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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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(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, 2022

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

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**Aclaris Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)  
640 Lee Road, Suite 200  
Wayne, PA  
(Address of principal executive offices)

46-0571712  
(I.R.S. Employer  
Identification No.)

19087  
(Zip Code)

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

N/A

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, \$0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes  No

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on October 31, 2022 was 66,683,191.

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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)

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 61,653	\$ 27,349
Short-term marketable securities	186,409	164,065
Accounts receivable, net	597	623
Prepaid expenses and other current assets	7,914	12,995
Total current assets	<u>256,573</u>	<u>205,032</u>
Marketable securities	—	34,242
Property and equipment, net	1,145	1,335
Intangible assets	6,992	7,048
Other assets	2,922	3,554
Total assets	<u>\$ 267,632</u>	<u>\$ 251,211</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 7,667	\$ 9,985
Accrued expenses	9,154	10,051
Current portion of lease liabilities	766	693
Discontinued operations	2,202	2,202
Total current liabilities	<u>19,789</u>	<u>22,931</u>
Other liabilities	1,638	2,172
Contingent consideration	26,000	28,400
Deferred tax liability	367	367
Total liabilities	<u>47,794</u>	<u>53,870</u>
Commitments and contingencies (Note 16)		
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.00001 par value; 100,000,000 shares authorized at September 30, 2022 and December 31, 2021; 66,679,641 and 61,228,446 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in capital	875,982	792,971
Accumulated other comprehensive loss	(1,465)	(224)
Accumulated deficit	(654,680)	(595,407)
Total stockholders' equity	<u>219,838</u>	<u>197,341</u>
Total liabilities and stockholders' equity	<u>\$ 267,632</u>	<u>\$ 251,211</u>

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,	
	2022	2021	2022	2021
<b>Revenues:</b>				
Contract research	\$ 1,090	\$ 1,415	\$ 3,529	\$ 4,556
Licensing	17,898	214	18,378	612
Other	30	30	92	92
<b>Total revenue</b>	<b>19,018</b>	<b>1,659</b>	<b>21,999</b>	<b>5,260</b>
<b>Costs and expenses:</b>				
Cost of revenue	923	1,099	3,146	3,564
Research and development	23,656	13,976	56,741	29,711
General and administrative	5,813	5,979	17,987	16,676
Licensing	7,300	—	7,300	—
Revaluation of contingent consideration	2,200	900	(2,400)	22,139
<b>Total costs and expenses</b>	<b>39,892</b>	<b>21,954</b>	<b>82,774</b>	<b>72,090</b>
Loss from operations	(20,874)	(20,295)	(60,775)	(66,830)
Other income (expense), net	922	(851)	1,502	(1,231)
<b>Net loss</b>	<b>\$ (19,952)</b>	<b>\$ (21,146)</b>	<b>\$ (59,273)</b>	<b>\$ (68,061)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.30)</b>	<b>\$ (0.35)</b>	<b>\$ (0.92)</b>	<b>\$ (1.23)</b>
Weighted average common shares outstanding, basic and diluted	66,675,337	61,219,321	64,718,008	55,215,037
<b>Other comprehensive (loss) income:</b>				
Unrealized gain (loss) on marketable securities, net of tax of \$0	\$ (139)	\$ 5	\$ (1,241)	\$ (5)
Foreign currency translation adjustment	—	176	—	96
<b>Total other comprehensive (loss) income</b>	<b>(139)</b>	<b>181</b>	<b>(1,241)</b>	<b>91</b>
<b>Comprehensive loss</b>	<b>\$ (20,091)</b>	<b>\$ (20,965)</b>	<b>\$ (60,514)</b>	<b>\$ (67,970)</b>

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)**

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

  

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>		<b>Total</b>
	<b>Shares</b>	<b>Par Value</b>	<b>Paid-in Capital</b>	<b>Other Comprehensive Income (Loss)</b>	<b>Accumulated Deficit</b>	<b>Stockholders' Equity</b>
<b>Balance at December 31, 2020</b>	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)
<b>Balance at March 31, 2021</b>	<u>52,081,729</u>	<u>\$ —</u>	<u>\$ 645,730</u>	<u>\$ (140)</u>	<u>\$ (533,296)</u>	<u>\$ 112,294</u>
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)
<b>Balance at June 30, 2021</b>	<u>61,204,987</u>	<u>\$ 1</u>	<u>\$ 785,455</u>	<u>\$ (184)</u>	<u>\$ (551,457)</u>	<u>\$ 233,815</u>
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)
<b>Balance at September 30, 2021</b>	<u>61,226,750</u>	<u>\$ 1</u>	<u>\$ 789,186</u>	<u>\$ (3)</u>	<u>\$ (572,603)</u>	<u>\$ 216,581</u>

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,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (59,273)	\$ (68,061)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	607	726
Stock-based compensation expense	10,226	10,209
Revaluation of contingent consideration	(2,400)	22,139
Loss on extinguishment of debt	—	752
Changes in operating assets and liabilities:		
Accounts receivable	26	(39)
Prepaid expenses and other assets	3,408	(8)
Accounts payable	(2,319)	1,293
Accrued expenses	1,273	(2,070)
Net cash used in operating activities	<u>(48,452)</u>	<u>(35,059)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(500)	(108)
Purchases of marketable securities	(118,729)	(199,862)
Proceeds from sales and maturities of marketable securities	129,155	41,514
Net cash provided by (used in) investing activities	<u>9,926</u>	<u>(158,456)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	—	238,200
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	72,744	—
Repayment of debt	—	(11,483)
Payments of employee withholding taxes related to restricted stock unit award vesting	(34)	(3,122)
Proceeds from exercise of employee stock options and the issuance of stock	120	1,459
Net cash provided by financing activities	<u>72,830</u>	<u>225,054</u>
<b>Net increase in cash and cash equivalents</b>	<u>34,304</u>	<u>31,539</u>
<b>Cash and cash equivalents at beginning of period</b>	<u>27,349</u>	<u>22,063</u>
<b>Cash and cash equivalents at end of period</b>	<u>\$ 61,653</u>	<u>\$ 53,602</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Additions to property and equipment included in accounts payable	\$ 4	\$ —

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

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

**1. Organization and Nature of Business**

**Overview**

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. In 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 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, 2022, the Company had cash, cash equivalents and marketable securities of \$248.1 million and an accumulated deficit of \$654.7 million. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence, the Company had never generated revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, including clinical and preclinical testing of the Company’s drug candidates, will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its drug candidates and to generate revenue from identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize its development assets or to raise additional capital to finance its operations. The Company will require additional capital to complete the clinical development of zunsemetinib (ATI-450), ATI-1777 and ATI-2138, 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 the potential worsening of global economic conditions, including inflationary pressures, and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic and geopolitical tensions. 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.

