# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark one)  $\times$ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 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

# 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)

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:

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

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

Non-accelerated filer

Accelerated filer

Smaller reporting company  $\Box$ 

Emerging growth company  $\Box$ 

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.  $\Box$ 

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 July 29, 2022 was 66,671,750.

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

(Zip Code)

PART I. FINANCIAL INFORMATION

# ACLARIS THERAPEUTICS, INC.

# **INDEX TO FORM 10-Q**

Item 1. Financial Statements	2
Unaudited Condensed Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021	2
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2022 and 2021	3
Unaudited Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2022 and 2021	4
Unaudited Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021	5
Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3. Quantitative and Qualitative Disclosures about Market Risk	34
Item 4. Controls and Procedures	35
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	36
Item 1A. Risk Factors	36
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	36
Item 6. Exhibits	36
Signatures	38

# Part I. FINANCIAL INFORMATION Item 1. Financial Statements

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

# (In thousands, except share and per share data)

	 June 30, 2022	De	cember 31, 2021
Assets			
Current assets:			
Cash and cash equivalents	\$ 68,264	\$	27,349
Short-term marketable securities	180,339		164,065
Accounts receivable, net	637		623
Prepaid expenses and other current assets	 10,114		12,995
Total current assets	259,354		205,032
Marketable securities	7,221		34,242
Property and equipment, net	1,276		1,335
Intangible assets	7,011		7,048
Other assets	3,114		3,554
Total assets	\$ 277,976	\$	251,211
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$ 5,703	\$	9,985
Accrued expenses	7,571		10,051
Current portion of lease liabilities	741		693
Discontinued operations	2,202		2,202
Total current liabilities	 16,217		22,931
Other liabilities	1,840		2,172
Contingent consideration	23,800		28,400
Deferred tax liability	367		367
Total liabilities	 42,224		53,870
Commitments and contingencies (Note 16)			
Stockholders' Equity:			
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued			
or outstanding at June 30, 2022 and December 31, 2021	—		_
Common stock, \$0.00001 par value; 100,000,000 shares authorized at June 30, 2022 and			
December 31, 2021; 66,667,580 and 61,228,446 shares issued and outstanding at			
June 30, 2022 and December 31, 2021, respectively	1		1
Additional paid-in capital	871,805		792,971
Accumulated other comprehensive loss	(1,326)		(224)
Accumulated deficit	 (634,728)		(595,407)
Total stockholders' equity	235,752		197,341
Total liabilities and stockholders' equity	\$ 277,976	\$	251,211

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 June 30,					Six Months Ended June 30,			
		2022	,	2021		2022	,	2021	
Revenues:									
Contract research	\$	1,218	\$	1,606	\$	2,439	\$	3,141	
Other revenue		310		218		542		460	
Total revenue		1,528		1,824		2,981		3,601	
Costs and expenses:									
Cost of revenue		1,068		1,263		2,223		2,465	
Research and development		18,779		7,897		33,085		15,735	
General and administrative		6,075		5,870		12,174		10,697	
Revaluation of contingent consideration		(3,400)		4,800		(4,600)		21,239	
Total costs and expenses		22,522		19,830		42,882		50,136	
Loss from operations		(20,994)	_	(18,006)	_	(39,901)		(46,535)	
Other income (expense), net		462		(155)		580		(380)	
Net loss	\$	(20,532)	\$	(18,161)	\$	(39,321)	\$	(46,915)	
Net loss per share, basic and diluted Weighted average common shares outstanding, basic and	\$	(0.31)	\$	(0.34)	\$	(0.62)	\$	(0.90)	
diluted	6	5,990,031		53,968,405		63,723,123	5	52,163,136	
Other comprehensive loss:									
Unrealized gain (loss) on marketable securities, net of tax of \$0	\$	(254)	¢	25	\$	(1.101)	¢	(10)	
	Э	(354)	\$	25	Э	(1,101)	\$	(10)	
Foreign currency translation adjustment		(254)		(69)		(1.101)		(80)	
Total other comprehensive loss	<u>_</u>	(354)	<u>_</u>	(44)	<u>_</u>	(1,101)	<u>_</u>	(90)	
Comprehensive loss	\$	(20,886)	\$	(18,205)	\$	(40,422)	\$	(47,005)	

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)

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

	Common	Total				
	Shares	Par Value	Paid-in Capital	Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
Balance at December 31, 2020	45,109,314	\$ —	\$ 542,286	\$ (94)	\$ (504,542)	\$ 37,650
Issuance of common stock in connection with exercise of stock options and warrants and vesting of restricted stock						
units	666,144	—	(2,579)	_	_	(2,579)
Issuance of common stock in connection with public						
offering, net of offering costs of \$7,011	6,306,271	—	103,348	—	_	103,348
Unrealized loss on marketable securities	_			(35)	_	(35)
Foreign currency translation adjustment	—	—	—	(11)	—	(11)
Stock-based compensation expense			2,675		—	2,675
Net loss					(28,754)	(28,754)
Balance at March 31, 2021	52,081,729	\$ -	\$ 645,730	\$ (140)	\$ (533,296)	\$ 112,294
Issuance of common stock in connection with vesting of						
restricted stock units	1,024,666		1,041	_	_	1,041
Issuance of common stock in connection with public						
offering, net of offering costs of \$8,899	8,098,592	1	134,851		—	134,852
Unrealized gain on marketable securities		—		25	—	25
Foreign currency translation adjustment				(69)	—	(69)
Stock-based compensation expense	—	—	3,833	—	—	3,833
Net loss					(18,161)	(18,161)
Balance at June 30, 2021	61,204,987	\$ 1	\$ 785,455	\$ (184)	\$ (551,457)	\$ 233,815

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)

	Six Months Ended June 30,			nded
		2022	,	2021
Cash flows from operating activities:				
Net loss	\$	(39,321)	\$	(46,915)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		414		535
Stock-based compensation expense		6,038		6,507
Revaluation of contingent consideration		(4,600)		21,239
Changes in operating assets and liabilities:				
Accounts receivable		(14)		(167)
Prepaid expenses and other assets		1,309		(5,223)
Accounts payable		(4,283)		(1,290)
Accrued expenses		(178)		861
Net cash used in operating activities		(40,635)		(24,453)
Cash flows from investing activities:				
Purchases of property and equipment		(350)		(52)
Purchases of marketable securities		(85,096)		(147,289)
Proceeds from sales and maturities of marketable securities		94,155		26,557
Net cash provided by (used in) investing activities		8,709		(120,784)
Cash flows from financing activities:		· · · ·		
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		
Payments of employee withholding taxes related to restricted stock unit award vesting		(23)		(3,038)
Proceeds from exercise of employee stock options and the issuance of stock		120		1,459
Net cash provided by financing activities		72.841		236.621
Net increase in cash and cash equivalents		40.915		91,384
Cash and cash equivalents at beginning of period		27,349		22,063
Cash and cash equivalents at end of period	\$	68,264	\$	113,447
Supplemental disclosure of non-cash investing and financing activities:	¢	70	¢	27
Additions to property and equipment included in accounts payable	\$ \$	72	\$ \$	37 28
Offering costs included in accounts payable	\$	—	\$	28

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 June 30, 2022, the Company had cash, cash equivalents and marketable securities of \$255.8 million and an accumulated deficit of \$634.7 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 pressure, 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 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 June 30, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021, the condensed consolidated statement of stockholders' equity for the three and six months ended June 30, 2022 and 2021, and the condensed consolidated statements of cash flows for the six months ended June 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 June 30, 2022, the results of its operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021, its changes in stockholders' equity for the three and six months ended June 30, 2022 and 2021 and its cash flows for the six months ended June 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 six months ended June 30, 2022 and 2021 are unaudited. The results for the three and six months ended June 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.

#### **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 June 30, 2022. Additionally, estimated future sales levels and the risk-adjusted discount rate ranged between 10.2% and 10.9% depending on the year of each potential payment.

