in part and denied in part on March 29, 2021, and the issues in dispute significantly narrowed. The defendants filed an answer to the remaining aspects of the consolidated amended complaint on April 19, 2021.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Securities Action. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to the putative class and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to the putative class. The proposed settlement is subject to final approval by the court.

The Company had $2.65 million accrued as of September 30, 2021 for its estimated financial obligation. The Company expects its financial obligation to be within the limits of its insurance coverage and accordingly recorded a receivable for an insurance recovery equal to the settlement amount. The insurance recovery receivable and the litigation settlement liability are recorded in prepaid expenses and other current assets and accrued expenses, respectively, in the condensed consolidated balance sheet.

Stockholder Derivative Action

On November 15, 2019, plaintiff Keith Allred ("Allred") filed a derivative stockholder complaint captioned *Allred v. Walker et al.* in the U.S. District Court for the Southern District of New York against certain of the Company's directors and executive officers. The complaint alleges that the defendants, among other things, breached their fiduciary duties as directors and/or officers in connection with the claims alleged in the Consolidated Securities Action. The complaint seeks, among other things, unspecified compensatory damages on behalf of the Company.

On November 25, 2019, an additional plaintiff, Bruce Brown ("Brown"), filed a substantially identical complaint captioned *Brown v. Walker et al.* in the same court against the same defendants.

On December 12, 2019, the court consolidated the Allred and Brown actions under the caption *In re Aclaris Therapeutics, Inc. Derivative Litigation* (the "Consolidated Derivative Action") and directed that future derivative cases filed in or transferred to the court arising out of substantially the same transactions or events be similarly consolidated. Thereafter, on January 11, 2020, the court stayed – subject to certain conditions – all deadlines in the Consolidated Derivative Action pending resolution of the defendants' then-anticipated motion to dismiss the Consolidated Securities Action. On May 18, 2021, the court extended the stay – subject to certain conditions – until the resolution of a motion for summary judgment in the Consolidated Securities Action, which defendants in that action intended to file had the parties to the Consolidated Securities Action not reached an agreement to settle.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Derivative Action. The agreed terms provide for the Company to implement certain policies and for attorneys' fees to be paid to plaintiff's counsel. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to the Company's stockholders and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to the Company's stockholders. The proposed settlement is subject to final approval by the court.

The Company had $425 thousand accrued as of September 30, 2021 for its estimated financial obligation. The Company expects its financial obligation to be within the limits of its insurance coverage and accordingly recorded a receivable for an insurance recovery equal to the settlement amount. The insurance recovery receivable and the litigation settlement liability are recorded in prepaid expenses and other current assets and accrued expenses, respectively, in the condensed consolidated balance sheet.

Product Liability Lawsuit

On December 18, 2020, plaintiff Daurie Mancini filed an amended complaint under the caption *Daurie Mancini v. Aclaris Therapeutics, Inc. et al* in the Superior Court of New Jersey Ocean County against the Company and certain third parties alleging injuries as a result of the plaintiff's alleged treatment with ESKATA in 2019. The amended complaint seeks unspecified compensatory and punitive damages. The Company filed a motion to dismiss the amended complaint on March 15, 2021. The Company's motion to dismiss was granted on July 9, 2021. The Court dismissed the majority of claims against the Company with prejudice. All remaining claims against the Company were dismissed without prejudice.

18. Subsequent Event

On November 1, 2021, Kamil Ali-Jackson, Co-Founder, Chief Legal Officer, Chief Compliance Officer and Corporate Secretary notified the Company that she will retire from her position effective January 3, 2022. In connection with her retirement, the Company entered into a Severance Agreement containing a release of claims against the Company. Under the Severance Agreement, Ms. Ali-Jackson will receive a lump sum cash payment of $615 thousand, equal to her annual base salary, her 2021 target bonus, and accrued but unused paid-time off. She will also receive continuation of health insurance benefits for 12 months, acceleration of vesting of options and restricted stock units, to the extent the award would have vested had she remained employed through March 31, 2022, and acceleration of additional currently outstanding restricted stock units held by her, with respect to a number of shares equal to (i) $157 thousand divided by (ii)

the fair market value of the Company's common stock on January 3, 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, 2020, which are included in our Annual Report on Form 10-K filed with the SEC on February 25, 2021.

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.