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that its condensed consolidated financial statements are issued. As of the report date, the Company does not believe that substantial doubt exists about its ability to continue as a going concern. The Company believes its existing cash, cash equivalents and marketable securities are sufficient to fund its operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of these condensed consolidated financial statements.

## **2. Summary of Significant Accounting Policies**

### **Unaudited Interim Financial Information**

The accompanying condensed consolidated balance sheet as of September 30, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statement of stockholders' equity for the three and nine months ended September 30, 2022 and 2021, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021 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 24, 2022 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, 2022, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2022 and 2021, its changes in stockholders' equity for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021. The condensed consolidated balance sheet data as of December 31, 2021 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, 2022 and 2021 are unaudited. The results for the three and nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, 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, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on February 24, 2022.

### **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, contingent consideration and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require an update to its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. Actual results could differ from the Company's estimates.

### **Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year 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, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on February 24, 2022. 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 10% and 40% at September 30, 2022. 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 10.9% and 11.6% depending on the year of each potential payment.

#### ***Revenue Recognition***

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

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

#### ***Licensing Revenue***

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

**Milestone and Royalty Payments** – The Company considers any future potential milestones and sales-based royalties to be variable consideration. The Company recognizes royalties and commercial milestone payments as revenue when the sales occur or the milestones are achieved pursuant to the sales-based royalty exception under ASC 606-10-55-65. The Company recognizes revenue from regulatory milestones when the regulatory milestone is achieved.

### 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:

(In thousands)	September 30, 2022			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Cash equivalents	\$ 46,713	\$ —	\$ —	\$ 46,713
Marketable securities	—	186,409	—	186,409
<b>Total assets</b>	<b>\$ 46,713</b>	<b>\$ 186,409</b>	<b>\$ —</b>	<b>\$ 233,122</b>
<b>Liabilities:</b>				
Contingent consideration	\$ —	\$ —	\$ 26,000	\$ 26,000
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 26,000</b>	<b>\$ 26,000</b>

  

(In thousands)	December 31, 2021			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Cash equivalents	\$ 21,678	\$ —	\$ —	\$ 21,678
Marketable securities	—	198,307	—	198,307
<b>Total assets</b>	<b>\$ 21,678</b>	<b>\$ 198,307</b>	<b>\$ —</b>	<b>\$ 219,985</b>
<b>Liabilities:</b>				
Contingent consideration	\$ —	\$ —	\$ 28,400	\$ 28,400
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 28,400</b>	<b>\$ 28,400</b>

As of September 30, 2022 and December 31, 2021, the Company’s cash equivalents consisted of a money market fund, which was valued based upon Level 1 inputs. The Company’s marketable securities as of September 30, 2022 and December 31, 2021 consisted of commercial paper, and asset-backed, U.S. government, foreign government agency and corporate debt securities, which were all valued based upon Level 2 inputs. Marketable securities also included U.S. government agency debt securities as of September 30, 2022, which were valued based upon Level 2 inputs.

In determining the fair value of its Level 2 investments, the Company relies on quoted prices for identical securities in markets that are not active. These quoted prices are obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. 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 three and nine months ended September 30, 2022 and 2021, there were no transfers into or out of Level 3.

The overall \$2.4 million decrease in the fair value of the contingent consideration liability during the nine months ended September 30, 2022 was mainly due to higher discount rates, resulting from higher risk-free rates and wider credit spreads, being applied to potential payments relative to prior periods. The decrease was partially offset by an increase in the contingent consideration liability as a result of the impact of the passage of time and other valuation model assumption modifications.

As of September 30, 2022 and December 31, 2021, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

(In thousands)	September 30, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 47,270	\$ —	\$ (472)	\$ 46,798
Commercial paper	59,659	—	—	59,659
Asset-backed debt securities	21,366	—	(176)	21,190
Foreign government agency debt securities	4,039	—	(27)	4,012
U.S. government and agency debt securities	55,542	—	(792)	54,750
<b>Total marketable securities</b>	<b>\$ 187,876</b>	<b>\$ —</b>	<b>\$ (1,467)</b>	<b>\$ 186,409</b>

(In thousands)	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities <sup>(1)</sup>	\$ 40,993	\$ 6	\$ (50)	\$ 40,949
Commercial paper	71,837	—	—	71,837
Asset-backed debt securities	36,166	—	(43)	36,123
Foreign government agency debt securities	4,073	—	(13)	4,060
U.S. government debt securities <sup>(2)</sup>	45,465	—	(127)	45,338
<b>Total marketable securities</b>	<b>\$ 198,534</b>	<b>\$ 6</b>	<b>\$ (233)</b>	<b>\$ 198,307</b>

<sup>(1)</sup> Included in Corporate debt securities is \$9.2 million with maturity dates between one and five years.

<sup>(2)</sup> Included in US government debt securities is \$25.0 million with maturity dates between one and five years.

#### 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
Computer equipment	\$ 1,381	\$ 1,380
Lab equipment	1,886	1,605
Furniture and fixtures	620	620
Leasehold improvements	1,123	1,123
Property and equipment, gross	5,010	4,728
Accumulated depreciation	(3,865)	(3,393)
<b>Property and equipment, net</b>	<b>\$ 1,145</b>	<b>\$ 1,335</b>

Depreciation expense was \$0.2 million for each of the three months ended September 30, 2022 and 2021, and \$0.6 million for each of the nine months ended September 30, 2022 and 2021.