# 3. Fair Value of Financial Assets and Liabilities

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

	June 30, 2022					
(In thousands)	Level 1	Level 2	Level 3	Total		
Assets:						
Cash equivalents	\$ 63,838	\$ —	\$ —	\$ 63,838		
Marketable securities		187,560	—	187,560		
Total assets	\$ 63,838	\$ 187,560	\$ —	\$ 251,398		
Liabilities:						
Contingent consideration	\$ —	\$ —	\$ 23,800	\$ 23,800		
Total liabilities	\$ —	\$	\$ 23,800	\$ 23,800		
		Decembe	er 31, 2021			
(In thousands)	Level 1	Decembe	er 31, 2021 Level 3	Total		
<u>(In thousands)</u> Assets:	Level 1			Total		
	Level 1 \$ 21,678			<b>Total</b> \$ 21,678		
Assets:		Level 2	Level 3			
Assets: Cash equivalents Marketable securities		<u>Level 2</u> \$ —	Level 3	\$ 21,678		
Assets: Cash equivalents	\$ 21,678 	Level 2 \$ 198,307	Level 3	\$ 21,678 198,307		
Assets: Cash equivalents Marketable securities	\$ 21,678 	Level 2 \$ 198,307	Level 3	\$ 21,678 198,307		
Assets: Cash equivalents Marketable securities	\$ 21,678 	Level 2 \$ 198,307	Level 3	\$ 21,678 198,307		
Assets: Cash equivalents Marketable securities Total assets	\$ 21,678 	Level 2 \$ 198,307	Level 3	\$ 21,678 198,307		
Assets: Cash equivalents Marketable securities Total assets Liabilities:	\$ 21,678  <u>\$ 21,678</u>	Level 2 \$ 198,307 <u>\$ 198,307</u>	Level 3 \$ \$	\$ 21,678 198,307 \$ 219,985		

As of June 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 June 30, 2022 and December

31, 2021 consisted of commercial paper and corporate, asset-backed and U.S. government agency debt securities, which were all valued based upon Level 2 inputs. Marketable securities as of December 31, 2021 also included foreign government agency debt securities which were all valued based upon Level 2 inputs.

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

A decrease in the fair value of the contingent consideration liability of \$4.6 million during the six months ended June 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 overall decrease was partially offset by an increase in the contingent consideration liability as a result of the impact of the passage of time.

As of June 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:

	June 30, 2022				
(In thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	
Marketable securities:					
Corporate debt securities	\$ 47,201	\$	\$ (398)	\$ 46,803	
Commercial paper	56,053		—	56,053	
Asset-backed debt securities <sup>(1)</sup>	28,423	—	(175)	28,248	
U.S. government agency debt securities	57,211		(755)	56,456	
Total marketable securities	\$ 188,888	\$ —	\$ (1,328)	\$ 187,560	
<sup>(1)</sup> Included in Asset-backed debt securities is \$7.2 million with maturity dates between one and five years					

(1) Included in Asset-backed debt securities is \$7.2 million with maturity dates between one and five years.

	December 31, 2021							
(In thousands)	Ar	nortized Cost	Unre	ross ealized ain	Uni	Gross realized 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 agency debt securities <sup>(2)</sup>		45,465		—		(127)		45,338
Total marketable securities	\$ 1	98,534	\$	6	\$	(233)	\$	198,307
(1) Included in Corporate debt securities is \$9.2 million with maturity dates between one and five years.								

(2) Included in US government agency 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)	June 30, 2022		De	cember 31, 2021
Computer equipment	\$	1,355	\$	1,380
Lab equipment		1,879		1,605
Furniture and fixtures		620		620
Leasehold improvements		1,123		1,123
Property and equipment, gross		4,977		4,728
Accumulated depreciation		(3,701)		(3,393)
Property and equipment, net	\$	1,276	\$	1,335

Depreciation expense was \$0.2 million for each of the three months ended June 30, 2022 and 2021, and \$0.4 million for each of the six months ended June 30, 2022 and 2021.

# 5. Intangible Assets

Intangible assets consisted of the following:

			Gro	st	A	ccumulat	ed An	ortization																																														
	Remaining		June 30, December 31,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30,		June 30, December 3		June 30, December 31,		June 30, December 31,		June 30,		J	une 30,	De	ecember 31,																
(In thousands, except years)	Life (years)		2022		2022		2022		2021	2022		2021																																										
Other intangible assets	5.1	\$	751	\$	751	\$	369	\$	332																																													
In-process research and development	n/a		6,629		6,629				_																																													
Total intangible assets		\$	7,380	\$	7,380	\$	369	\$	332																																													

Amortization expense was \$19 thousand for each of the three months ended June 30, 2022 and 2021, and \$38 thousand for each of the six months ended June 30, 2022 and 2021.

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

	Year Ending
(In thousands)	December 31,
2022	\$ 37
2023	75
2024	75
2025	75
2026	75
Thereafter	45
Total	\$ 382

# 6. Accrued Expenses

Accrued expenses consisted of the following:

	June 30,		December 31,			
(In thousands)	2022			2021		
Employee compensation expenses	\$	2,885	\$	4,389		
Research and development expenses		2,771		1,278		
Litigation settlements (see Note 16)				2,650		
Other		1,915		1,734		
Total accrued expenses	\$	7,571	\$	10,051		

# 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 June 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 June 30, 2022 or December 31, 2021.

## **Common Stock**

As of June 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 66,667,580 and 61,228,446 shares of common stock issued and outstanding as of June 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 June 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 June 30, 2022, 3,372,766 shares remained available for grant under the 2015 Plan. The Company had 4,130,376 stock options and 1,454,934 RSUs outstanding as of June 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 410,600 stock options and 2,375 RSUs outstanding as of June 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 June 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 six months ended June 30, 2022 and 2021 were as follows:

	Six Months Ended June 30,				
	2022	2021			
Risk-free interest rate	1.90 %	0.91 %			
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 six months ended June 30, 2022:

(In thousands, except share and per share data and years)	Number of Shares	A	Veighted Average Exercise Price	Weighted Average Remaining Contractual <u>Term</u> (in years)	eggregate Intrinsic Value
Outstanding as of December 31, 2021	3,792,450	\$	17.50	6.8	\$ 13,710
Granted	1,891,950		14.40		
Exercised	(85,672)		1.40		1,115
Forfeited and cancelled	(583,775)		15.70		
Outstanding as of June 30, 2022	5,014,953	\$	16.81	7.1	\$ 10,817
Options vested and expected to vest as of June 30, 2022	5,014,953	\$	16.81	7.1	\$ 10,817
Options exercisable as of June 30, 2022	2,519,499	\$	18.26	4.8	\$ 7,784

The weighted average grant date fair value of stock options granted during the six months ended June 30, 2022 was \$9.89 per share.



# **Restricted Stock Units**

The following table summarizes RSU activity for the six months ended June 30, 2022:

		Weighted							
		Average							
		Gr	ant Date	Α	ggregate				
	Number	Fa	ir Value	I	ntrinsic				
(In thousands, except share and per share data)	of Shares	Pe	er Share		Value				
Outstanding as of December 31, 2021	1,496,946	\$	12.75						
Granted	720,134		14.44						
Vested	(513,958)		11.55	\$	7,645				
Forfeited and cancelled	(245,813)		12.17						
Outstanding as of June 30, 2022	1,457,309	\$	14.11						

#### **Stock-Based Compensation**

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

	Three Months Ended June 30,					Six Mont Jun		nded
(In thousands)	2022 2021		2021	2022		2021		
Cost of revenue	\$	302	\$	335	\$	530	\$	582
Research and development		941		1,154		828		2,030
General and administrative		2,449		2,343		4,680		3,895
Total stock-based compensation expense	\$	3,692	\$	3,832	\$	6,038	\$	6,507

As of June 30, 2022, the Company had unrecognized stock-based compensation expense for stock options and RSUs of \$23.7 million and \$18.3 million, respectively, which is expected to be recognized over weighted average periods of 3.2 years and 3.0 years, respectively.

#### 10. Net Loss per Share

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

		Three Months Ended June 30,					onths Ended une 30,							
(In thousands, except for share and per share data)		2022 2021			2022			2022		2021				
Numerator:														
Net loss	\$	(20,532)	\$	(18,161)	\$	(39,321)	\$	(46,915)						
Denominator:														
Weighted average shares of common stock														
outstanding, basic and diluted	65,990,031		65,990,031 53,968,40		63,723,123		5	2,163,136						
Net loss per share, basic and diluted	\$	\$ (0.31)		\$ (0.31)		\$ (0.31)		(0.31) \$ (0.34)		(0.34)	\$ (0.62)		\$ (0.90)	

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

	June	e 30,
	2022	2021
Options to purchase common stock	5,014,953	3,738,625
Restricted stock unit awards	1,457,309	1,498,716
Total potential shares of common stock	6,472,262	5,237,341

# 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-sublease 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:

In thousands) Dperating Leases:		June 30, 2022	D	ecember 31, 2021
Gross cost	\$	5,240	\$	5,240
Accumulated amortization		(2,173)		(1,803)
Other assets	\$	3,067	\$	3,437
Current portion of lease liabilities	\$	741	\$	693
Other liabilities		1,820		2,151
Total operating lease liabilities	\$	2,561	\$	2,844

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 June 30, 2022 and 2021 and \$0.5 million for each of the six months ended June 30, 2022 and 2021.

