42,919,291.

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

		Washington, D.C. 20549	
		FORM 10-Q	•
(Mark one)	QUARTERLY REPORT PURSUAL ACT OF 1934	NT TO SECTION 13 OR 1	5(d) OF THE SECURITIES EXCHANGE
	For the qua	arterly period ended September 30	), 2020
	TRANSITION REPORT PURSUA ACT OF 1934	OR NT TO SECTION 13 OR 1	5(d) OF THE SECURITIES EXCHANGE
	For the transition	period from to	
	Com	mission File Number 001-37581	
		ris Therapeutics, Ir	
	Delaware (State or Other Jurisdiction of Incorporation or Organization) 640 Lee Road, Suite 200 Wayne, PA (Address of principal executive offices)		46-0571712 (I.R.S. Employer Identification No.) 19087 (Zip Code)
	Registrant's te	lephone number, including area co	ode: (484) 324-7933
		N/A	
	(Former name, former add	ress and former fiscal year, if cha	nged since last report) -
Securities regis	tered pursuant to Section 12(b) of the Act:		
Com	Title of Each Class: nmon Stock, \$0.00001 par value	Trading Symbol(s) ACRS	Name of Each Exchange on which Registered The Nasdaq Stock Market, LLC
during the prece	<u> </u>		ction 13 or 15(d) of the Securities Exchange Act of 193 le such reports), and (2) has been subject to such filing
	(§ 232.405 of this chapter) during the preceding		ta File required to be submitted pursuant to Rule 405 of period that the registrant was required to submit such
emerging grow		erated filer," "accelerated filer," "	non-accelerated filer, a smaller reporting company, or a smaller reporting company" and "emerging growth
	Large accelerated filer $\Box$		Accelerated filer
	Non-accelerated filer $\ \square$		Smaller reporting company ⊠
			Emerging growth company ⊠
	growth company, indicate by check mark if the financial accounting standards provided pursua		the extended transition period for complying with any $\log$ Act. $\boxtimes$
Indicate by che	ck mark whether the registrant is a shell compa	any (as defined in Rule 12b-2 of the	he Securities Exchange Act of 1934). Yes □ No ⊠

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on October 31, 2020 was

# ACLARIS THERAPEUTICS, INC.

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# Part I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

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

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

	September 30, 2020			
Assets				
Current assets:				
Cash and cash equivalents	\$	23,643	\$	34,187
Restricted cash		1,753		1,750
Marketable securities		29,834		39,078
Accounts receivable, net		887		704
Prepaid expenses and other current assets		1,880		3,118
Discontinued operations - current assets		_		4,966
Total current assets		57,997		83,803
Property and equipment, net		1,920		2,470
Intangible assets		7,142		7,199
Other assets		4,843		4,825
Total assets	\$	71,902	\$	98,297
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	5,081	\$	9,917
Accrued expenses		3,816		7,721
Current portion of lease liabilities		591		637
Discontinued operations - current liabilities		3,300		4,157
Total current liabilities		12,788		22,432
Other liabilities		3,134		3,736
Long-term debt, net		10,613		_
Contingent consideration		4,061		1,668
Deferred tax liability		549		549
Total liabilities		31,145		28,385
Stockholders' Equity:				
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued				
or outstanding at September 30, 2020 and December 31, 2019		_		_
Common stock, \$0.00001 par value; 100,000,000 shares authorized at				
September 30, 2020 and December 31, 2019; 42,916,387 and 41,485,638 shares issued				
and outstanding at September 30, 2020 and December 31, 2019, respectively		_		_
Additional paid-in capital		532,170		523,505
Accumulated other comprehensive loss		(44)		(66)
Accumulated deficit		(491,369)	(	(453,527)
Total stockholders' equity		40,757		69,912
Total liabilities and stockholders' equity	\$	71,902	\$	98,297