Clinical Programs

Zunsemetinib (ATI-450), an Investigational Oral MK2 Inhibitor

We submitted an Investigational New Drug Application, or IND, in April 2019 for zunsemetinib, an investigational oral, novel, small molecule selective mitogen-activated protein kinase-activated protein kinase 2, or MK2, inhibitor compound, for the treatment of rheumatoid arthritis, which was allowed by the U.S. Food and Drug Administration, or FDA, in May 2019. MK2 is a key regulator of pro-inflammatory mediators including TNFα, IL1β, IL6, IL8 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 biologics and JAK inhibitors for treating certain immuno-inflammatory diseases. Zunsemetinib has been adopted as the nonproprietary name for ATI-450.

We initiated a Phase 1 single (at 10mg, 30mg, 50mg and 100mg doses) and multiple ascending (at 10mg, 30mg and 50mg doses) dose clinical trial evaluating zunsemetinib in 77 healthy subjects in August 2019 (ATI-450-PKPD-101). Final data from this trial demonstrated that zunsemetinib resulted in marked inhibition of TNFα, IL1β, IL8 and IL6. We also observed that zunsemetinib had dose-proportional pharmacokinetics with a terminal half-life of 9-12 hours in the multiple ascending dose cohort, and had no meaningful food effect or drug-drug interaction with methotrexate. Zunsemetinib was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received zunsemetinib) were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain and nausea.

Zunsemetinib was also evaluated at 80mg and 120mg doses twice daily in a second Phase 1 clinical trial in healthy subjects (ATI-450-PKPD-102). Final data from this trial showed that no dose-limiting toxicity was observed. Ex vivo analysis of blood samples from this Phase 1 trial showed that increased cytokine inhibition was achieved with these higher doses of zunsemetinib relative to doses tested in the first Phase 1 trial. No serious adverse events were reported and all adverse events were mild to moderate. The most common adverse events (reported by 2 or more subjects who received zunsemetinib) were headache, dizziness, nausea, parasthesia and, in the post-dosing follow-up period of the trial, dry skin. These adverse events were all mild in severity.

Moderate to Severe Rheumatoid Arthritis

Following the completion of the first Phase 1 clinical trial, in March 2020 we initiated a 12-week, Phase 2a, multicenter, randomized, investigator and patient-blind, sponsor-unblinded, parallel group, placebo-controlled clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-201). In the trial, which consisted of a 12-week treatment period and a 4-week follow-up period, 19 subjects were randomized in a 3:1 ratio and received either zunsemetinib at 50 mg twice daily or placebo, in combination with methotrexate, for 12 weeks.

The final per-protocol analysis, which consisted of the 17 subjects who completed the treatment period (15 in the treatment arm and two in the placebo arm), confirmed that zunsemetinib demonstrated durable clinical activity, as defined by a marked and sustained reduction in DAS28-CRP and improvement of ACR20/50/70 responses over 12 weeks. Zunsemetinib was generally well tolerated. All adverse events were mild to moderate. The most common adverse events (each reported in 2 subjects) were urinary tract infection, or UTI, and ventricular extrasystoles, all of which were determined to be unrelated to treatment except for one UTI. Two subjects withdrew from the trial during the treatment period, one in the treatment arm and one in the placebo arm. The subject in the treatment arm withdrew due to an elevated creatine phosphokinase, or CPK, level, which was determined by the site investigator to be treatment-related; this subject also had palpitations and ventricular extrasystoles, which were unrelated to the trial medication. The subject in the placebo arm withdrew as a result of prohibited medication needed to treat muscle strain. There was also one non-treatment-related serious adverse event (COVID-19) reported in the 4-week follow-up period of the trial in a subject who was no longer receiving treatment; the subject withdrew during the 4-week follow-up period of the trial.

A final analysis, which consisted of the 17 subjects, of ex vivo stimulated cytokines from blood samples taken from the treatment arm showed a marked and durable inhibition of TNFα, IL1β, IL6, and IL8 over the 12-week treatment period. Similarly, analysis of endogenous inflammation biomarkers also demonstrated a marked and sustained inhibition of median concentrations of hsCRP, TNFα, IL6, IL8 and MIP1β in the treatment arm over the 12-week period.

We plan to submit for publication a full analysis of the Phase 2a data in a peer-reviewed scientific journal which will include data from other secondary and exploratory endpoints evaluated in the trial, including the 4-week follow-up data and a full analysis of MRI, pharmacodynamic and pharmacokinetic data.