# 12. Agreements Related to Intellectual Property

#### Asset Purchase Agreement - EPI Health, LLC

In October 2019, the Company sold RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") to EPI Health, LLC ("EPI Health") pursuant to an asset purchase agreement. EPI Health agreed to pay the Company a high single-digit royalty calculated as a percentage of net sales on a country-by-country basis until the date that the patent rights related to RHOFADE have expired or, if later, ten years from the date of the first commercial sale of RHOFADE in such country. The Company recorded royalty income under the asset purchase agreement of \$0.3 million and \$0.2 million

during the three months ended June 30, 2022 and 2021, respectively, and \$0.5 million and \$0.4 million during the six months ended June 30, 2022 and 2021, respectively. Royalty income is included in other revenue on the condensed consolidated statements of operations and comprehensive loss. EPI Health has also agreed to pay the Company potential sales milestone payments of up to \$20.0 million in the aggregate upon the achievement of specified levels of net sales of products covered by the asset purchase agreement, and 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the disposition in any territory outside of the United States, subject to specified exceptions.

#### Agreement and Plan of Merger - Confluence

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 June 30, 2022 and December 31, 2021, the balance of the Company's contingent consideration liability was \$23.8 million and \$28.4 million, respectively (see Note 3).

# 13. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three and six months ended June 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:

	J	une 30,	Dec	cember 31,		
(In thousands)		2022	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 six months ended June 30, 2022 and 2021 are summarized in the tables below:

(In thousands) Three Months Ended June 30, 2022	ть	erapeutics		ontract esearch		rporate I Other	C	Total ompany
Total revenue	\$	309	\$	4,399	_	(3,180)	\$	1,528
Cost of revenue	φ	507	φ	4,041	φ	(2,973)	φ	1,068
Research and development		18,986				(207)		18,779
General and administrative				854		5,221		6,075
Revaluation of contingent consideration		(3,400)						(3,400)
Loss from operations	\$	(15,277)	\$	(496)	\$	(5,221)	\$	(20,994)
(In thousands)			С	ontract	Со	rporate		Total
<u>Three Months Ended June 30, 2021</u>	Th	erapeutics	R	esearch	and	l Other	C	ompany
Total revenue	\$	218	\$	3,481	\$	(1,875)	\$	1,824
Cost of revenue		—		3,024		(1,761)		1,263
Research and development		8,011		_		(114)		7,897
Sales and marketing		_		_		_		-
General and administrative		—		879		4,991		5,870
Revaluation of contingent consideration		4,800		-		-		4,800
Loss from operations	\$	(12,593)	\$	(422)	\$	(4,991)	\$	(18,006)
(In thousands)	aru.			ontract		rporate	~	Total
Six Months Ended June 30, 2022	<u>1h</u> \$	erapeutics	_	esearch	_	l Other	_	ompany
Total revenue	\$	541	\$	8,495	\$	(6,055)	\$	2,981
Cost of revenue		22 466		7,897		(5,674) (381)		2,223 33,085
Research and development General and administrative		33,466		1,695		10,479		12,174
Revaluation of contingent consideration		(4,600)		1,095		10,479		(4,600)
Revaluation of contingent consideration		(4,000)				10,479)	\$	(39,901)
Loss from operations	¢	(28 225)	¢	(1.007)	¢ (			(39,901)
Loss from operations	\$	(28,325)	\$	(1,097)	\$ (	10,479)	Ф	
Loss from operations (In thousands)	\$	(28,325)		(1,097) ontract		rporate	\$	Total
		(28,325) erapeutics	C	( ))	Co		·	Total ompany
(In thousands)			C	ontract	Con and	rporate	·	
(In thousands) <u>Six Months Ended June 30, 2021</u>	Th	erapeutics	C R	ontract esearch	Con and	rporate <u>l Other</u>	<u> </u>	ompany
(In thousands) <u>Six Months Ended June 30, 2021</u> Total revenue	Th	erapeutics 460	C R	ontract esearch 6,681	Con and	rporate <u>I Other</u> (3,540)	<u> </u>	ompany 3,601
(In thousands) <u>Six Months Ended June 30, 2021</u> Total revenue Cost of revenue	Th	erapeutics 460	C R	ontract esearch 6,681	Con and	rporate <u>1 Other</u> (3,540) (3,328)	<u> </u>	ompany 3,601 2,465
(In thousands) <u>Six Months Ended June 30, 2021</u> Total revenue Cost of revenue Research and development	Th	erapeutics 460	C R	ontract esearch 6,681 5,793	Con <u>anc</u> \$	rporate <u>1 Other</u> (3,540) (3,328) (211)	<u> </u>	ompany 3,601 2,465 15,735

# **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 June 30, 2022 and 2021, respectively, and \$6.1 million and \$3.5 million for the six months ended June 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 immunoinflammatory 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 2023.

#### Moderate to Severe Hidradenitis Suppurativa

In December 2021, we initiated study activities in a Phase 2a, randomized, multicenter, double-blind, placebocontrolled 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, and seeks to enroll approximately 70 subjects in the United States. The primary endpoint is the change in inflammatory nodule and abscess count at week 12. We expect topline data in the first half of 2023.

#### Moderate to Severe Psoriatic Arthritis

In June 2022, we initiated study activities in a Phase 2a, randomized, multicenter, double-blind, placebocontrolled 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 12week treatment period and a 30-day follow-up period, and seeks to enroll approximately 70 subjects in the United States and in Poland. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We expect topline data in the first half of 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, parallelgroup 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, vehiclecontrolled, 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 ITJ Inhibitor

We are developing ATI-2138, an investigational oral 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. We submitted an Investigational New Drug application, or IND, for ATI-2138 for the treatment of psoriasis in October 2021, which 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). We expect topline data in 2022.

If the Phase 1 SAD trial is successful, we currently plan to initiate a Phase 1 multiple ascending dose (MAD) trial of ATI-2138 in subjects with psoriasis in 2022, with topline data expected in the first half of 2023. We are also currently exploring alternative indications that are relevant to the mechanism of action, which may impact the trial design and require the submission of additional INDs to different reviewing divisions of the FDA before we can conduct further clinical trials.

#### **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 may 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 \$39.3 million for the six months ended June 30, 2022 and \$90.9 million for the year ended December 31, 2021. As of June 30, 2022, we had an accumulated deficit of \$634.7 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 virtual operations strategy, including teleworking, staggered work schedules for lab personnel and other alternative work arrangements for our employees, intended to protect the health and safety of our employees while enabling us to continue to develop our drug candidates and provide contract research services to our clients. We are focused on ensuring the continuity of our operations. However, COVID-19 has caused disruptions to our business.

If COVID-19 continues to spread, we may experience additional disruptions that could severely impact our business, results of operations and prospects, including the timing of our development programs and our clinical trials, including our trials of zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immunoinflammatory 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 RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which included the assignment of certain licenses for related intellectual property assets, or the Disposition.

Pursuant to the asset purchase agreement, EPI Health paid us 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 RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country and (iii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the Disposition in any territory outside of the United States, subject to specified exceptions. In addition, EPI Health has agreed to assume our obligation to pay specified royalties and milestone payments under certain agreements with third parties.

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

# Revenue

# **Contract Research**

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

### **Other Revenue**

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

## **Cost of Revenue**

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

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

# **Research and Development Expenses**

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

- expenses incurred under agreements with contract research organizations, or CROs, as well as clinical trial sites and consultants that conduct our clinical trials and preclinical studies, and investigator-initiated trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing active pharmaceutical
  ingredients and preclinical and clinical trial materials, including domestic technology transfer expenses;
- 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 Expenses**

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

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

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

#### Other 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 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 June 30, 2022 compared to between 4% and 40% at June 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 10.2% and 10.9% depending on the year of each potential payment.

During the six months ended June 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 a decrease in contingent consideration of \$4.6 million. The overall decrease was partially offset by the increase in contingent consideration as a result of the impact of the passage of time.

During the six months ended June 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 \$21.2 million.