## 5. Intangible Assets

Intangible assets consisted of the following:

(In thousands, except years)	Remaining Life (years)	Gross Cost		Accumulated Amortization	
		September 30,	December 31,	September 30,	December 31,
		2022	2021	2022	2021
Other intangible assets	4.8	\$ 751	\$ 751	\$ 388	\$ 332
In-process research and development	n/a	6,629	6,629	—	—
<b>Total intangible assets</b>		<b>\$ 7,380</b>	<b>\$ 7,380</b>	<b>\$ 388</b>	<b>\$ 332</b>

Amortization expense was \$19 thousand for each of the three months ended September 30, 2022 and 2021, and \$56 thousand for each of the nine months ended September 30, 2022 and 2021.

As of September 30, 2022, estimated future amortization expense was as follows:

(In thousands)	Year Ending December 31,
2022	\$ 18
2023	75
2024	75
2025	75
2026	75
Thereafter	45
<b>Total</b>	<b>\$ 363</b>

## 6. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
Employee compensation expenses	\$ 3,830	\$ 4,389
Research and development expenses	3,587	1,278
Litigation settlements (see Note 16)	—	2,650
Other	1,737	1,734
<b>Total accrued expenses</b>	<b>\$ 9,154</b>	<b>\$ 10,051</b>

## 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.

## **8. Stockholders' Equity**

### **Preferred Stock**

As of September 30, 2022 and December 31, 2021, 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, 2022 or December 31, 2021.

### **Common Stock**

As of September 30, 2022 and December 31, 2021, 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. There were 66,679,641 and 61,228,446 shares of common stock issued and outstanding as of September 30, 2022 and December 31, 2021, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to any preferential dividend rights of any series of preferred stock that may be outstanding. No dividends have been declared through September 30, 2022.

### **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 388,119 shares of common stock to SVB.

### **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.

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

In April 2022, the Company sold 4,838,709 shares of its common stock at a weighted average price per share of \$15.50, for aggregate gross proceeds of \$75.0 million, pursuant to a sales agreement with SVB Securities LLC and Cantor Fitzgerald & Co., as sales agents, dated May 20, 2021. The Company paid selling commissions and other fees of \$2.2 million in connection with the sale.

## 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, 2022, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 2,449,137 shares. As of September 30, 2022, 3,019,432 shares remained available for grant under the 2015 Plan. The Company had 4,343,087 stock options and 1,585,184 RSUs outstanding as of September 30, 2022 under the 2015 Plan.

### 2017 Inducement Plan

In July 2017, the Company's board of directors adopted the 2017 Inducement Plan (the "2017 Inducement Plan"). The 2017 Inducement Plan is a non-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Company had 370,600 stock options outstanding as of September 30, 2022 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 473,977 were outstanding as of September 30, 2022. 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, 2022 and 2021 were as follows:

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	2.07 %	0.90 %
Expected term (in years)	6.2	6.2
Expected volatility	77.95 %	76.60 %
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, 2022:

<b>(In thousands, except share and per share data and years)</b>	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding as of December 31, 2021	3,792,450	\$ 17.50	6.8	\$ 13,710
Granted	2,334,750	14.27		
Exercised	(85,672)	1.40		1,115
Forfeited and cancelled	(853,864)	18.70		
Outstanding as of September 30, 2022	<u>5,187,664</u>	\$ 16.11	7.4	\$ 15,376
Options vested and expected to vest as of September 30, 2022	<u>5,187,664</u>	\$ 16.11	7.4	\$ 15,376
Options exercisable as of September 30, 2022	<u>2,307,984</u>	\$ 17.35	5.2	\$ 9,345

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2022 was \$9.83 per share.

### Restricted Stock Units

The following table summarizes RSU activity for the nine months ended September 30, 2022:

<b>(In thousands, except share and per share data)</b>	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value Per Share</b>	<b>Aggregate Intrinsic Value</b>
Outstanding as of December 31, 2021	1,496,946	\$ 12.75	
Granted	867,707	14.33	
Vested	(526,706)	11.55	\$ 7,839
Forfeited and cancelled	(252,763)	12.30	
Outstanding as of September 30, 2022	<u>1,585,184</u>	\$ 14.09	

### Stock-Based Compensation

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

<b>(In thousands)</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Cost of revenue	\$ 307	\$ 206	\$ 837	\$ 787
Research and development	1,400	939	2,228	2,969
General and administrative	2,481	2,557	7,161	6,453
Total stock-based compensation expense	<u>\$ 4,188</u>	<u>\$ 3,702</u>	<u>\$ 10,226</u>	<u>\$ 10,209</u>

As of September 30, 2022, the Company had unrecognized stock-based compensation expense for stock options and RSUs of \$25.5 million and \$18.3 million, respectively, which is expected to be recognized over weighted average periods of 3.1 years and 2.9 years, respectively.

## 10. Net Loss per Share

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

(In thousands, except for share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	\$ (19,952)	\$ (21,146)	\$ (59,273)	\$ (68,061)
Denominator:				
Weighted average shares of common stock outstanding, basic and diluted	66,675,337	61,219,321	64,718,008	55,215,037
Net loss per share, basic and diluted	\$ (0.30)	\$ (0.35)	\$ (0.92)	\$ (1.23)

The Company's potentially dilutive securities, which include stock options and RSUs, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential shares of common stock excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2022 and 2021. All share amounts presented in the table below represent the total number outstanding as of September 30, 2022 and 2021.

	September 30,	
	2022	2021
Options to purchase common stock	5,187,664	3,743,725
Restricted stock unit awards	1,585,184	1,465,963
Total potential shares of common stock	6,772,848	5,209,688

## 11. Leases

### Operating Leases

#### *Agreements for Office and Laboratory Space*

The Company has a sublease agreement 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 the 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 to a third party. 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:

<u>(In thousands)</u>	<u>September 30,</u>	<u>December 31,</u>
	<u>2022</u>	<u>2021</u>
<b>Operating Leases:</b>		
Gross cost	\$ 5,240	\$ 5,240
Accumulated amortization	(2,364)	(1,803)
Other assets	<u>\$ 2,876</u>	<u>\$ 3,437</u>
Current portion of lease liabilities	\$ 766	\$ 693
Other liabilities	1,617	2,151
Total operating lease liabilities	<u>\$ 2,383</u>	<u>\$ 2,844</u>

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, 2022 and 2021 and \$0.8 million for each of the nine months ended September 30, 2022 and 2021.