Based on the results observed in the Phase 2a trial, we intend to progress zunsemetinib into a Phase 2b trial in moderate to severe rheumatoid arthritis in the fourth quarter of 2021.

Psoriatic Arthritis and Moderate to Severe Hidradenitis Suppurativa

As part of the planned expansion of our Phase 2 immuno-inflammatory clinical development programs, we also plan to progress zunsemetinib into Phase 2 trials in psoriatic arthritis and moderate to severe hidradenitis suppurativa.

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

In June 2020, we submitted an IND for ATI-1777, an investigational topical "soft" JAK 1/3 inhibitor compound, for the treatment of moderate 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 October 2020, we initiated a Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe atopic dermatitis (ATI-1777-AD-201). In the trial, which consisted of a 4-week treatment period and a 2-week follow-up period during which no treatment was given, 50 subjects with moderate to severe atopic dermatitis were randomized in a 1:1 ratio into one of two arms: ATI-1777 topical solution 2.0% w/w or vehicle applied twice daily. In June 2021, we announced that the trial achieved its primary endpoint, which was the percent change from baseline in the modified Eczema Area and Severity Index, or mEASI, score at week 4, with a high degree of statistical significance ($p<0.001$) (one-sided p-value), which corresponded to a 74.4% reduction in mEASI score from baseline at week 4 in subjects applying ATI-1777 compared to a 41.4% reduction in subjects applying vehicle. The final data was based on the full analysis set, or FAS, which was comprised of 48 subjects randomized and documented to have received at least one dose of trial medication. Positive trends in favor of ATI-1777 were observed in key secondary efficacy endpoints, such as improvement in itch, percent of mEASI-50 responders, investigator's global assessment responder analysis, and reduction in body surface area impacted by disease. In addition, the FAS analysis also showed positive trends in favor of ATI-1777 in percent of mEASI-75 responders (65.2% for ATI-1777 compared to 24.0% for vehicle) and mEASI-90 responders (30.4% for ATI-1777 compared to 20.0% for vehicle). These secondary efficacy endpoints were not powered for statistical significance. Based on an analysis of pharmacokinetic plasma samples in the ATI-1777 arm at multiple timepoints, minimal systemic exposure was observed which supports a "soft" topical JAK inhibitor approach.

ATI-1777 was generally well tolerated. No serious adverse events were reported. The most common adverse events (reported in at least 2 subjects in the trial) were increased blood CPK levels and headache in subjects in the ATI-1777 arm and urinary tract infection (one in each of the ATI-1777 and the vehicle arm); none of these adverse events in the ATI-1777 arm were determined by the clinical trial investigators to be related to ATI-1777. One treatment-related adverse event, application site pruritus, was reported in one subject in the ATI-1777 arm.

We plan to submit the final trial results for publication in a peer-reviewed scientific journal.

Based on the results observed in the Phase 2a trial, we intend to progress ATI-1777 into a Phase 2b trial in moderate to severe atopic dermatitis in the first half of 2022. In this trial, we plan to explore multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777.

Preclinical Programs

ATI-2138, an Investigational ITJ Inhibitor

We are developing ATI-2138, an investigational oral ITK/TXK/JAK3, or ITJ, inhibitor compound, as a potential treatment for psoriasis and/or inflammatory bowel disease, which are both T-cell mediated autoimmune diseases. The ITJ compound interrupts T cell signaling through the combined inhibition of ITK/TXK/JAK3 pathways in lymphocytes. We submitted an IND for ATI-2138 for the treatment of psoriasis in October 2021. If allowed, we plan to progress to a first-in-human Phase 1 single ascending dose trial of ATI-2138 in healthy volunteers.

ATI-2231, an Investigational Oral MK2 Inhibitor

We are exploring the use of ATI-2231, an investigational oral MK2 inhibitor compound 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 currently conducting IND-enabling studies.

Discovery Programs

We are developing oral gut-restricted JAK inhibitors with limited systemic exposure as potential treatments for inflammatory bowel disease. In addition, we are engaged in research to identify brain penetrant kinase inhibitor candidates as potential treatments for neurodegenerative diseases.

Our Other Drug Candidates

We continue to seek third-party partners for our dermatology investigational drug candidate A-101 45% Topical Solution as a potential treatment for common warts (verruca vulgaris).