### **Results of Operations**

#### Comparison of Three and Six Months Ended June 30, 2022 and 2021

	Three	une 30,	S	Six Months Ended June 30,							
(In thousands)	2022	_	2021		Change	2022			2021	(	Change
Revenues:											
Contract research	\$ 1,218	8	\$ 1,60	6	\$ (388)	\$ 2,4	39	\$	3,141	\$	(702)
Other revenue	310	)	21	8	92	5	42		460		82
Total revenue	1,528	3	1,82	4	(296)	2,9	81		3,601		(620)
Costs and expenses:											
Cost of revenue	1,068	3	1,26	3	(195)	2,2	23		2,465		(242)
Research and development	18,779	)	7,89	7	10,882	33,0	85		15,735		17,350
General and administrative	6,075	5	5,87	0	205	12,1	74		10,697		1,477
Revaluation of contingent consideration	(3,400	))	4,80	0	(8,200)	(4,6	00)		21,239	(	(25,839)
Total costs and expenses	22,522	2	19,83	0	2,692	42,8	82		50,136		(7,254)
Loss from operations	(20,994	ł)	(18,00	6)	(2,988)	(39,9	01)	(	(46,535)		6,634
Other income (expense), net	462	2	(15	5)	617	5	80		(380)		960
Net loss	\$ (20,532	2)	\$ (18,16	1)	\$ (2,371)	\$ (39,3	21)	\$	(46,915)	\$	7,594

#### Revenue

Contract research revenue was \$1.2 million and \$1.6 million for the three months ended June 30, 2022 and 2021, respectively, and was comprised of fees earned from the provision of laboratory services. The \$0.4 million decrease was driven by lower overall hours billed, partially offset by a higher average billing rate. Other revenue for the three months ended June 30, 2022 and 2021 primarily consisted of \$0.3 million and \$0.2 million of royalties earned on net sales of RHOFADE, respectively.

Contract research revenue was \$2.4 million and \$3.1 million for the six months ended June 30, 2022 and 2021, respectively, and was comprised of fees earned from the provision of laboratory services. The \$0.7 million decrease was driven by lower overall hours billed, partially offset by a higher average billing rate. Other revenue for the six months ended June 30, 2022 and 2021 primarily consisted of \$0.5 million and \$0.4 million of royalties earned on net sales of RHOFADE, respectively.

#### **Cost of Revenue**

Cost of revenue was \$1.1 million and \$2.2 million for the three and six months ended June 30, 2022, respectively, and \$1.3 million and \$2.5 million for the three and six months ended June 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 six months ended June 30, 2022 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 Expenses**

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

	Three	ee Months E June 30,	nded	Six Months Ended June 30,				
(In thousands)	2022	2021 Change		2022	2021	Change		
Zunsemetinib	\$ 6,606	\$ 2,252	\$ 4,354	\$ 11,318	\$ 4,325	\$ 6,993		
ATI-1777	3,510	497	3,013	5,866	1,444	4,422		
ATI-2138	1,141	967	174	2,267	2,350	(83)		
ATI-2231	1,503	70	1,433	3,089	70	3,019		
Discovery	1,183	774	409	2,272	1,466	806		
Other research and development	343	385	(42)	665	800	(135)		
Personnel	3,552	1,798	1,754	6,780	3,250	3,530		
Stock-based compensation	941	1,154	(213)	828	2,030	(1,202)		
Total research and development expenses	\$ 18,779	\$ 7,897	\$ 10,882	\$ 33,085	\$ 15,735	\$ 17,350		

#### Zunsemetinib

The increase in expenses for zunsemetinib during the three and six months ended June 30, 2022 compared to the three and six months ended June 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 and start-up activities for a Phase 2a trial in subjects with psoriatic arthritis, which initiated in June 2022.

# ATI-1777

The increase in expenses for ATI-1777 during the three and six months ended June 30, 2022 compared to the three and six months ended June 30, 2021 was primarily due to higher costs associated with drug candidate manufacturing and other preclinical development activities as well start-up 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

Expenses for ATI-2138 were relatively flat during the three and six months ended June 30, 2022 compared to the three and six months ended June 30, 2021 due to a decrease in preclinical development activities and IND-enabling study expenses following our IND submission in October 2021, offset by clinical development expenses associated with a Phase 1 SAD trial, which initiated in December 2021.

#### ATI-2231

Expenses for ATI-2231 were higher during the three and six months ended June 30, 2022 compared to the three and six months ended June 30, 2021 primarily due to preclinical development activities and IND-enabling studies.

#### Discovery

Expenses related to discovery increased during the three and six months ended June 30, 2022 compared to the three and six months ended June 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 six months ended June 30, 2022 compared to the three and six months ended June 30, 2021 primarily due to an increase in costs associated with higher average headcount. For the six months ended June 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 between the period.

### **General and Administrative Expenses**

The following table summarizes our general and administrative expenses:

	Thre	e Months Ei June 30,	nded	Six Months Ended June 30,				
(In thousands)	2022	2021	Change	2022	2021	Change		
Personnel	\$ 1,365	\$ 1,147	\$ 218	\$ 2,938	\$ 2,106	\$ 832		
Professional and legal fees	1,160	1,336	(176)	2,289	2,691	(402)		
Facility and support services	482	414	68	1,091	812	279		
Other general and administrative	619	630	(11)	1,176	1,193	(17)		
Stock-based compensation	2,449	2,343	106	4,680	3,895	785		
Total general and administrative expenses	\$ 6,075	\$ 5,870	<u>\$ 205</u>	\$ 12,174	\$ 10,697	\$ 1,477		

# Personnel and stock-based compensation

Personnel and stock-based compensation expenses in the aggregate increased during the three and six months ended June 30, 2022 compared to the three and six months ended June 30, 2021 primarily due to an increase in costs associated with 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 six months ended June 30, 2022 compared to the three and six months ended June 30, 2021 primarily as a result of lower legal fees, partially offset by higher Sarbanes-Oxley and other accounting compliance expenses.

# Facility and support services

Facility and support services, including general office expenses, information technology costs and other expenses, was relatively flat during the three months ended June 30, 2022 compared to the three months ended June 30, 2021.

Facility and support services, including general office expenses, information technology costs and other expenses, increased during the six months ended June 30, 2022 compared to the six months ended June 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 decrease in the fair value of our contingent consideration liability during the three months ended June 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 in 2022. Additionally, increases recorded during the three months ended June 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 ATI-1777 in subjects with atopic dermatitis contributed to the decrease.

The decrease in the fair value of our contingent consideration liability during the six months ended June 30, 2022 compared to the six months ended June 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 prior periods in 2022. Additionally, increases recorded during the six months ended June 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 six months ended June 30, 2021.

# Other Income (Expense), net

Other income (expense), net increased during the three and six months ended June 30, 2022 compared to the three and six months ended June 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 from EPI Health in connection with the sale of RHOFADE. 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 June 30, 2022, we had cash, cash equivalents and marketable securities of \$255.8 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 Pursuant to At-the-Market Offering

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 \$68.3 million as of June 30, 2022 compared to \$27.3 million as of December 31, 2021. We also had \$187.6 million in short- and long-term marketable securities as of June 30, 2022 compared to \$198.3 million as of December 31, 2021.

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

	Six Months Ended June 30,			
(In thousands)		2022		2021
Cash and cash equivalents beginning balance	\$	27,349	\$	22,063
Net cash used in operating activities		(40,635)		(24,453)
Net cash provided by (used in) investing activities		8,709		(120,784)
Net cash provided by financing activities		72,841		236,621
Cash and cash equivalents ending balance	\$	68,264	\$	113,447

#### **Operating** Activities

Cash flow related to operating activities was the result of:

	Six Months Ended June 30,			
(In thousands)	2022		2021	
Net loss	\$	(39,321)	\$	(46,915)
Non-cash adjustments to reconcile net loss to net cash used in operating activities		1,852		28,281
Change in accounts payable and accrued expenses		(4,461)		(429)
Change in accounts receivable		(14)		(167)
Change in prepaid expenses and other assets		1,309		(5,223)
Net cash used in operating activities	\$	(40,635)	\$	(24,453)

Net cash used in operating activities increased for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 primarily as a result of higher net losses after adjusting for non-cash items and an increase in cash paid for accounts payable and accrued expenses. The increase was partially offset by 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 six months ended June 30, 2022 compared to the six months ended June 30, 2021 due to higher discount rates, resulting from higher risk-free rates and wider credit spreads, being applied to potential payments relative to prior periods in 2022. Additionally, increases recorded during the six months ended June 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 six months ended June 30, 2021.