## 12. Agreements Related to Intellectual Property

### Asset Purchase Agreement – EPI Health, LLC

In October 2019, the Company sold RHOFADÉ (oxymetazoline hydrochloride) cream, 1% (“RHOFADÉ”) 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 RHOFADÉ have expired or, if later, ten years from the date of the first commercial sale of RHOFADÉ in such country. The Company recorded royalty income under the asset purchase agreement of \$0.3 million and \$0.2 million during the three months ended September 30, 2022 and 2021, respectively, and \$0.8 million and \$0.6 million during the nine months ended September 30, 2022 and 2021, respectively. Royalty income is included in licensing 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

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

As of September 30, 2022 and December 31, 2021, the balance of the Company’s contingent consideration liability was \$26.0 million and \$28.4 million, respectively (see Note 3).

### License Agreement – Eli Lilly and Company

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

The Company accounts for the Lilly license agreement under ASC Topic 606 and identified the non-exclusive license as a distinct performance obligation, since Lilly can benefit from the license on its own by developing and commercializing the underlying product using its own resources. The Company determined that the license was a right to use the intellectual property and that the Company had provided all necessary information to Lilly to benefit from the license.

During the three months ended September 30, 2022, the Company received \$17.6 million from Lilly, a portion of which represented payments for regulatory and commercial milestones that were deemed to have been achieved as of the execution of the license agreement. The Company remains eligible to receive future milestone payments, all of which will be paid by the Company to third parties following receipt as described above. The Company recognized the upfront payment and milestone payments received during the three months ended September 30, 2022, and will recognize future anniversary payments, milestone payments and royalties that may be received from Lilly under the license agreement, as licensing revenue on its condensed consolidated statements of operations and comprehensive loss. During each of the three and nine months ended September 30, 2022, the Company recorded amounts paid to third parties of \$7.3 million, and will record amounts it pays out to third parties under its contractual obligations in the future, as licensing expense on its condensed consolidated statements of operations and comprehensive loss.

The Company considers any future potential milestones and the sales-based royalty to be variable consideration. The Company expects that the royalties and commercial milestone payments will be recognized as revenue when the sales occur or the milestones are achieved pursuant to the sales-based royalty exception under ASC Subtopic 606-10-55-65 because the license is the predominant item to which the royalty or sales-based milestones relate.

### 13. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three and nine months ended September 30, 2022 and 2021. 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.

### 14. 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, 2022	December 31, 2021
Accrued expenses	\$ 2,202	\$ 2,202
Discontinued operations - current liabilities	\$ 2,202	\$ 2,202

## 15. 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, 2022 and 2021 are summarized in the tables below:

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

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

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

<b>(In thousands)</b>		<b>Contract</b>	<b>Corporate</b>	<b>Total</b>
<b>Nine Months Ended September 30, 2021</b>	<b>Therapeutics</b>	<b>Research</b>	<b>and Other</b>	<b>Company</b>
Total revenue	\$ 704	\$ 10,016	\$ (5,460)	\$ 5,260
Cost of revenue	—	8,705	(5,141)	3,564
Research and development expense	30,030	—	(319)	29,711
General and administrative expense	—	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)

### Intersegment Revenue

Revenue for the contract research segment included \$3.2 million and \$1.9 million for services performed on behalf of the therapeutics segment for the three months ended September 30, 2022 and 2021, respectively, and \$9.3 million and \$5.5 million for the nine months ended September 30, 2022 and 2021, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

## 16. 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 alleged 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) (“ESKATA”) and find that the materials minimized the risks or overstated the efficacy of the product. The complaint sought 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 court granted final approval of the settlement on December 9, 2021.

The Company’s financial obligation under the settlement was \$2.7 million, which was within the limits of its insurance coverage.

## 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, 2021, which are included in our Annual Report on Form 10-K filed with the SEC on February 24, 2022.

### 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, an Investigational Oral MK2 Inhibitor*

We are developing zunsemetinib, an investigational oral, novel, small molecule selective MK2 inhibitor compound, as a potential treatment for rheumatoid arthritis and other immuno-inflammatory diseases. MK2 is a key regulator of pro-inflammatory mediators including TNF $\alpha$ , IL1 $\beta$ , IL6, IL8, IL17 and other essential pathogenic signals in chronic immuno-inflammatory diseases, as well as in oncology. As an oral drug candidate, we are developing zunsemetinib as a potential alternative to injectable anti-TNF/IL1/IL6 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 10 mg, 30 mg, 50 mg and 100 mg doses) and multiple ascending (at 10 mg, 30 mg and 50 mg 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 TNF $\alpha$ , IL1 $\beta$ , 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 80 mg and 120 mg 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. 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.

*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), showed that zunsemetinib demonstrated durable clinical activity, as defined by a marked and sustained reduction in DAS28-CRP and improvement of American College of Rheumatology 20%/50%/70% (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 TNF $\alpha$ , IL1 $\beta$ , 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, TNF $\alpha$ , IL6, IL8 and MIP1 $\beta$  in the treatment arm over the 12-week period.

In December 2021, we initiated study activities in a Phase 2b randomized, multicenter, double-blind, parallel group, placebo-controlled, dose-ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-202). This trial consists of a 12-week treatment period and a 30-day follow-up period, and seeks to enroll approximately 240 subjects in the United States and in multiple countries in Europe. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We expect topline data in the second half of 2023.

*Moderate to Severe Hidradenitis Suppurativa*

In December 2021, we initiated study activities in a Phase 2a, randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50 mg twice daily) in subjects with moderate to severe hidradenitis suppurativa (ATI-450-HS-201). This trial consists of a 12-week treatment period and a 30-day follow-up period. The primary endpoint is the change in inflammatory nodule and abscess count at week 12. The trial has completed enrollment with 95 subjects randomized in the United States. We expect topline data in mid-first half of 2023.

*Moderate to Severe Psoriatic Arthritis*

In June 2022, we initiated study activities in a Phase 2a, randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis (ATI-450-PsA-201). This trial consists of a 12-week treatment period and a 30-day follow-up period, and seeks to enroll approximately 70 subjects in the United States

and in Poland. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We expect topline data in the second half of 2023.