Financial Overview

Since our inception, we have incurred significant operating losses. Our net loss was $68.1 million for the nine months ended September 30, 2021 and $51.0 million for the year ended December 31, 2020. As of September 30, 2021, we had an accumulated deficit of $572.6 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 to support our expanding and advancing development pipeline. 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 COVID-19 on Our Business

The impacts of the global COVID-19 pandemic continue to evolve. We have implemented a virtual operations strategy, including teleworking and other alternative work arrangements for our employees, intended to protect the health and safety of our employees while enabling us to continue to develop our drug candidates and provide contract research services to our clients. We are focused on ensuring the continuity of our operations. However, COVID-19 has caused disruptions to our business.

If COVID-19 continues to spread, we may experience additional disruptions that could severely impact our business, results of operations and prospects, including the timing of our development programs and our clinical trials, including our trials of zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis and the supply of active pharmaceutical ingredients and drug product for our clinical trials. The extent to which the COVID-19 pandemic impacts our business, our preclinical and clinical development and our regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted, such as the spread of the disease, the duration of the pandemic, travel restrictions, quarantines, stay-at-home orders, social distancing requirements, business closures and supply chain and other disruptions in the United States and other countries, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, including the administration of vaccines. Accordingly, we do not yet know the full extent of the potential impacts on our business, our preclinical and clinical development and regulatory activities.

Acquisition and License Agreements

Agreement and Plan of Merger with Confluence

In August 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, the Merger Sub merged with and into Confluence, with

Confluence surviving as our wholly-owned subsidiary. We paid closing consideration of $10.3 million in cash and issued 349,527 shares of our common stock with a fair value of $9.7 million to the former Confluence equity holders.

In November 2018, a development milestone specified in the Confluence Agreement was achieved, as a result of which we paid the former Confluence equity holders $2.5 million in cash and issued 253,208 shares of our common stock with a fair value of $2.2 million. Under the Confluence Agreement, we also 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 October 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, or the Disposition.

Pursuant to the asset purchase agreement, EPI Health paid us an upfront payment of $35.0 million, $1.75 million of which was placed in escrow, and $0.2 million for inventory. In addition, EPI Health has 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 has agreed to assume our obligation to pay specified royalties and milestone payments under certain agreements with third parties.

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.

Other Revenue

Other revenue primarily consists of royalties earned on net sales of RHOFADE pursuant to the asset purchase agreement with EPI Health described above.

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 Expenses

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;
- outsourced professional scientific development services;
- medical affairs expenses related to our drug candidates;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- depreciation of manufacturing equipment;
- payments made under agreements with third parties under which we have acquired or licensed intellectual property;
- 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 other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, continue the development of our preclinical compounds, and continue to 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, facilities 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 the COVID-19 pandemic;

- 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, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. 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 Expenses

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, insurance costs and travel expenses.

Revaluation of Contingent Consideration

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

Other Expense, Net

Other expense, net primarily consists of interest earned on our cash, cash equivalents and marketable securities, interest expense related to our debt obligations, and gains and losses on transactions denominated in foreign currencies.

Critical Accounting Policies and Significant Judgments and 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 these 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. Except as described below, 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, 2020 included in our Annual Report on Form 10-K filed with the SEC on February 25, 2021.

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. 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 condensed 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 4% and 40%. 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 5.9% and 7.8% depending on the year of each potential payment.

During the nine months ended September 30, 2021, we updated assumptions for probability of success and estimated future sales levels as a result of the completion of a Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis and as a result of the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis. We also included estimated future sales of zunsemetinib as a potential treatment for psoriatic arthritis and moderate to severe hidradenitis suppurativa, which are additional planned indications for zunsemetinib. These updates resulted in a charge of $22.1 million.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2021 and 2020

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Revenues:						
Contract research	$ 1,415	$ 1,331	**$ 84**	$ 4,556	$ 4,373	**$ 183**
Other revenue	244	118	**126**	704	529	**175**
Total revenue	1,659	1,449	**210**	5,260	4,902	**358**
Costs and expenses:						
Cost of revenue	1,099	1,189	**(90)**	3,564	3,847	**(283)**
Research and development	13,976	6,240	**7,736**	29,711	20,382	**9,329**
General and administrative	5,979	3,859	**2,120**	16,676	15,632	**1,044**
Revaluation of contingent consideration	900	626	**274**	22,139	2,393	**19,746**
Total costs and expenses	21,954	11,914	**10,040**	72,090	42,254	**29,836**
Loss from operations	(20,295)	(10,465)	**(9,830)**	(66,830)	(37,352)	**(29,478)**
Other expense, net	(851)	(194)	**(657)**	(1,231)	(205)	**(1,026)**
Loss from continuing operations	(21,146)	(10,659)	**(10,487)**	(68,061)	(37,557)	**(30,504)**
Loss from discontinued operations	—	—	**—**	—	(285)	**285**
Net loss	$ (21,146)	$ (10,659)	**$ (10,487)**	$ (68,061)	$ (37,842)	**$ (30,219)**