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

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

Revenues:         2020         2019         2020         2019           Contract research         \$ 1,331         \$ 983         \$ 4,373         \$ 3,132           Other revenue         118         —         529         —           Total revenue         1,449         983         4,902         3,132           Costs and expenses:           Cost of revenue         1,189         826         3,847         3,028           Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (32,181)         (281)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1,34)         (20.9)		Three Months Ended September 30,			Nine Months Ended September 30,				
Contract research         \$ 1,331         \$ 983         \$ 4,373         \$ 3,132           Other revenue         1,449         983         4,902         3,132           Costs and expenses:         \$ 2         \$ 3,847         3,028           Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,868         15,183         22,775         53,334           General and administrative         3,859         6,868         15,183         22,775         53,334           General and administrative         3,859         6,868         15,632         21,771         3604           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (19,494)         (274)         (205)         (589)           Loss from discontinued operations         (10,659)         (23,181)         (285)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         (1,53)         (1,53)         (1,47)         (2,12)         (2,13)         (3,7,857)         (3,48) <td< th=""><th></th><th></th><th colspan="2">2020</th><th colspan="2">2019</th><th colspan="2">2020</th><th>2019</th></td<>			2020		2019		2020		2019
Other revenue         118         —         529         —           Total revenue         1,449         983         4,902         3,132           Costs and expenses:           Cost of revenue         1,189         826         3,847         3,028           Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         (1.34)         (205)         (3,7842)         (142,760)           Weighted average common shares outstanding, basic and diluted									
Total revenue         1,449         983         4,902         3,132           Costs and expenses:	Contract research	\$		\$	983	\$		\$	3,132
Costs and expenses:           Cost of revenue         1,189         826         3,847         3,028           Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           <	Other revenue		118				529		
Cost of revenue         1,189         826         3,847         3,028           Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         \$ (2,802,582)         \$ (1,34)         \$ (2,187,140)         \$ (1,296,377)           Other comprehensive income (los	Total revenue		1,449		983		4,902		3,132
Cost of revenue         1,189         826         3,847         3,028           Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         \$ (2,802,582)         \$ (1,34)         \$ (2,187,140)         \$ (1,296,377)           Other comprehensive income (los	Costs and expenses:								
Research and development         6,866         16,183         22,775         53,334           General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27			1 100		926		2 0 4 7		2 020
General and administrative         3,859         6,838         15,632         21,771           Goodwill impairment         —         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         \$ (36)         14         22         27           Total other comprehensive income (loss)         \$ (60)         (9)         21         6							,		,
Goodwill impairment         —         —         —         18,504           Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         \$ (36)         14         22         27           Total other comprehensive income (loss)         660         (9)         21         68	•								
Total costs and expenses         11,914         23,847         42,254         96,637           Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68			3,039 —		0,030		15,052		,
Loss from operations         (10,465)         (22,864)         (37,352)         (93,505)           Other expense, net         (194)         (274)         (205)         (589)           Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (0.90)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         * (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68	•		11,914	-	23,847		42,254	_	
Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68	-		(10,465)		(22,864)		(37,352)		(93,505)
Loss from continuing operations         (10,659)         (23,138)         (37,557)         (94,094)           Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68									
Loss from discontinued operations         —         (32,181)         (285)         (48,666)           Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68	Other expense, net		(194)		(274)		(205)		(589)
Net loss         \$ (10,659)         \$ (55,319)         \$ (37,842)         \$ (142,760)           Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68	Loss from continuing operations		(10,659)		(23,138)		(37,557)		(94,094)
Net loss per share, basic and diluted         \$ (0.25)         \$ (1.34)         \$ (0.90)         \$ (3.46)           Weighted average common shares outstanding, basic and diluted         42,802,582         41,364,387         42,187,140         41,296,377           Other comprehensive income (loss):         Unrealized gain (loss) on marketable securities, net of tax of \$0         \$ (24)         \$ (23)         \$ (1)         \$ 41           Foreign currency translation adjustments         (36)         14         22         27           Total other comprehensive income (loss)         (60)         (9)         21         68	Loss from discontinued operations		_		(32,181)		(285)		(48,666)
Weighted average common shares outstanding, basic and diluted  42,802,582 41,364,387 42,187,140 41,296,377  Other comprehensive income (loss):  Unrealized gain (loss) on marketable securities, net of tax of \$0 \$ (24) \$ (23) \$ (1) \$ 41  Foreign currency translation adjustments (36) 14 22 27  Total other comprehensive income (loss) (60) (9) 21 68	Net loss	\$	(10,659)	\$	(55,319)	\$	(37,842)	\$	(142,760)
Weighted average common shares outstanding, basic and diluted  42,802,582 41,364,387 42,187,140 41,296,377  Other comprehensive income (loss):  Unrealized gain (loss) on marketable securities, net of tax of \$0 \$ (24) \$ (23) \$ (1) \$ 41  Foreign currency translation adjustments (36) 14 22 27  Total other comprehensive income (loss) (60) (9) 21 68									
diluted     42,802,582     41,364,387     42,187,140     41,296,377       Other comprehensive income (loss):       Unrealized gain (loss) on marketable securities, net of tax of \$0     \$ (24)     \$ (23)     \$ (1)     \$ 41       Foreign currency translation adjustments     (36)     14     22     27       Total other comprehensive income (loss)     (60)     (9)     21     68		\$	(0.25)	\$	(1.34)	\$	(0.90)	\$	(3.46)
Other comprehensive income (loss):  Unrealized gain (loss) on marketable securities, net of tax of \$0 \$ (24) \$ (23) \$ (1) \$ 41  Foreign currency translation adjustments (36) 14 22 27  Total other comprehensive income (loss) (60) (9) 21 68			0.000 500		14 264 205		40 405 440		44 000 000
Unrealized gain (loss) on marketable securities, net of tax of \$0 \$ (24) \$ (23) \$ (1) \$ 41 Foreign currency translation adjustments (36) 14 22 27 Total other comprehensive income (loss) (60) (9) 21 68	diluted	4	2,802,582		11,364,387		42,187,140	=	41,296,3//
Unrealized gain (loss) on marketable securities, net of tax of \$0 \$ (24) \$ (23) \$ (1) \$ 41 Foreign currency translation adjustments (36) 14 22 27 Total other comprehensive income (loss) (60) (9) 21 68	Other comprehensive income (loss):								
tax of \$0       \$ (24) \$ (23) \$ (1) \$ 41         Foreign currency translation adjustments       (36) 14 22 27         Total other comprehensive income (loss)       (60) (9) 21 68									
Foreign currency translation adjustments (36) 14 22 27 Total other comprehensive income (loss) (60) (9) 21 68		\$	(24)	\$	(23)	\$	(1)	\$	41
Total other comprehensive income (loss) (60) (9) 21 68		4	` '	Ψ	` '	Ψ		Ψ	
(t) (t)	· · · · · · · · · · · · · · · · · · ·		<u> </u>			_		_	
Comprehensive loss \$ (10,719) \$ (55,328) \$ (37,821) \$ (142,692)	Comprehensive loss	\$	(10,719)	\$	(55,328)	\$	(37,821)	\$	(142,692)