***ATI-1777, an Investigational Topical “Soft” JAK 1/3 Inhibitor***

We are developing ATI-1777, an investigational topical “soft” JAK 1/3 inhibitor compound, as a potential treatment for 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.

In May 2022, we activated multiple clinical sites in a Phase 2b, multicenter, randomized, double-blind, vehicle-controlled, parallel-group trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe atopic dermatitis (ATI-1777-AD-202). In this trial, we will explore multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777, in patients 12 years and older. This trial will consist of a 4-week treatment period and a 2-week follow-up period, and seeks to enroll approximately 240 subjects in the United States. The primary endpoint is the percentage change from baseline in EASI score at week 4. We expect topline data in the first half of 2023.

***ATI-2138, an Investigational Oral Covalent ITJ Inhibitor***

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

In October 2021, we submitted an Investigational New Drug application, or IND, for ATI-2138 for the treatment of psoriasis. The IND was allowed by the U.S. Food and Drug Administration, or FDA, in November 2021.

In December 2021, we initiated a Phase 1 randomized, observer-blind, placebo-controlled, single ascending dose (SAD) trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-2138 in healthy subjects (ATI-2138-PKPD-101), which we completed in November 2022. In this trial, 64 male and female healthy

volunteer subjects were randomized in a 3:1 ratio into seven doses in eight cohorts. Each cohort consisted of eight randomized subjects, with six receiving ATI-2138 and two receiving placebo. Single dose levels were 1 mg, 3 mg, 5 mg, 15 mg, 25 mg, 50 mg and 80 mg. Preliminary data from this trial showed that ATI-2138 was generally well tolerated at all doses tested in the trial. No serious adverse events or severe adverse events were reported. The most common adverse events in subjects treated with ATI-2138, headache (four subjects) and lightheadedness (two subjects), were mild and transient. ATI-2138 demonstrated linear pharmacokinetic data and absorption with a favorable pharmacokinetic profile up to the 80 mg single dose. The terminal half-life ranged from 1.5 to 2.5 hours. In addition, no significant food effect at the 15 mg dose (fasted versus fed) was observed, and similar pharmacokinetic data was observed with the capsule versus tablet formulation at the 25 mg dose. We also observed dose-dependent inhibition of both ITK and JAK3 exploratory pharmacodynamic biomarkers, and near complete inhibition of the dual ITK and JAK3-stimulated interferon production at the 15 mg through 80 mg doses.

We have selected ulcerative colitis as the intended first clinical development target for ATI-2138. We are also exploring additional indications that are relevant to the mechanism of action. In October 2022, we submitted a new IND for ATI-2138 for the treatment of ulcerative colitis. If the IND is allowed, we plan to initiate a Phase 1 multiple ascending dose (MAD) trial of ATI-2138 in healthy subjects by the end of 2022, with topline data expected in the first half of 2023.

### **Preclinical Programs**

#### ***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. IND-enabling studies are currently underway. We expect to submit an IND for ATI-2231 by the end of 2022. If allowed, we expect to progress ATI-2231 into the clinic in 2023. We are currently evaluating the clinical development program for this asset, which could include a collaboration with a third party.

### **Discovery Programs**

We are developing oral gut-biased 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.

### **Financial Overview**

Since our inception, we have incurred significant net losses. Our net loss was \$59.3 million for the nine months ended September 30, 2022 and \$90.9 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of \$654.7 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical and clinical development. In addition, our drug candidates, even if they are approved by regulatory agencies for marketing, may not achieve commercial success. We may also not be successful in pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates.

Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. We also expect to add additional personnel to support our operational plans and strategic direction. As a result, we will need substantial additional funding to support our continuing operations.

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



## **Impacts of COVID-19 on Our Business**

The impacts of the global COVID-19 pandemic continue to evolve. We have implemented a hybrid work model of remote and in-person operations for our employees that enables 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.

If COVID-19 continues to spread, we may experience 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 other immuno-inflammatory diseases 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 introduction and spread of new variants, travel restrictions, quarantines, stay-at-home orders, social distancing requirements, business closures, staffing shortages, 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 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 2017, we entered into an Agreement and Plan of Merger, or the Confluence Agreement, with Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence, Aclaris Life Sciences, Inc., our wholly-owned subsidiary, or Merger Sub, and Fortis Advisors LLC, as representative of the equity holders of Confluence. Pursuant to the terms of the Confluence Agreement, Merger Sub merged with and into Confluence, with Confluence surviving as our wholly-owned subsidiary.

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

### ***Asset Purchase Agreement with EPI Health***

In 2019, we entered into an asset purchase agreement with EPI Health, LLC, or EPI Health, pursuant to which we sold the worldwide rights to RHOFADÉ (oxymetazoline hydrochloride) cream, 1%, or RHOFADÉ, 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 closing consideration of \$35.2 million. 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 RHOFADÉ, have expired, provided, that with respect to sales of RHOFADÉ in any territory outside of the United States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADÉ patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADÉ 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.

#### ***License Agreement with Eli Lilly and Company***

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

During the three months ended September 30, 2022, we received \$17.6 million from Lilly, a portion of which represented payments for regulatory and commercial milestones that were deemed to have been achieved as of the execution of the license agreement. We remain eligible to receive future milestone payments, all of which will be paid by us to third parties following receipt as described above. We recorded amounts paid to third parties of \$7.3 million during the three months ended September 30, 2022.

### **Components of Our Results of Operations**

#### **Revenue**

##### ***Contract Research***

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

##### ***Licensing***

Licensing revenue primarily consists of upfront consideration, royalties and milestone payments earned pursuant to the asset purchase agreement with EPI Health and the license agreement with Lilly described above.

##### ***Other***

Other revenue consists of amounts earned from the sub-sublease of our office space.