The increase in cash paid for accounts payable and accrued expenses was primarily driven by the timing of receipt and payment of invoices around quarter-end relative to the prior year period. The decrease in cash paid for prepaid expenses and other assets resulted from an increase in the prepaid research and development balance at June 30, 2021 relative to the balance at December 31, 2020, as compared to the prepaid research and development balance at June 30, 2022 which was flat relative to the balance at December 31, 2021.

#### **Investing** Activities

Cash flow related to investing activities was the result of:

	Six Months Ended June 30,			
(In thousands)		2022		2021
Purchases of property and equipment	\$	(350)	\$	(52)
Purchases of marketable securities		(85,096)		(147,289)
Proceeds from sales and maturities of marketable securities		94,155		26,557
Net cash provided by (used in) investing activities	\$	8,709	\$	(120,784)

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

# **Financing** Activities

Cash flow related to financing activities was the result of:

	Six Months Ended June 30,			ided
(In thousands)	2022		2021	
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		_
Payments of employee withholding taxes related to restricted stock unit award vesting		(23)		(3,038)
Proceeds from exercise of employee stock options and the issuance of stock		120		1,459
Net cash provided by financing activities	\$	72,841	\$	236,621

Net cash provided by financing activities decreased for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 primarily due to our January 2021 and June 2021 public offerings, partially offset by our April 2022 sales 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 spaces was \$3.3 million as of June 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 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 June 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 June 30, 2022, the end of the period covered by this Ouarterly Report on Form 10-O. 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 June 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 June 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

Exhibit No.	Document
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on June 24, 2020).
10.1*+	Employment Agreement, dated as of June 27, 2022, by and between the Registrant and Gail Cawkwell.
10.2+	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).
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document

- 101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document
  - 104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup> 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.

<sup>+</sup> Indicates management contract or compensatory plan.

<sup>37</sup> 

## 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.

Date: August 3, 2022

ACLARIS THERAPEUTICS, INC.

By: /s/ Neal Walker

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

Date: August 3, 2022

By: /s/ Frank Ruffo

Frank Ruffo Chief Financial Officer (Principal Financial Officer)

## **EMPLOYMENT AGREEMENT**

This EMPLOYMENT AGREEMENT (the "*Employment Agreement*"), effective as of June 27, 2022 ("*Agreement Effective Date*"), is made by and between Aclaris Therapeutics, Inc., a corporation organized under the laws of the State of Delaware ("*Employer*") and Gail Cawkwell ("*Executive*").

WHEREAS, Executive desires to provide services to Employer and Employer desires to retain the services of Executive;

WHEREAS, Employer and Executive desire to formalize the terms and conditions of Executive's employment with Employer; and

WHEREAS, this Employment Agreement has been duly approved and its execution has been duly authorized by the Employer's Board of Directors (the "*Board*").

NOW, THEREFORE, Employer and Executive hereby agree as follows:

## **SECTION 1. EMPLOYMENT**

**1.1 General.** Employer hereby agrees to employ Executive in the capacity of Chief Medical Officer ("*CMO*"). Executive hereby accepts such employment upon the terms and subject to the conditions herein contained.

**1.2** Authority and Duties. Executive shall have full responsibility as the CMO of Employer and all authority normally accorded to such position. Executive agrees to perform such duties and responsibilities commensurate with the position of CMO as may reasonably be determined by the Board.

**1.2.1 Reporting.** During Executive's employment with Employer, Executive will report directly to, and take direction from, the Chief Executive Officer (the "*CEO*").

**1.2.2 Time to Be Devoted to Employment.** During Executive's Employment with Employer, Executive shall diligently devote her efforts, business time, attention and energies to the business of Employer and will not, while employed by Employer, undertake or engage in any other employment, occupation or business enterprise that would interfere with Executive's responsibilities and the performance of Executive's duties hereunder except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; and (iii) reasonable time devoted to service as a member of the board of directors of the entities listed on Exhibit A or as otherwise permitted pursuant to Section 1.3. This restriction shall not, however, preclude Executive (x) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (y) from employment or service in any capacity with Affiliates of Employer. As used in this Employment Agreement, "Affiliates" means an entity under common management or control with Employer.

Other Responsibilities. Notwithstanding Section 1.2.2 above, Executive will not 1.3 engage in any other for-profit business, profession or occupation, including as a member of a board of directors of any third party, for compensation which would materially conflict or materially interfere with the rendition of services hereunder, without the prior written consent of the Board, which shall not be unreasonably withheld. Any uncertainty as to whether such a conflict exists will be raised by Executive for determination by the Board, acting reasonably. The Board acknowledges that Executive has ongoing participation in other private and public businesses that have been disclosed by Executive and are listed on Exhibit A and that such participation does not, in any way, conflict with her role at Employer. Except for the businesses listed on Exhibit A. which have already been approved, Executive agrees to disclose to the Board and receive prior written consent from the Board to participate as a director, with any competing company whether it is a private or public company. Executive further agrees to disclose any other director positions with any other company that may materially affect her ability to perform her duties and responsibilities under this Employment Agreement. Notwithstanding the above, nothing herein shall limit or preclude Executive from managing any passive investments made by Executive.

**1.4** Location of Employment. Executive's principal place of employment during her employment with Employer shall be Executive's primary residence (or other remote work location) or such other location as Employer and Executive shall agree; provided however, that from time to time Executive may be required to travel to Employer's principal executive office currently located in Wayne, Pennsylvania.

## **SECTION 2. COMPENSATION AND BENEFITS**

**2.1** Salary. Employer will pay to Executive an annual base salary of \$480,000 payable subject to standard federal and state payroll withholding requirements in accordance with the regular payroll practices of Employer ("*Base Salary*"). The annual Base Salary may be increased (but not decreased) during the term of this Employment Agreement by the Board in its sole discretion.

**2.2** Additional Compensation. In addition to the salary set forth in Section 2.1, Executive shall be entitled to receive a cash bonus in accordance with the terms of this Section 2.2. For each fiscal year of Employer, beginning January 1, during the Employment Term (as defined in Section 2.5 hereof), Executive shall be eligible to receive a cash bonus based on (i) the "*Annual Bonus Expectancy Amount*," which shall be an amount equal to 40% of Executive's Base Salary for the applicable fiscal year, and (ii) Executive's attainment of performance targets and other reasonable criteria established by the Board, to the extent possible, by the end of the first month of such fiscal year. Depending on the targets and criteria which are achieved or met, the amount of the cash bonus actually payable to Executive for each fiscal year will be an amount from zero to and including the Annual Bonus Expectancy Amount. Any cash bonus amount payable pursuant to this Section 2.2 shall be paid to Executive as soon as practicable, but in no event later than two and one-half (2 1/2) months, following the end of the fiscal year to which it relates. For the avoidance of doubt, Executive does not have to be employed by Employer on the date such bonus is approved or paid by Employer to receive such bonus.

**2.3** Signing Bonus. Within thirty (30) days of the Agreement Effective Date, Employer will pay Employee a one-time signing bonus in the amount of \$25,000 (the "Signing Bonus"), subject to standard federal and state payroll withholding requirements in accordance with the regular payroll practices of Employer. If, within twelve (12) months from the Agreement Effective Date, Executive terminates her employment with the Company without Good Reason or the Company terminates Executive's employment for Cause, then Executive will promptly repay a percentage of the Signing Bonus equal to the following: 1 - (x / 365), where "x" equals Executive's total number of days of service as an employee of the Company.

**2.4 Executive Benefits.** In addition to the salary and additional compensation set forth in Sections 2.1 through 2.3, Executive shall also be entitled to the following benefits during Executive's employment hereunder:

**2.4.1 Expenses.** Employer will promptly reimburse Executive for expenses she reasonably incurs in connection with the performance of her duties (including business travel and entertainment expenses), in accordance with Employer's standard expense reimbursement policy, as the same may be modified by Employer from time to time; provided, however, that Executive has provided Employer with documentation of such expenses in accordance with the Employer's expense reimbursement policies and applicable tax requirements. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "*Code*"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Employment Agreement will not be subject to liquidation or exchange for another benefit.

**2.4.2 Employer Plans.** Executive will be eligible to participate on the same basis as similarly situated employees in Employer's employee benefit plans and programs, as they may be interpreted, adopted, revised or deleted from time to time in Employer's sole discretion, subject to and on a basis consistent with the terms, conditions and overall administration of such plans and programs. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. Employer retains the unilateral right to amend, modify or terminate any of its employee benefit plans and programs at any time.