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

(In thousands, except share data)

	Common	Stock	Additional	Accumulated Other		Total
	Shares	Par Value	Paid-in Capital	Comprehensive Income (Loss)	Deficit	Stockholders' Equity
Balance at December 31, 2019	41,485,638	\$ —	\$ 523,505	\$ (66)	\$ (453,527)	\$ 69,912
Vesting of restricted stock units	346,582	_	(121)	<u>—</u>		(121)
Fair value of warrants issued	_	_	378	_	_	378
Unrealized gain on marketable securities	_	_	_	60	_	60
Foreign currency translation adjustment	_	_	_	53	_	53
Stock-based compensation expense	_	_	3,453	_	_	3,453
Net loss					(15,586)	(15,586)
Balance at March 31, 2020	41,832,220	<u>\$                                    </u>	\$ 527,215	\$ 47	\$ (469,113)	\$ 58,149
Vesting of restricted stock units	858,894	_	(463)	_	_	(463)
Unrealized loss on marketable securities		_	_	(37)	_	(37)
Foreign currency translation adjustment	_	_	_	5	_	5
Stock-based compensation expense	_	_	3,309	_	_	3,309
Net loss	_	_		_	(11,597)	(11,597)
Balance at June 30, 2020	42,691,114	\$ —	\$ 530,061	\$ 15	\$ (480,710)	\$ 49,366
Vesting of restricted stock units	103,689	_	(95)	_	_	(95)
Issuance of common stock in connection with equity purchase agreement	121.584	_	263	_	_	263
Unrealized loss on marketable securities	121,504		203	(24)		(24)
Foreign currency translation adjustment				(35)		(35)
Stock-based compensation expense			1,941	(55)		1,941
Net loss	_		1,541	_	(10,659)	(10,659)
Balance at September 30, 2020	42,916,387	<u>s                                    </u>	\$ 532,170	\$ (44)	\$ (491,369)	\$ 40,757
	Common		_ Additional			Total
	<u>Common</u> Shares	Stock Par Value	Paid-in	Other		Total l Stockholders' Equity
Balance at December 31, 2018		Par	Paid-in	Other Comprehensiv Income (Loss)	Deficit	l Stockholders' Equity
Balance at December 31, 2018  Vesting of restricted stock units	Shares	Par Value	Paid-in Capital	Other Comprehensiv Income (Loss) \$ (69	Deficit	Stockholders' Equity  \$ 215,124
	Shares 41,210,725	Par Value	Paid-in Capital \$ 507,366	Other Comprehensiv Income (Loss) \$ (69	Deficit \$ (292,173	Stockholders' Equity  \$ 215,124
Vesting of restricted stock units	Shares 41,210,725	Par Value	Paid-in Capital \$ 507,366	Other Comprehensiv Income (Loss) \$ (69	Deficit (292,173	Stockholders'   Equity   \$ 215,124 (188)   34
Vesting of restricted stock units Unrealized gain on marketable securities	Shares 41,210,725	Par Value	Paid-in Capital \$ 507,366	Other Comprehensiv Income (Loss) \$ (69	Deficit (292,173	Stockholders'   Equity   \$ 215,124 (188)   34
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment	Shares 41,210,725	Par Value	Paid-in Capital \$ 507,366 (188	Other Comprehensiv Income (Loss) \$ (69	Deficit (292,173	Stockholders'   Equity   \$ 215,124   (188)   34   (14)   4,862
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense	Shares 41,210,725	Par Value	Paid-in Capital \$ 507,366 (188	Other Comprehensiv Income (Loss)  \$ (69)  34  (14	Deficit (292,173) (292,173	i Stockholders' Equity ) \$ 215,124 (188) 34 (14) 4,862 ) (37,565)
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019	Shares 41,210,725 58,918 — — —	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188	Other Comprehensiv Income (Loss)  (69)  34  (14)	Deficit (292,173) (292,173	i Stockholders' Equity ) \$ 215,124 (188) 34 (14) 4,862 ) (37,565)
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock	Shares 41,210,725 58,918 41,269,643	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188 	Other Comprehensive Income (Loss)  \$ (69)  34  (14)  \$ (49)	Deficit (292,173) (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units	Shares 41,210,725 58,918 — — —	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188	Other Comprehensiv Income (Loss)  \$ (69)  34  (14)  \$ (49)	Deficit   (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities	Shares 41,210,725 58,918 41,269,643	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188 	Other Comprehensiv Income (Loss)  \$ (69)  34  (14)  \$ (49)	Deficit \$ (292,173	Stockholders'   Equity   \$ 215,124   (188)   34   (14)   4,862   (37,565)   \$ 182,253   (18)   30