#### **Cost and Expenses**

##### ***Cost of Revenue***

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

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

### ***Research and Development***

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

- expenses incurred under agreements with contract research organizations, or CROs, as well as clinical trial sites and consultants that conduct our clinical trials and preclinical studies, and investigator-initiated trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing active pharmaceutical ingredients and preclinical and clinical trial materials, including domestic technology transfer expenses;
- quality assurance and quality control costs;
- outsourced professional scientific development services;
- medical affairs expenses related to our drug candidates;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- 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, ATI-1777 as a potential treatment for moderate to severe atopic dermatitis and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases, and as we continue the development of our preclinical compounds and discover and develop additional drug candidates. We expense research and development costs as incurred. Our direct research and development expenses primarily consist of external costs including fees paid to CROs, consultants, clinical trial sites, regulatory agencies and third parties that manufacture our preclinical and clinical trial materials, and are tracked on a program-by-program basis. We do not allocate personnel costs or other indirect expenses to specific research and development programs.

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

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable subjects;
- the number of subjects that ultimately participate in the trials;
- the number of doses subjects receive;
- the impact on the recruitment, enrollment, conduct and timing of our clinical trials due to 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. We may obtain unexpected results from our clinical trials or other development activities. We may elect to discontinue, delay or modify the development, including clinical trials, of some drug candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

### ***General and Administrative***

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

### ***Licensing***

Licensing expenses consist of third party contractual obligations incurred related to the receipt of specified payments under the Lilly license agreement described above.

### ***Revaluation of Contingent Consideration***

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

### ***Other Income (Expense), Net***

Other income (expense), net primarily consists of interest earned on our cash, cash equivalents and marketable securities and in prior periods included interest expense related to our debt obligations.

### **Critical Accounting Estimates**

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and judgments on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. 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, 2021 included in our Annual Report on Form 10-K filed with the SEC on February 24, 2022.

### **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 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 10% and 40% at September 30, 2022 compared to between 4% and 40% at September 30, 2021. 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 10.9% and 11.6% depending on the year of each potential payment.

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

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 hidradenitis suppurativa and psoriatic arthritis, which are additional planned indications for zunsemetinib. These updates resulted in an increase in the fair value of the contingent consideration liability of \$22.1 million.

## Results of Operations

### Comparison of Three and Nine Months Ended September 30, 2022 and 2021

(In thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
<b>Revenues:</b>						
Contract research	\$ 1,090	\$ 1,415	\$ (325)	\$ 3,529	\$ 4,556	\$ (1,027)
Licensing	17,898	214	17,684	18,378	612	17,766
Other	30	30	—	92	92	—
Total revenue	19,018	1,659	17,359	21,999	5,260	16,739
<b>Costs and expenses:</b>						
Cost of revenue	923	1,099	(176)	3,146	3,564	(418)
Research and development	23,656	13,976	9,680	56,741	29,711	27,030
General and administrative	5,813	5,979	(166)	17,987	16,676	1,311
Licensing	7,300	—	7,300	7,300	—	7,300
Revaluation of contingent consideration	2,200	900	1,300	(2,400)	22,139	(24,539)
Total costs and expenses	39,892	21,954	17,938	82,774	72,090	10,684
Loss from operations	(20,874)	(20,295)	(579)	(60,775)	(66,830)	6,055
Other income (expense), net	922	(851)	1,773	1,502	(1,231)	2,733
Net loss	\$ (19,952)	\$ (21,146)	\$ 1,194	\$ (59,273)	\$ (68,061)	\$ 8,788

### Revenue

#### Contract research

Contract research revenue was \$1.1 million and \$1.4 million for the three months ended September 30, 2022 and 2021, respectively, and was comprised of fees earned from the provision of laboratory services. The decrease was driven by lower overall hours billed, partially offset by a higher average billing rate.

Contract research revenue was \$3.5 million and \$4.6 million for the nine months ended September 30, 2022 and 2021, respectively, and was comprised of fees earned from the provision of laboratory services. The decrease was driven by lower overall hours billed, partially offset by a higher average billing rate.

### ***Licensing***

Licensing revenue was \$17.9 million and \$0.2 million for the three months ended September 30, 2022 and 2021, respectively. The increase was driven by \$17.6 million of upfront and milestone payments received under the Lilly agreement.

Licensing revenue was \$18.4 million and \$0.6 million for the nine months ended September 30, 2022 and 2021, respectively. The increase was driven by \$17.6 million of upfront and milestone payments received under the Lilly agreement.

### **Costs and Expenses**

#### ***Cost of Revenue***

Cost of revenue was \$0.9 million and \$3.1 million for the three and nine months ended September 30, 2022, respectively, and \$1.1 million and \$3.6 million for the three and nine months ended September 30, 2021, respectively. In each case, cost of revenue related to providing laboratory services. Changes in cost of revenue generally correlate to changes in contract research revenue. Cost of revenue decreased in the three and nine months ended September 30, 2022 compared to the corresponding prior year periods due to lower variable costs resulting from the decrease in hours billed, partially offset by an increase in fixed overhead costs, including personnel-related costs.

#### ***Research and Development***

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

<b>(In thousands)</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2022</b>	<b>2021</b>	<b>Change</b>	<b>2022</b>	<b>2021</b>	<b>Change</b>
Zunsemetinib	\$ 10,182	\$ 8,207	\$ 1,975	\$ 21,500	\$ 12,532	\$ 8,968
ATI-1777	3,354	450	2,904	9,220	1,894	7,326
ATI-2138	1,793	980	813	4,060	3,330	730
ATI-2231	1,308	263	1,045	4,397	333	4,064
Discovery	1,141	935	206	3,411	2,401	1,010
Other research and development	418	469	(51)	1,084	1,268	(184)
Personnel	4,060	1,733	2,327	10,841	4,984	5,857
Stock-based compensation	1,400	939	461	2,228	2,969	(741)
<b>Total research and development expenses</b>	<b>\$ 23,656</b>	<b>\$ 13,976</b>	<b>\$ 9,680</b>	<b>\$ 56,741</b>	<b>\$ 29,711</b>	<b>\$ 27,030</b>

#### ***Zunsemetinib***

The increase in expenses for zunsemetinib during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 was primarily due to costs associated with clinical development activities for a Phase 2b trial in subjects with rheumatoid arthritis, which initiated in December 2021, a Phase 2a trial in subjects with hidradenitis suppurativa, which initiated in December 2021, a Phase 2a trial in subjects with psoriatic arthritis, which initiated in June 2022, and several ancillary clinical trials.