**2.4.3 Vacation**. Executive shall be eligible for paid vacation leave (not including regular holidays) consistent with the needs of the business. Vacation must be scheduled at those times convenient to Employer's business as reasonably determined by the CEO.

**2.4.4 Coverage**. Nothing in this Employment Agreement shall prevent Executive from participating in any other compensation plan or benefit plan made available to her by Employer.

**2.4.5 Withholding**. All compensation shall be subject to withholding of taxes and deductions of other amounts as may be required by law.

**2.5** Employment Term. Unless earlier terminated pursuant to Section 3.1, Executive's employment by Employer pursuant to this Employment Agreement shall continue until the second anniversary of the Agreement Effective Date (the "*Initial Term*"). Thereafter, this Employment Agreement shall be automatically renewed for successive one (1) year periods (any subsequent employment period being referred to herein as the "*Renewal Term*", and together with the Initial Term, the "*Employment Term*"); provided, however, that either party may elect to not renew this Employment Agreement by written notice to such effect delivered to the other party at least ninety (90) days prior to expiration of the Initial Term or the Renewal Term.

## **SECTION 3. TERMINATION OF EMPLOYMENT**

**3.1** Events of Termination. Executive's employment with Employer will terminate upon the occurrence of any one or more of the following events:

**3.1.1 Death.** In the event of Executive's death, Executive's employment will terminate on the date of death.

**3.1.2 Disability.** In the event of Executive's Disability (as hereinafter defined), Employer will have the option to terminate Executive's employment by giving a notice of termination to Executive. The notice of termination shall specify the date of termination, which date shall not be earlier than thirty (30) calendar days after the notice of termination is given. For purposes of this Employment Agreement, "*Disability*" has the meaning set forth in Employer's long term disability plan.

**3.1.3 Termination by Employer for Cause.** Employer may, at its option, terminate Executive's employment for Cause (as hereinafter defined) by unilateral action of the Board of Directors upon giving a notice of termination to Executive. "*Cause*" shall mean (i) Executive's conviction of, or guilty plea to, a felony (other than traffic violations); (ii) any act(s) or omission(s) by Executive which constitutes gross negligence or a material breach of Executive's duty of loyalty; (iii) any material breach by Executive of Employer's personnel policies; (iv) refusal to follow or implement a clear and reasonable directive of Employer; (v) breach of fiduciary duty; or (vi) a material violation or breach by Executive of this Employment Agreement (other than an event described in the foregoing clauses) or any other agreement between the parties.

**3.1.4 Without Cause By Employer.** Employer may, at its option, terminate Executive's employment for any reason whatsoever (other than for the other reasons set forth above in this Section 3.1 that would constitute "Cause" to terminate) by giving a notice of termination to Executive, and Executive's employment shall terminate on the later of the date the notice of termination is given or the date set forth in such notice of termination.

**3.1.5 By Executive.** Executive may, at any time, terminate Executive's employment for any reason whatsoever by giving a notice of termination to Employer. Executive's employment shall terminate on the earlier of (i) thirty (30) calendar days after the date of receipt by Employer of the notice of termination or (ii) such earlier date as the Employer and Executive shall agree.

**3.1.6 Termination Upon Non-Renewal.** Either party may terminate this Employment Agreement and Executive's employment hereunder by providing the other party notice in accordance with Section 2.5 above, in which case this Employment Agreement and Executive's employment hereunder shall terminate on the last date of the Initial Term or the Renewal Term, as the case may be. For the avoidance of doubt, Executive shall continue to be employed by Employer, on the same terms and conditions as set forth in this Employment Agreement during the ninety (90)-day notice period provided by either party to the other party in accordance with Section 2.5 above, unless, Employer, in its sole discretion determines that it does not want Executive to continue to work for Employer, in any capacity, during such notice period. In such event, Employer shall pay Executive all compensation in accordance with Section 3.2.3.

**3.1.7 For Good Reason by Executive**. Executive may, at her option, terminate Executive's employment for "*Good Reason*" by giving a notice of termination to Employer in the event that, in the absence of events that would support a termination of Executive for Cause:

(i) there is a material failure of Employer (or successor employer) to pay Executive's salary or additional compensation or benefits hereunder in accordance with this Employment Agreement;

consent;

(ii) Executive's Base Salary is materially decreased without her prior written

(iii) Executive is assigned duties materially inconsistent with her title and the responsibilities set forth in Executive's job description, without Executive's prior written consent;

(iv) Executive's place of employment is changed to a location that is greater than fifty (50) miles from Executive's current place of employment (disregarding for this purpose any remote work arrangements); or

(v) any other material violation or breach by Employer of this Employment Agreement. Notwithstanding the foregoing, none of the events described in clauses (i) through (iv) above shall constitute Good Reason unless Executive shall have notified Employer in writing describing the event which constitute Good Reason within thirty (30) days after Executive first becomes aware of such event and then only if Employer shall have failed to reasonably cure such events, if curable, within thirty (30) days after Employer's receipt of such written notice and Executive elects to terminate her employment as a result within thirty (30) days following the end of such thirty (30) day period (assuming, for the avoidance of doubt, that Employer does not elect to cure).

**3.2 Certain Obligations of Employer Following Termination of Executive's Employment**. Following the termination of Executive's employment under the circumstances described below, Employer will pay to Executive, subject to standard federal and state payroll withholding requirements and in accordance with its regular payroll practices, the following compensation and provide the following benefits (provided that the continuing payments of

Executive's then-current Base Salary, as described below, shall occur no less frequently than monthly):

**3.2.1 Death; Disability; Termination by Employer Without Cause or by Executive for Good Reason.** In the event that Executive's employment is terminated by Employer pursuant to Section 3.1.1 ("*Death*"), Section 3.1.2 ("*Disability*"), Section 3.1.4 ("*Without Cause by Employer*") or by Executive pursuant to Section 3.1.7 ("*Termination by Executive for Good Reason*") hereof, and Executive, or her estate, as the case may be, executes and does not revoke a separation agreement containing a release upon such termination, in a form provided by the Employer, of any and all claims against Employer and all related parties with respect to all matters arising out of Executive's employment by Employer, or the termination thereof (the "*Release*") in accordance with Section 3.7, Executive, or her estate, as the case may be, shall be entitled to the following payments and benefits, which payments and benefits shall be paid in accordance with this Section 3.2.1 and Section 3.7:

(i) Continuing payments of Executive's then-current Base Salary for the Severance Period (as defined in Section 3.5 herein), payable subject to standard federal and state payroll withholding requirements in accordance with Employer's regular payroll practices on Employer's normal payroll schedule over the Severance Period, subject to Section 3.7;

(ii) Employer shall pay to Executive a lump sum payment equal to the gross sum of any bonuses or portion thereof for any preceding year or for the year of termination which have been or are approved by Employer, but has not been received by Executive prior to the effective date of termination, less applicable deductions and withholdings, paid in accordance with Section 2.2 but in no event later than two and one-half (2 1/2) months following the end of the fiscal year to which it relates. For the avoidance of doubt, Executive does not have to be employed by Employer on the date such bonuses are approved by Employer to receive such bonuses;

So long as Executive is eligible, and so long as Executive remains eligible, (iii) for and upon her timely election of coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or, if applicable, state or local insurance laws ("COBRA"), Employer will continue to pay, directly to the healthcare provider when due, Employer's portion of the medical, vision and dental coverage premiums (and Executive will be responsible for Executive's portion) for a period of twelve (12) months after the effective date of Executive's termination (the "COBRA Payment Period"); provided that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h) (2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period: and

(iv) In the event such termination of employment occurs on or within three (3) months prior to or within twelve (12) months following the effective date of a Change of Control (as defined herein), Executive shall be entitled to the <u>additional</u> following payments and benefits (for the avoidance of doubt, Executive shall also be entitled to the amounts set forth in Section 3.2.1(i)-(iii)):

(1) Employer shall pay to Executive a lump sum payment equal to the Annual Expectancy Bonus Amount (target bonus), less applicable deductions and withholdings, paid within thirty (30) days of the later of (a) the effective date of the Change of Control or (b) Executive's termination, if such termination occurs on or after the effective date of a Change of Control; and

(2) In the event such termination of employment occurs (A) on or within three (3) months prior to the effective date of a Change of Control, all unvested stock options and other equity awards held by Executive and outstanding on the effective date of termination shall become fully vested on the effective date of the Change of Control, or (B) within twelve (12) months following the effective date of a Change of Control, provided that any surviving corporation or acquiring corporation assumes Executive's stock options and/or other equity awards, as applicable, or substitutes similar stock options or equity awards for Executive's stock options and/or equity awards, as applicable, in accordance with the terms of Employer's applicable equity incentive plans, all such unvested stock options and other equity awards held by Executive and outstanding on the effective date of termination shall become fully vested on the date of such termination.