Revenue

Contract research revenue was $1.4 million and $1.3 million for the three months ended September 30, 2021 and 2020, respectively, and was comprised of fees earned from the provision of laboratory services. The $0.1 million increase was driven by a higher average bill rate offset by a reduction in overall hours billed. Other revenue for the three months ended September 30, 2021 and 2020 primarily consisted of $0.2 million and $0.1 million of royalties earned on net sales of RHOFADE, respectively.

Contract research revenue was $4.6 million and $4.4 million for the nine months ended September 30, 2021 and 2020, respectively, and was comprised of fees earned from the provision of laboratory services. The $0.2 million increase was driven by a higher average bill rate. Other revenue for the nine months ended September 30, 2021 and 2020 primarily consisted of $0.6 million and $0.5 million of royalties earned on net sales of RHOFADE, respectively.

Cost of Revenue

Cost of revenue was $1.1 million and $3.6 million for the three and nine months ended September 30, 2021, respectively, and $1.2 million and $3.8 million for the three and nine months ended September 30, 2020, respectively, and in each case related to providing laboratory services to our customers. The decrease in cost of revenue in the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 was primarily the result of COVID-19 employee-retention tax credits. Changes in cost of revenue generally correlate to changes in contract research revenue.

Research and Development Expenses

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)	2021	2020	Change	2021	2020	Change
Zunsemetinib	$ 8,207	2,216	**$ 5,991**	$ 12,532	4,925	**$ 7,607**
ATI-1777	450	694	**(244)**	1,894	2,553	**(659)**
ATI-2138	980	599	**381**	3,330	1,753	**1,577**
ATI-2231	263	—	**263**	333	—	**333**
Discovery	935	455	**480**	2,401	1,700	**701**
Other research and development	469	398	**71**	1,268	2,068	**(800)**
Personnel	1,733	1,441	**292**	4,984	5,191	**(207)**
Stock-based compensation	939	437	**502**	2,969	2,192	**777**
Total research and development expenses	$ 13,976	$ 6,240	**$ 7,736**	$ 29,711	$ 20,382	**$ 9,329**

Zunsemetinib

The increase in expenses for zunsemetinib during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 was primarily due to costs associated with drug product manufacturing and clinical development activities for a Phase 2b trial in subjects with moderate to severe rheumatoid arthritis and a Phase 2 trial in subjects with moderate to severe hidradenitis suppurativa.

ATI-1777

The decrease in expenses for ATI-1777 during the three months ended September 30, 2021 compared to the three months ended September 30, 2020 was primarily due to lower costs associated with a Phase 2a clinical trial in subjects with moderate to severe atopic dermatitis, which concluded in the second quarter 2021.

The decrease in expenses for ATI-1777 during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily due to a decrease in development costs, including toxicology studies, partially offset by an increase in costs associated with a Phase 2a clinical trial in subjects with moderate to severe atopic dermatitis, which began in the third quarter of 2020 and concluded in the second quarter of 2021.

ATI-2138

Expenses for ATI-2138 were higher during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 primarily due to preclinical development activities and IND-enabling studies as we progressed towards an IND submission.

ATI-2231

Expenses for ATI-2231 were higher during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 primarily due to preclinical development activities and IND-enabling studies.

Discovery and other research and development

Expenses related to discovery increased during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 due to continued investment in our discovery-stage programs.

Other research and development expenses, which primarily include expenses for our legacy dermatology assets and medical affairs activities, were lower during the nine months ended September 30, 2021 compared to September 30, 2020 due to a decrease in costs for our legacy dermatology assets following the decision to discontinue investment in those programs.

Personnel and stock-based compensation

Compensation related expenses increased during the three months ended September 30, 2021 compared to the three months ended September 30, 2020 primarily due to an increase in stock-based compensation expense associated with new equity awards granted in 2021 as well as higher average headcount.