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment	Shares 41,210,725 58,918 41,269,643	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040	Other Comprehensiv Income (Loss)  (1)  (3)  (4)  (4)  (4)  (4)  (5)  (6)  (7)  (4)  (8)  (9)  (9)  (1)  (1)  (1)  (1)  (1)  (1	Deficit \$ (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense	Shares 41,210,725 58,918 41,269,643	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188 	Other Comprehensiv Income (Loss)  (1)  (3)  (4)  (4)  (4)  (4)  (5)  (6)  (7)  (4)  (8)  (9)  (9)  (1)  (1)  (1)  (1)  (1)  (1	Deficit   (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment	Shares 41,210,725 58,918 41,269,643	Par Value \$ — — — —	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040	Other Comprehensive Income (Loss)  \$ (69)  34  (14)  \$ (49)  30  27	Deficit   (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at June 30, 2019	Shares 41,210,725 58,918 — — 41,269,643  8,927 — — — — — — — — — — — — — — — — — — —	Par Value \$	Paid-in Capital \$ 507,366 (188	Other Comprehensive Income (Loss)  \$ (69)  34  (14)  \$ (49)  27	Deficit   (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at June 30, 2019  Exercise of stock options and vesting of restricted stock	Shares 41,210,725 58,918 41,269,643  8,927 41,278,570	Par Value \$	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040 (18 4,814 5 516,836 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	Other Comprehensiv Income (Loss) \$ (69)   34 (14)   5 (49	Deficit   (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss Balance at June 30, 2019  Exercise of stock options and vesting of restricted stock units	Shares 41,210,725 58,918 — — 41,269,643  8,927 — — — — — — — — — — — — — — — — — — —	Par Value \$	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040  (18 4,814 5 516,836	Other Comprehensive Income (Loss) \$ (69) 34 (14	Deficit   (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at June 30, 2019  Exercise of stock options and vesting of restricted stock units Unrealized loss on marketable securities	Shares 41,210,725 58,918 41,269,643  8,927 41,278,570	Par Value \$	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040 (18 4,814 5 516,836 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	Other Comprehensive Income (Loss)  \$ (69)  34  (14)  \$ (49)  30)  27  \$ 8	Deficit   \$ (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at June 30, 2019  Exercise of stock options and vesting of restricted stock units Unrealized loss on marketable securities Foreign currency translation adjustment	Shares 41,210,725 58,918 41,269,643  8,927 41,278,570	Par Value \$	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040 (18 4,814 \$ 516,836 53	Other Comprehensiv Income (Loss) \$ (69) 34 (14	Deficit   \$ (292,173	Stockholders'   Equity     \$ 215,124   (188)     4,865     (37,565)     182,253     (18)     30     27     4,814     (49,876)     53     (23)     53     (23)     14
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at June 30, 2019  Exercise of stock options and vesting of restricted stock units Unrealized loss on marketable securities Foreign currency translation adjustment Stock-based compensation expense	Shares 41,210,725 58,918 41,269,643  8,927 41,278,570	Par Value \$	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040  (18 4,814 5 516,836	Other Comprehensiv Income (Loss) \$ (69) 34 (14	Deficit   \$ (292,173	Stockholders'   Equity
Vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at March 31, 2019  Exercise of stock options and vesting of restricted stock units Unrealized gain on marketable securities Foreign currency translation adjustment Stock-based compensation expense Net loss  Balance at June 30, 2019  Exercise of stock options and vesting of restricted stock units Unrealized loss on marketable securities Foreign currency translation adjustment	Shares 41,210,725 58,918 41,269,643  8,927 41,278,570	Par Value \$	Paid-in Capital \$ 507,366 (188 4,862 \$ 512,040 (18 4,814 \$ 516,836 53	Other Comprehensive Income (Loss) \$ (69) 34 (14	Deficit   \$ (292,173	Stockholders'   Equity