#### ***ATI-1777***

The increase in expenses for ATI-1777 during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 was primarily due to higher costs associated with drug candidate

manufacturing and other preclinical development activities as well as costs associated with a Phase 2b clinical trial in subjects with atopic dermatitis. Lower costs associated with a Phase 2a clinical trial in subjects with atopic dermatitis, which commenced in 2020 and concluded in 2021, partially offset the overall increase in expenses.

*ATI-2138*

The increase in expenses for ATI-2138 during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 was primarily due to an increase in clinical development expenses associated with a Phase 1 SAD trial, which initiated in December 2021, offset by a decrease in preclinical development activities.

*ATI-2231*

Expenses for ATI-2231 were higher during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 primarily due to preclinical development activities and IND-enabling studies as we progressed the program toward IND submission.

*Discovery*

Expenses related to discovery increased during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 due to continued investment in our discovery-stage programs as we progressed programs toward candidate selection.

*Personnel and stock-based compensation*

Personnel and stock-based compensation expenses increased in the aggregate during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 primarily due to an increase in costs associated with higher average headcount. For the nine months ended September 30, 2022 the increase in costs associated with higher average headcount was partially offset by a decrease in stock-based compensation expense mainly attributable to forfeiture credits recorded during the period.

***General and Administrative***

The following table summarizes our general and administrative expenses:

<b>(In thousands)</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2022</b>	<b>2021</b>	<b>Change</b>	<b>2022</b>	<b>2021</b>	<b>Change</b>
Personnel	\$ 1,283	\$ 1,099	\$ 184	\$ 4,221	\$ 3,205	\$ 1,016
Professional and legal fees	877	1,207	(330)	3,167	3,898	(731)
Facility and support services	601	557	44	1,692	1,369	323
Other general and administrative	571	559	12	1,746	1,751	(5)
Stock-based compensation	2,481	2,557	(76)	7,161	6,453	708
Total general and administrative expenses	<u>\$ 5,813</u>	<u>\$ 5,979</u>	<u>\$ (166)</u>	<u>\$ 17,987</u>	<u>\$ 16,676</u>	<u>\$ 1,311</u>

*Personnel and stock-based compensation*

Personnel and stock-based compensation expenses in the aggregate increased during the three months ended September 30, 2022 compared to the three months ended September 30, 2021 primarily due to higher average headcount.

Personnel and stock-based compensation expenses in the aggregate increased during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 primarily due to higher average headcount and an increase in stock-based compensation expense associated with new equity awards granted in 2022.

#### *Professional and legal fees*

Professional and legal fees, including accounting, investor relations and corporate communication costs, decreased during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 primarily as a result of lower accounting and other professional expenses due to a reduction in temporary staffing costs.

#### *Facility and support services*

Facility and support services, including general office expenses, information technology costs and other expenses, increased during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 primarily due to an increase in overhead expenses, including increases in tax and license fees and information technology support costs.

#### **Revaluation of Contingent Consideration**

The increase in the fair value of our contingent consideration liability during the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was mainly due to the modification of a valuation model assumption, offset by higher discount rates being applied to potential payments.

The decrease in the fair value of our contingent consideration liability during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was mainly due to higher discount rates, resulting from higher risk-free rates and wider credit spreads, being applied to potential payments relative to the prior year period. We recorded increases during the nine months ended September 30, 2021 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 rheumatoid arthritis, as well as the completion of a Phase 2a clinical trial of ATI-1777 in subjects with atopic dermatitis. Additionally, the inclusion of estimated future sales of zunsemetinib as a potential treatment for hidradenitis suppurativa and psoriatic arthritis, which are additional planned indications for zunsemetinib, also contributed to the increase during the nine months ended September 30, 2021.

#### **Other Income (Expense), net**

Other income (expense), net increased during the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021 due to lower interest expense associated with the Loan and Security Agreement with Silicon Valley Bank, or SVB, which was repaid in July 2021, and higher interest income on investment portfolio balances.

#### **Liquidity and Capital Resources**

##### **Overview**

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

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$248.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards liquidity and capital preservation.



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

### **Equity Financing**

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

In April 2022, we sold 4,838,709 shares of our common stock at a weighted average price per share of \$15.50, for aggregate gross proceeds of \$75.0 million, pursuant to a sales agreement with SVB Securities LLC and Cantor Fitzgerald & Co., as sales agents, dated May 20, 2021. We paid selling commissions and other fees of \$2.2 million in connection with the sale.

#### ***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.

#### ***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.

### **Debt Financing**

#### ***Loan and Security Agreement with Silicon Valley Bank***

In March 2020, we entered into a Loan and Security Agreement with 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.

**Cash Flows**

Cash and cash equivalents were \$61.7 million as of September 30, 2022 compared to \$27.3 million as of December 31, 2021. We also had \$186.4 million in short-term marketable securities as of September 30, 2022 compared to \$198.3 million in short- and long-term marketable securities as of December 31, 2021.

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

(In thousands)	Nine Months Ended September 30,	
	2022	2021
Cash and cash equivalents beginning balance	\$ 27,349	\$ 22,063
Net cash used in operating activities	(48,452)	(35,059)
Net cash provided by (used in) investing activities	9,926	(158,456)
Net cash provided by financing activities	72,830	225,054
Cash and cash equivalents ending balance	\$ 61,653	\$ 53,602

**Operating Activities**

Cash flow related to operating activities was the result of:

(In thousands)	Nine Months Ended September 30,	
	2022	2021
Net loss	\$ (59,273)	\$ (68,061)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	8,433	33,826
Change in accounts payable and accrued expenses	(1,046)	(777)
Change in accounts receivable	26	(39)
Change in prepaid expenses and other assets	3,408	(8)
Net cash used in operating activities	\$ (48,452)	\$ (35,059)

Net cash used in operating activities increased for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 primarily as a result of higher net losses after adjusting for non-cash items and a decrease in cash paid for prepaid expenses and other assets.