For purposes of this Employment Agreement, "Change of Control" means, in each case as approved by the Board and the requisite stockholders of Employer, (i) any consolidation or merger of Employer with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of Employer immediately prior to such consolidation, merger or reorganization, own, in the aggregate, less than 50% of the surviving entity's voting power and/or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions (including any transaction which results from an option agreement or binding letter of intent with a third party) to which Employer or any of its stockholders is a party in which in excess of 50% of Employer's voting power and/or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains in excess of 50% of Employer's voting power and/or outstanding capital stock, excluding any consolidation or merger effected exclusively to change the domicile of Employer; or (ii) any sale, license or other disposition (including through a Board and stockholder approved division or spin-off transaction) of all or substantially all of the assets of Employer and/or any of its subsidiaries or any sale, exclusive license or other disposition of all or substantially all of Employer's intellectual property, as reasonably determined based upon the potential earning power of the assets or intellectual property; provided, however, that none of the following shall constitute a Change of Control: (A) transfers of capital stock by an existing stockholder as a result of death or otherwise for estate planning purposes or to such stockholder's affiliates or to any of Employer's other existing stockholders, and (B) issuances of equity securities of Employer in

connection with financings for working capital and other general corporate purposes; and, provided further, that such "Change of Control" qualifies as either a change in ownership of Employer as defined in Section 409A of the Code ("*Section 409A*") or a change in the ownership of a substantial portion of Employer's assets as defined in Section 409A, as the case may be.

**3.2.2 Termination by Executive Other than For Good Reason; Termination Upon Non-Renewal by Executive; Termination by Employer for Cause**. In the event Executive's employment is terminated by Executive other than for Good Reason pursuant to Section 3.1.5 hereof (*"By Executive"*) or by Executive pursuant to Section 3.1.6 hereof (*"Termination Upon Non-Renewal"*) or by Employer pursuant to Section 3.1.3 hereof (*"Termination by Employer for Cause"*), Executive shall be entitled to no further compensation or other benefits under this Employment Agreement except as to that portion of any unpaid salary and other benefits accrued and earned by her hereunder up to and including the effective date of such termination and to offer COBRA coverage at Executive's cost pursuant to applicable law.

**3.2.3 Termination Upon Non-Renewal by Employer**. In the event Executive's employment is terminated by Employer pursuant to Section 3.1.6 hereof, then during the ninety (90)-day notice period of Section 2.5, Employer shall continue to pay to Executive her then-current Base Salary and benefits subject to standard federal and state payroll withholding requirements and in accordance with Employer's regular payroll practices, and no later than the effective date of termination of employment, Employer shall pay to Executive any such unpaid salary accrued and earned by her up to and including the effective date of termination. In addition, in the event Executive's employment is terminated by Employer pursuant to Section 3.1.6 hereof, then provided Executive executes and does not revoke a Release in accordance with Section 3.7, Executive shall be entitled to the following, which payments and benefits shall be paid in accordance with this Section 3.2.3 and Section 3.7:

(i) Continuing payments of Executive's then-current Base Salary for the Severance Period payable subject to standard federal and state payroll withholding requirements in accordance with Employer's regular payroll practices on Employer's normal payroll schedule over the Severance Period, subject to Section 3.7;

(ii) Employer shall pay to Executive a lump sum payment equal to the gross sum of any bonuses or portion thereof for any preceding year or for the year of termination which have been or are approved by Employer, but has not been received by Executive prior to the effective date of termination, less applicable deductions and withholdings, paid in accordance with Section 2.2 but in no event later than two and one-half (2 1/2) months following the end of the fiscal year to which it relates. For the avoidance of doubt, Executive does not have to be employed by Employer on the date such bonuses are approved by Employer to receive such bonuses; and

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon her timely election of coverage under COBRA, Employer will continue to pay, directly to the healthcare provider when due, Employer's portion of the medical, vision and dental coverage premiums (and Executive will be responsible for Executive's

portion) for the COBRA Payment Period; provided that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period.

**3.3** Nature of Payments. All amounts to be paid by Employer to Executive pursuant to Sections 3.2.1(i) — (iv) and 3.2.3(i) — (iii) are considered by the parties to be severance payments and are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Employer severance plan, policy or program.

**3.4 Duties Upon Termination.** During the Severance Period, if there is a Severance Period applicable to Executive's termination of employment from Employer, Executive shall fully cooperate with Employer in all matters relating to the winding up of Executive's pending work including, but not limited to, any litigation in which Employer is involved, and the orderly transfer of any such pending work to such other employees as may be designated by Employer. Notwithstanding the foregoing, such cooperation requirement shall not unreasonably interfere with her then current employment or business activities. With Employer's prior approval, Executive shall be reimbursed for all expenses reasonably incurred in connection with such cooperation. Following the end of the Severance Period, Executive will be released from any duties and obligations hereunder (except those duties and obligations set forth in Article 4 hereof). In the event of termination of Executive's employment pursuant to Sections 3.1.1 through 3.1.7 hereof, the obligations of Employer to Executive will be as set forth in Section 3.2 hereof. Upon termination, Executive shall immediately resign from her position as CMO of Employer.

**3.5** Severance Period. "Severance Period" shall mean a period of twelve (12) months beginning on the effective date of Executive's termination of employment with Employer.

**3.6 Release**. Notwithstanding any provision of this Employment Agreement to the contrary, in no event shall the timing of Executive's execution of the Release, directly or indirectly, result in Executive designating the calendar year of payment, and if a payment that is subject to the requirements of Section 409A of the Code and is subject to execution of the Release could be made in more than one taxable year based on when the Release is executed or becomes effective, payment shall be made in the later year.

**3.7** Commencement of Severance Payments. The severance payments and benefits set forth in Sections 3.2.1(i) — (iv) (Termination by Employer for Death, Disability, Without Cause, by Executive for Good Reason) and Sections 3.2.3(i) — (iii) (Termination Upon Non-Renewal by Employer) above will not be paid or provided unless Executive executes and does not revoke the Release and the Release is enforceable and effective as provided in the Release on or before the date that is the sixtieth (60th) day following the effective date of termination (such

60th day, the "*Severance Pay Commencement Date*"). No cash severance payments will be paid pursuant to Sections 3.2.1 or 3.2.3 prior to the Severance Pay Commencement Date. On the Severance Pay Commencement Date, Employer will pay in a lump sum the aggregate amount of the cash severance payments that Employer would have paid Executive through such date had the payments commenced on the effective date of termination through the Severance Pay Commencement Date, with the balance paid thereafter on the applicable schedules described above. Notwithstanding any other provision of this Employment Agreement to the contrary, it is intended that the payment of severance upon termination for Good Reason by Executive in accordance with Section 3.1.7 satisfy the safe harbor set forth in Treasury Regulation Section 1.409A-1(n)(2)(ii), and any severance payment made pursuant to this Employment Agreement shall satisfy the exemptions from the application of Section 409A of the Code provided under Treasury Regulation Sections 1.409A-1(b)(4), and 1.409A-1(b)(9).

# SECTION 4. CONFIDENTIALITY, INVENTION RIGHTS, NON-COMPETITION AND NON-SOLICITATION

**4.1 Confidentiality, Invention Rights, Non-Competition and Non-Solicitation.** The parties hereto have entered into a Confidentiality, Invention Rights, Non-Competition, and Non-Solicitation Agreement, which may be amended by the parties from time to time without regard to this Employment Agreement. The Confidentiality, Invention Rights, Non-Competition, and Non-Solicitation Agreement contains provisions that are intended by the parties to survive and do survive termination of this Employment Agreement.

**4.2 Remedies**. Executive acknowledges and agrees that (a) Employer will be irreparably injured in the event of a breach by Executive of any of her obligations under this Article 4; (b) monetary damages will not be an adequate remedy for any such breach; and (c) in the event of any such breach, the Employer will be entitled to injunctive relief, in addition to any other remedy which it may have, and Executive shall not oppose such injunctive relief based upon the extent of the harm or the adequacy of monetary damages.