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

# (In thousands)

	Nine Months Ended September 30,			
		2020		2019
Cash flows from operating activities:				
Net loss	\$	(37,842)	\$ (	(142,760)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		1,773		6,089
Stock-based compensation expense		8,703		12,996
Change in fair value of contingent consideration		2,393		734
Goodwill impairment charge		_		18,504
Intangible asset impairment charge		_		27,638
Changes in operating assets and liabilities:				
Accounts receivable		4,783		(13,003)
Prepaid expenses and other assets		1,303		3,880
Accounts payable		(5,448)		3,050
Accrued expenses		(5,441)		6,817
Net cash used in operating activities		(29,776)		(76,055)
Cash flows from investing activities:				
Purchases of property and equipment		(445)		(1,347)
Purchases of marketable securities		(39,898)	(	(121,303)
Proceeds from sales and maturities of marketable securities		49,035		171,891
Net cash provided by investing activities		8,692		49,241
Cash flows from financing activities:				
Proceeds from debt financing (including warrants), net of issuance costs		10,913		_
Finance lease payments		(128)		(392)
Deferred issuance costs		(242)		_
Proceeds from exercise of employee stock options and the issuance of stock		_		85
Net cash provided by (used in) financing activities		10,543		(307)
Net decrease in cash, cash equivalents and restricted cash		(10,541)		(27,121)
Cash, cash equivalents and restricted cash at beginning of period		35,937		57,019
Cash, cash equivalents and restricted cash at end of period	\$	25,396	\$	29,898
Supplemental disclosure of non-cash investing and financing activities:	_			
Additions to property and equipment included in accounts payable	\$		\$	207
Operating lease asset recorded as a result of new accounting standard	\$	_	\$	2,132
Fair value of common stock issued in connection with equity purchase agreement	\$	263	\$	_

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

#### 1. Organization and Nature of Business

#### Overview

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. In July 2015, Aclaris Therapeutics International Limited ("ATIL") was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. In August 2017, Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) ("Confluence") was acquired by Aclaris Therapeutics, Inc. and became a wholly-owned subsidiary thereof. Aclaris Therapeutics, Inc., ATIL and Confluence are referred to collectively as the "Company." The Company is a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. The Company currently has a pipeline of drug candidates focused on immuno-inflammatory diseases, as well as one product approved by the U.S. Food and Drug Administration ("FDA") that it is not currently distributing, marketing or selling. In September 2019, the Company announced the completion of a strategic review of its business, as a result of which it refocused its resources on its immuno-inflammatory development programs. 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 drug candidates and ESKATA (hydrogen peroxide) topical solution, 40% (w/w) ("ESKATA"), the Company's non-marketed FDA-approved product.