The decrease in non-cash adjustments to reconcile net loss to net cash used in operating activities was mainly the result of a decrease in revaluation of contingent consideration during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 due to higher discount rates, resulting from higher risk-free rates and wider credit spreads, being applied to potential payments relative to the prior period. We recorded increases during the nine months ended September 30, 2021 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 rheumatoid arthritis, as well as the completion of a Phase 2a clinical trial of ATI-1777 in subjects with atopic dermatitis. Additionally, the inclusion of estimated future sales of zunsemetinib as a potential treatment for hidradenitis suppurativa and psoriatic arthritis, which are additional planned indications for zunsemetinib, also contributed to the increase during the nine months ended September 30, 2021.

The decrease in cash paid for prepaid expenses and other assets resulted from a decrease in the prepaid research and development balance at September 30, 2022 relative to the balance at December 31, 2021, as compared to the prepaid research and development balance at September 30, 2021 relative to the balance at December 31, 2020. Additionally, the decrease resulted from the realization of previously recorded assets during the nine months ended September 30, 2022.

### ***Investing Activities***

Cash flow related to investing activities was the result of:

<b>(In thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
Purchases of property and equipment	\$ (500)	\$ (108)
Purchases of marketable securities	(118,729)	(199,862)
Proceeds from sales and maturities of marketable securities	129,155	41,514
Net cash provided by (used in) investing activities	<u>\$ 9,926</u>	<u>\$ (158,456)</u>

Net cash provided by investing activities for the nine months ended September 30, 2022 compared to net cash used in investing activities for the nine months ended September 30, 2021 primarily resulted from higher sales and maturities of marketable securities during the nine months ended September 30, 2022, which were used to fund our operations, and a reduction of purchases of marketable securities, which were higher during the nine months ended September 30, 2021 following our January 2021 and June 2021 public offerings.

### ***Financing Activities***

Cash flow related to financing activities was the result of:

<b>(In thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	\$ —	\$ 238,200
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	72,744	—
Repayment of debt	—	(11,483)
Payments of employee withholding taxes related to restricted stock unit award vesting	(34)	(3,122)
Proceeds from exercise of employee stock options and the issuance of stock	120	1,459
Net cash provided by financing activities	<u>\$ 72,830</u>	<u>\$ 225,054</u>

Net cash provided by financing activities decreased for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 primarily due to our January 2021 and June 2021 public offerings, partially offset by the proceeds from our April 2022 sale under the at-the-market sales agreement.

### **Funding Requirements**

We anticipate we will incur net losses in the near term as we continue the clinical development of zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immuno-inflammatory diseases, ATI-1777 as a potential treatment for moderate to severe atopic dermatitis and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases, as well as continue the development of our preclinical compounds and discover and develop additional drug candidates. We may not be able to generate revenue from these programs if, among other things, our clinical trials are not successful, the FDA does not approve our drug candidates currently in clinical trials when we expect, or at all, or we are not able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. We expect to add additional personnel to support our operational plans and strategic direction. Our future funding requirements will be heavily determined by the resources needed to support the development of our drug candidates.

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

We believe our existing cash, cash equivalents and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of our condensed consolidated financial statements that appear in Item 1 of this Quarterly Report on Form 10-Q based on our current operating assumptions. We will require additional capital to complete the clinical development of zunsemetinib, ATI-1777 and ATI-2138, to develop our preclinical compounds, and to support our discovery efforts. Additional funds may not be available on a timely basis, on commercially acceptable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Our ability to raise additional capital may be adversely impacted by the potential worsening of global economic conditions, including inflationary pressures, and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic and geopolitical tensions. 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
- our ability to earn revenue as a result of licenses to, or partnerships or other arrangements with, third parties.

#### *Leases*

We occupy space for our headquarters in Wayne, Pennsylvania under a 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 to a third party. 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. Our aggregate remaining lease payment obligations for these two facilities was \$3.1 million as of September 30, 2022.

#### *Agreement and Plan of Merger – Confluence*

Under the Confluence Agreement, we have agreed to pay the former Confluence equity holders aggregate remaining contingent consideration of up to \$75.0 million based upon the achievement of specified future regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders future royalty payments calculated as a low single-digit percentage of annual net sales, subject to specified

reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. In addition to the payments described above, if we sell, license or transfer any of the intellectual property acquired from Confluence pursuant to the Confluence Agreement to a third party, we will be obligated to pay the former Confluence equity holders a portion of any consideration received from such sale, license or transfer in specified circumstances.

#### ***R&D Obligations***

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

#### **Segment Information**

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

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

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

The uncertainty that exists with respect to the economic impact of the global COVID-19 pandemic and ongoing geopolitical tensions has introduced significant volatility in the financial markets during and subsequent to the quarter ended September 30, 2022.

#### **Item 4. Controls and Procedures**

##### *(a) Evaluation of Disclosure Controls and Procedures*

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. The term “disclosure controls and procedures,” as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and

procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 24, 2022.

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

None.

### Item 6. Exhibits

<u>Exhibit No.</u>	<u>Document</u>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
10.1+	<a href="#">Employment Agreement, dated as of August 1, 2022, by and between the Registrant and Douglas Manion (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K (File No. 001-37581), filed with the SEC on August 1, 2022).</a>
31.1*	<a href="#">Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.</a>
31.2*	<a href="#">Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.</a>
32.1**	<a href="#">Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.</a>
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)

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\* Filed herewith.

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

+ Indicates management contract or compensatory plan.



**SIGNATURES**

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

ACLARIS THERAPEUTICS, INC.

Date: November 8, 2022

By: /s/ Neal Walker

Neal Walker  
Chief Executive Officer  
*(On behalf of the Registrant)*

Date: November 8, 2022

By: /s/ Frank Ruffo

Frank Ruffo  
Chief Financial Officer  
*(Principal Financial Officer)*

**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, 2022 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 8, 2022

/s/ Neal Walker  
\_\_\_\_\_  
Neal Walker  
Chief Executive Officer  
(principal executive officer)

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**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, 2022 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 8, 2022

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

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**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, 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, 2022, 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 8th day of November, 2022.

/s/ Neal Walker

\_\_\_\_\_  
Neal Walker  
Chief Executive Officer  
(principal executive officer)

/s/ Frank Ruffo

\_\_\_\_\_  
Frank Ruffo  
Chief Financial 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.

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