## SECTION 5. MISCELLANEOUS PROVISIONS

**5.1** Severability. If in any jurisdiction any term or provision hereof is determined to be invalid or unenforceable, (a) the remaining terms and provisions hereof shall be unimpaired, (b) any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction, and (c) the invalid or unenforceable term or provision shall, for purposes of such jurisdiction, be deemed replaced by a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision.

**5.2 Execution in Counterparts**. This Employment Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement (and all signatures need not appear on any one counterpart), and this Employment Agreement shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying

with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

**5.3** Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed duly given when delivered by hand, or when delivered if mailed by registered or certified mail, postage prepaid, return receipt requested, or private courier service or via facsimile (with written confirmation of receipt) or email (with written confirmation of receipt) as follows:

If to Employer, to:

Aclaris Therapeutics, Inc. 640 Lee Road, Suite 200 Wayne, PA 19087 Attention: Neal Walker E-mail: nwalker@aclaristx.com

If to Executive, to the current address on file with Employer,

or to such other address(es) as a party hereto shall have designated by like notice to the other parties hereto.

**5.4 Amendment.** No provision of this Employment Agreement may be modified, amended, waived or discharged in any manner except by a written instrument executed by Employer and Executive.

**5.5** Entire Agreement. This Employment Agreement constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties hereto, oral or written, with respect to the subject matter hereof, including but not limited to any prior offer letter or written embodiment of the employment relationship between Executive and Employer. No representation, promise or inducement has been made by either party that is not embodied in this Employment Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

**5.6** Applicable Law. This Employment Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania applicable to contracts made and to be wholly performed therein without regard to its conflicts or choice of law provisions.

**5.7 Headings.** The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Employment Agreement.

**5.8 Binding Effect; Successors and Assigns.** Executive may not delegate her duties or assign her rights hereunder. This Employment Agreement will inure to the benefit of, and be

binding upon, the parties hereto and their respective heirs, legal representatives, and successors. Employer may assign this Employment Agreement to any entity purchasing all or substantially all of the assets of Employer.

**5.9** Waiver, etc. The failure of either of the parties hereto to at any time enforce any of the provisions of this Employment Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Employment Agreement or any provision hereof or the right of either of the parties hereto to thereafter enforce each and every provision of this Employment Agreement. No waiver of any breach of any of the provisions of this Employment Agreement shall be effective unless set forth in a written instrument executed by the party against whom or which enforcement of such waiver is sought, and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.

**5.10** Continuing Effect. Provisions of this Employment Agreement which by their terms must survive the termination of this Employment Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Executive's employment, or otherwise, for such period as may be appropriate under the circumstances.

**5.11 Representations and Warranties of Executive.** Executive hereby represents and warrants to Employer that to the knowledge of Executive, Executive is not bound by any non-competition or other agreement which would prevent her performance hereunder.

Section 409A of the Code. This Employment Agreement is intended to comply 5.12 with Section 409A of the Code and its corresponding regulations, or an exemption, and payments may only be made under this Employment Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable. Payment under this Employment Agreement is intended to be exempt from Code Section 409A under the "shortterm deferral" exception set forth in Treasury Regulation Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception set forth in Treasury Regulation Section 1.409A-1(b)(9), to the maximum extent applicable. All payments to be made upon a termination of employment under this Employment Agreement may only be made upon a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h) (or any successor provision) (a "Separation from Service"). For purposes of Code Section 409A, the right to a series of installment payments under this Employment Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the calendar year of a payment. If the termination of employment giving rise to the payments described in Section 3.2.1 is not a Separation from Service, then the amounts otherwise payable pursuant to Section 3.2.1 will instead be deferred without interest and paid when Executive experiences a Separation from Service. Notwithstanding anything in this Employment Agreement to the contrary or otherwise, with respect to any expense, reimbursement or in-kind benefit provided pursuant to this Employment Agreement that constitutes a "deferral of compensation" within the meaning of Section 409A of the Code and its implementing regulations and guidance, (a) the expenses eligible for reimbursement or in-kind benefits provided to Executive must be incurred during the Employment Term (or applicable

survival period), (b) the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive in any other calendar year, (c) the reimbursements for expenses for which Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (d) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit. Notwithstanding any provision to the contrary in this Employment Agreement, if Executive is deemed by Employer at the time of her Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and if any of the payments due upon Separation from Service set forth herein and/or under any other agreement with Employer are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a) (2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to Executive prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of Executive's Separation from Service with Employer, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 5.12 will be paid in a lump sum to Executive, and any remaining payments due will be paid as otherwise provided in this Employment Agreement or in the applicable agreement. No interest will be due on any amounts so deferred.

Section 280G. Notwithstanding any other provision of this Employment 5.13 Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by Employer or its affiliates to Executive or for Executive's benefit pursuant to the terms of this Employment Agreement or otherwise (the "Covered *Payments*") constitute parachute payments (the "*Parachute Payments*") within the meaning of Section 280G of the Code and, but for this Section 5.13, would be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the "Excise Tax"), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under clause (i) above is less than the amount under clause (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax. "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

(a) Any such reduction shall be made in accordance with Section 409A and the following:

- the Covered Payments consisting of cash severance benefits that do not constitute nonqualified deferred compensation subject to Section 409A shall be reduced first, in reverse chronological order; and
- (ii) all other Covered Payments consisting of cash payments, and Covered Payments consisting of accelerated vesting of equity based awards to which Treas. Reg. §1.280G-1 Q/A-24(c) does not apply, and that in either case do not constitute nonqualified deferred compensation subject to Section 409A, shall be reduced second, in reverse chronological order; and
- (iii) all Covered Payments consisting of cash payments that constitute nonqualified deferred compensation subject to Section 409A shall be reduced third, in reverse chronological order; and
- (iv) all Covered Payments consisting of accelerated vesting of equity-based awards to which Treas. Reg. § 1.280G-1 Q/A-24(c) applies shall be the last Covered Payments to be reduced.

(b) Any determination required under this Section 5.13 shall be made in writing in good faith by an independent accounting firm selected by Employer and reasonably acceptable to the Executive (the "*Accountants*"). Employer and Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order to make a determination under this Section 5.13. For purposes of making the calculations and determinations required by this Section 5.13, the Accountants may rely on reasonable, good-faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accountants' determinations shall be final and binding on Employer and Executive. Employer shall be responsible for all fees and expenses incurred by the Accountants in connection with the calculations required by this Section 5.13.

(c) It is possible that after the determinations and selections made pursuant to this Section 5.13. Executive will receive Covered Payments that are in the aggregate more than the amount intended or required to be provided after application of this Section 5.13 ("*Overpayment*") or less than the amount intended or required to be provided after application of this Section 5.13 ("*Underpayment*").

(i) In the event that: (A) the Accountants determine, based upon the assertion of a deficiency by the Internal Revenue Service against either Employer or Executive that the Accountants believe has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then Executive shall pay any such Overpayment to Employer together with interest at the applicable federal rate (as defined in Section 7872(f)(2)(A) of the Code) from the date of Executive's receipt of the Overpayment until the date of repayment.

(ii) In the event that: (A) the Accountants, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment will be paid promptly by Employer to or for the benefit of Executive together with interest at the applicable federal rate (as defined in Section 7872(f)(2)(A) of the Code) from the date the amount should have otherwise been paid to Executive until the payment date.

**Dispute Resolution.** The parties recognize that litigation in federal or state 5.14 courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Employer or out of this Employment Agreement, or the Executive's termination of employment or termination of this Employment Agreement, may not be in the best interests of either the Executive or Employer, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Employment Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Employment Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; provided *however*, that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Philadelphia, Pennsylvania metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by Employer. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Employment Agreement and continue after the termination of the employment relationship between Executive and Employer. The parties each further agree that the arbitration provisions of this Employment Agreement shall provide each party with its exclusive remedy, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Employment Agreement. By election arbitration as the means for final settlement of all claims, the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Employment Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.

## [SIGNATURE PAGE FOLLOWS]

**IN WITNESS WHEREOF** the parties have executed this Employment Agreement as of the date first above written.

# ACLARIS THERAPEUTICS, INC.

/s/ Neal Walker

Name:Neal WalkerTitlePresident & CEO

Agreed to and Accepted this <u>2</u> day of <u>June</u>, 2022.

## EXECUTIVE

/s/ Gail Cawkwell

Gail Cawkwell

# Exhibit A

# List of Entities Referenced in Section 1.2.2.

None.

## 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 June 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: August 3, 2022

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

## 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 June 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: August 3, 2022

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

### 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 June 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 3<sup>rd</sup> day of August, 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.