Compensation related expenses increased during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 primarily due to an increase in stock-based compensation expense associated with new equity awards granted in 2021, partially offset by lower average headcount and lower payroll taxes resulting from COVID-19 employee-retention tax credits taken during the nine months ended September 30, 2021.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Personnel	$ 1,099	$ 861	**$ 238**	$ 3,205	$ 4,130	**$ (925)**
Professional and legal fees	1,207	907	**300**	3,898	2,857	**1,041**
Facility and support services	557	362	**195**	1,369	1,294	**75**
Other general and administrative	559	441	**118**	1,751	1,568	**183**
Stock-based compensation	2,557	1,288	**1,269**	6,453	5,783	**670**
Total general and administrative expenses	$ 5,979	$ 3,859	**$ 2,120**	$ 16,676	$ 15,632	**$ 1,044**

Personnel and stock-based compensation

Compensation related expenses increased during the three months ended September 30, 2021 compared to the three months ended September 30, 2020 primarily due to an increase in stock-based compensation expense associated with new equity awards granted in 2021 and higher incentive compensation-related accruals.

Compensation related expenses decreased during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 primarily due to lower average headcount partially offset by an increase in stock-based compensation expense associated with new equity awards granted in 2021.

Professional and legal fees

Professional and legal fees, including accounting, investor relations and corporate communication costs, were higher during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 primarily as a result of increased costs associated with Sarbanes-Oxley compliance and other professional fees for temporary staffing.

Facility and support services and other general and administrative

Facility and support services, including general office expenses, information technology costs and other expenses, increased during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 primarily due to an increase in information technology costs resulting from higher headcount and infrastructure technology improvements.

Other general and administrative expenses increased during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020 primarily due to an increase in insurance premiums resulting from additional coverage in 2021 as compared to the prior year.

Revaluation of Contingent Consideration

The increase in revaluation of contingent consideration during the three months ended September 30, 2021 compared to the three months ended September 30, 2020 resulted from updates to the probability of success and estimated future sales level assumptions as a result of the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis.

The increase in revaluation of contingent consideration during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 resulted from updates to the probability of success and estimated future sales level assumptions as a result of the completion of a Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis, as well as the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis. Additionally, the inclusion of estimated future sales of zunsemetinib as a potential treatment for psoriatic arthritis and moderate to severe hidradenitis suppurativa, which are additional planned indications for zunsemetinib, also contributed to the increase.

Other Expense, net

Other expense, net increased during the three months ended September 30, 2021 compared to the three months ended September 30, 2020 primarily due to interest and fees associated with a payoff of the Silicon Valley Bank Loan and Security Agreement.

Other expense, net increased during the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 primarily due to interest and fees associated with a payoff of the Silicon Valley Bank Loan and Security Agreement and lower interest income.

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 in August 2017, 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. 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, 2021, we had cash, cash equivalents and marketable securities of $243.6 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

January 2021 Public Offering

In January 2021, we closed a public offering in which we sold 6,306,271 shares of common stock at a price to the public of $17.50 per share, for aggregate gross proceeds of $110.4 million. We paid underwriting discounts and commissions of $6.6 million, and also incurred expenses of $0.4 million in connection with the offering. As a result, the net offering proceeds received by us, after deducting underwriting discounts, commissions and offering expenses, were $103.3 million.

June 2021 Public Offering

In June 2021, we closed a public offering in which we sold 8,098,592 shares of common stock at a price to the public of $17.75 per share, for aggregate gross proceeds of $143.8 million. We paid underwriting discounts and commissions of $8.6 million, and also incurred expenses of $0.3 million in connection with the offering. As a result, the net offering proceeds received by us, after deducting underwriting discounts, commissions and offering expenses, were $134.9 million.

Equity Purchase Agreement with Lincoln Park Capital Fund, LLC

In August 2020, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provided that, upon the terms and subject to the conditions and limitations set forth therein, we could sell to Lincoln Park, at our discretion, up to $15.0 million of shares of our common stock over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 121,584 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of our common stock on the effective date of the Purchase Agreement resulting in an aggregate fair value of $0.3 million. Through December 31, 2020, we sold 2,111,170 shares of our common stock to Lincoln Park under the Purchase Agreement for net proceeds of $7.7 million. We terminated the Purchase Agreement in January 2021 in connection with the public offering of common stock described above. We did not sell any additional shares prior to terminating the Purchase Agreement.

Debt Financing

Loan and Security Agreement with Silicon Valley Bank

In March 2020, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB. The Loan and Security Agreement provided for $11.0 million in term loans, of which we borrowed the entire amount on March 30, 2020. In July 2021, we repaid in full the $11.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees as of the payoff date, for a total payment of $11.7 million.

Liquidity and Cash Flows

Cash and cash equivalents were $53.6 million as of September 30, 2021 compared to $22.1 million as of December 31, 2020. We also had $190.0 million in short- and long-term marketable securities as of September 30, 2021 compared to $32.1 million as of December 31, 2020.

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

	Nine Months Ended September 30,	
(In thousands)	**2021**	**2020**
Cash and cash equivalents beginning balance	$ 22,063	$ 35,937
Net cash used in operating activities	(35,059)	(29,776)
Net cash provided by (used in) investing activities	(158,456)	8,692
Net cash provided by financing activities	225,054	10,543
Cash and cash equivalents ending balance	$ 53,602	$ 25,396

Operating Activities

Operating activities use of cash was the result of:

	Nine Months Ended September 30,	
(In thousands)	**2021**	**2020**
Net loss	$ (68,061)	$ (37,842)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	33,826	12,869
Change in accounts payable and accrued expenses	(777)	(10,889)
Change in accounts receivable	(39)	4,783
Change in prepaid expenses and other assets	(8)	1,303
Net cash used in operating activities	$ (35,059)	$ (29,776)

Net cash used in operating activities increased for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 primarily as a result of higher net losses after adjusting for non-cash items, an increase in cash paid for prepaid expenses, and a reduction of cash collected from outstanding accounts receivable. The increase was partially offset by a decrease in cash paid to settle outstanding accounts payable balances.

The change in prepaid expenses and other assets was the result of higher prepaid research and development balances relative to the prior year period primarily associated with drug product manufacturing, clinical trials and other preclinical development activities. The change in accounts payable and accrued expenses was primarily driven by the timing of receipt and payment of invoices around quarter-end relative to the prior-year period. The change in accounts receivable was primarily the result of cash received during the nine months ended September 30, 2020 from Allergan Sales, LLC related to sales of RHOFADE that occurred after the date we sold RHOFADE to EPI Health.

Investing Activities

Cash flow from investing activities was the result of:

(In thousands)	Nine Months Ended September 30, 2021	2020
Purchases of property and equipment	$ (108)	$ (445)
Purchases of marketable securities	(199,862)	(39,898)
Proceeds from sales and maturities of marketable securities	41,514	49,035
Net cash provided by (used in) investing activities	$ (158,456)	$ 8,692

The change in net cash used in investing activities for the nine months ended September 30, 2021 compared to net cash provided by investing activities for the nine months ended September 30, 2020 primarily resulted from purchases of marketable securities following our January and June 2021 public offerings.

Financing Activities

Financing activities use of cash was the result of:

(In thousands)	Nine Months Ended September 30, 2021	2020
Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	$ 238,200	$ —
Proceeds from debt financing (including warrants), net of issuance costs	—	10,913
Repayment of debt	(11,483)	—
Restricted stock unit employee tax withholdings	(3,122)	—
Finance lease payments	—	(128)
Deferred issuance costs	—	(242)
Proceeds from exercise of employee stock options and the issuance of stock	1,459	—
Net cash provided by financing activities	$ 225,054	$ 10,543

Cash provided by financing activities increased for the nine months ended September 30, 2021 compared to September 30, 2020 primarily due to our January 2021 and June 2021 public offerings. The increase was partially offset by a decrease in proceeds from debt financing, an increase in debt repayments, and an increase in cash used for tax withholdings in connection with the vesting of restricted stock units.

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 other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, 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 in the near term 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. 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 and ATI-1777, 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 potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 the COVID-19 pandemic;
- 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 earn revenue from such arrangements; and
- the revenue earned from our commercial products as a result of licenses to, or partnerships with, third parties.

Contractual Obligations and Commitments

We occupy space for our headquarters in Wayne, Pennsylvania under a sublease agreement which has a term through October 2023. In December 2020, we entered into a sub-sublease agreement under which we sub-subleased 8,115 square feet. The sub-sublease term runs concurrently with the original sublease agreement. We occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through June 2029.

In March 2020, we borrowed $11.0 million under the Loan and Security Agreement with SVB. In July 2021, we repaid in full the $11.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees as of the payoff date, for a total payment of $11.7 million.

We enter into contracts in the normal course of business with CROs and contract manufacturing organizations 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

In connection with the Loan and Security Agreement with SVB, we were subject to risks relating to changes in market interest rates. We repaid the debt under the Loan and Security Agreement in full in July 2021.

The uncertainty that exists with respect to the economic impact of the global COVID-19 pandemic has introduced significant volatility in the financial markets during and subsequent to our quarter ended September 30, 2021.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021, the end of the period

covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level.

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

There have not been any changes in our internal control over financial reporting during our fiscal quarter ended September 30, 2021 that materially affected, or are 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, but, except as stated below, 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.

Securities Class Action

On July 30, 2019, plaintiff Linda Rosi, or 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 us and certain of our executive officers. The complaint alleges that the defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, our non-marketed FDA-approved product, and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired our securities between May 8, 2018 and June 20, 2019.

On September 5, 2019, an additional plaintiff, Robert Fulcher, or 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, or together, the Consolidated Securities Action, and appointed Fulcher “lead plaintiff” for the putative class.

On January 24, 2020, Fulcher filed a consolidated amended complaint in the Consolidated Securities Action, naming two additional executive officers as defendants, extending the putative class period to August 12, 2019, and adding allegations concerning, among other things, alleged statements and omissions throughout the putative class period concerning ESKATA’s risks, tolerability and effectiveness. The defendants filed a motion to dismiss the consolidated amended complaint on April 17, 2020. Following briefing and oral argument on February 25, 2021, the motion was granted in part and denied in part on March 29, 2021, and the issues in dispute significantly narrowed. The defendants filed an answer to the remaining aspects of the consolidated amended complaint on April 19, 2021.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Securities Action. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to the putative class and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to the putative class. The proposed settlement is subject to final approval by the court. We expect our financial obligation to be within the limits of our insurance coverage.

Stockholder Derivative Action

On November 15, 2019, plaintiff Keith Allred, or Allred, filed a derivative stockholder complaint captioned *Allred v. Walker et al*. in the U.S. District Court for the Southern District of New York against certain of our directors and executive officers. The complaint alleges that the defendants, among other things, breached their fiduciary duties as directors and/or officers in connection with the claims alleged in the Consolidated Securities Action. The complaint seeks, among other things, unspecified compensatory damages on behalf of our company.

On November 25, 2019, an additional plaintiff, Bruce Brown, or Brown, filed a substantially identical complaint captioned *Brown v. Walker et al.* in the same court against the same defendants.

On December 12, 2019, the court consolidated the Allred and Brown actions under the caption *In re Aclaris Therapeutics, Inc. Derivative Litigation*, or the Consolidated Derivative Action, and directed that future derivative cases filed in or transferred to the court arising out of substantially the same transactions or events be similarly consolidated. Thereafter, on January 11, 2020, the court stayed – subject to certain conditions – all deadlines in the Consolidated Derivative Action pending resolution of the defendants' then-anticipated motion to dismiss the Consolidated Securities Action. On May 18, 2021, the court extended the stay – subject to certain conditions – until the resolution of a motion for summary judgment in the Consolidated Securities Action, which defendants in that action intended to file had the parties to the Consolidated Securities Action not reached an agreement to settle.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Derivative Action. The agreed terms provide for us to implement certain policies and for attorneys' fees to be paid to plaintiff's counsel, which we expect to be within the limits of our insurance coverage. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to our stockholders and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to our stockholders. The proposed settlement is subject to final approval by the court.

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, 2020, filed with the SEC on February 25, 2021.

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

None.

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	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 2, 2021

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

Date: November 2, 2021

By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, Neal Walker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2021 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 2, 2021

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

Exhibit 31.2

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

I, Frank Ruffo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2021 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 2, 2021

/s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Neal Walker, President and Chief Executive Officer of Aclaris Therapeutics, Inc. (the "Company"), and Frank Ruffo, 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, 2021, 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 2nd day of November, 2021.

/s/ Neal Walker	/s/ Frank Ruffo
Neal Walker	Frank Ruffo
President and Chief Executive Officer	Chief Financial Officer
(principal executive officer)	(principal financial 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.