## Liquidity

The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. As of September 30, 2020, the Company had cash, cash equivalents, restricted cash and marketable securities of \$55.2 million and an accumulated deficit of \$491.4 million. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, the Company had never generated revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, including clinical and preclinical testing of the Company's drug candidates, will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its drug candidates and to generate revenue from identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize its development assets or to raise additional capital to finance its operations. The Company will require additional capital to complete the clinical development of ATI-450 and ATI-1777, to develop its preclinical compounds, and to support its discovery efforts.

The Company has taken a number of actions to support its operations and meet its liquidity needs. In September 2019, the Company announced the completion of a strategic review and its decision to refocus its resources on its immuno-inflammatory development programs and to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize its drug candidates and ESKATA. As a result of this decision, the Company restructured its operations and reduced its workforce, which lowered operating costs. In October 2019, the Company sold the worldwide rights to RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") to further its focus on its development programs and improve cash flow. In March 2020, the Company borrowed \$11.0 million under a term loan facility with Silicon Valley Bank. In August 2020, the Company entered into an equity purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to \$15.0 million of shares of its common stock over the 36-month term of the Purchase Agreement.

The Company's plans to further address its liquidity needs primarily include its ability to control the timing and spending on its research and development programs. The Company may also consider other plans to fund its operations including: (1) raising additional capital through debt or equity financings; (2) identifying third-party partners to further develop, obtain marketing approval for and/or commercialize its drug candidates and ESKATA, which may generate

revenue and/or milestone payments; (3) reducing spending on one or more research and development programs by delaying or discontinuing development; and/or (4) further restructuring its operations to change its overhead structure.

Additional funds may not be available on a timely basis, on commercially acceptable terms, or at all, and such funds, if raised, may not be sufficient to enable the Company to continue to implement its long-term business strategy. The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If the Company is unable to raise sufficient additional capital or generate revenue from transactions with third-party partners for the development and/or commercialization of its drug candidates, it may need to substantially curtail planned operations. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that its 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

#### **Basis of Presentation**

The accompanying condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("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 significant 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.

#### Reclassifications

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

# **Discontinued Operations**

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

The accompanying condensed consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to the Company's commercial products as discontinued operations (see Note 15).

# Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, research and development expenses, contingent consideration and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. The COVID-19 pandemic has resulted in a global slowdown in

economic activity. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require an update to its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. Actual results could differ from the Company's estimates.

#### **Unaudited Interim Financial Information**

The accompanying condensed consolidated balance sheet as of September 30, 2020, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019, the condensed consolidated statement of stockholders' equity for the three and nine months ended September 30, 2020 and 2019, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2020 and 2019 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements contained in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 25, 2020 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position as of September 30, 2020, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019, its changes in stockholders' equity for the three and nine months ended September 30, 2020 and 2019 and its cash flows for the nine months ended September 30, 2020 and 2019. The condensed consolidated balance sheet data as of December 31, 2019 was derived from audited financial statements but does not include all disclosures required by GAAP. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and 2019 are unaudited. The results for the three and nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, 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, 2019 included in the Company's annual report on Form 10-K filed with the SEC on February 25, 2020.

# **Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2019 included in the Company's annual report on Form 10-K filed with the SEC on February 25, 2020.

# Cash, Cash Equivalents and Restricted Cash

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which have consisted of money market accounts, commercial paper and corporate debt securities, are stated at fair value. Total cash, cash equivalents and restricted cash as shown in the condensed consolidated statements of cashflows as of September 30, 2020 and 2019 includes \$1.8 million and \$0, respectively, of restricted cash, consisting of funds in escrow pursuant to the asset purchase agreement with EPI Health, LLC ("EPI Health") (see Note 13). In October 2020, the cash in escrow was released to the Company in accordance with the asset purchase agreement.

# **Revenue Recognition**

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

To determine revenue recognition in accordance with ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize

revenue when (or as) performance obligations are satisfied. At contract inception, the Company assesses the goods or services promised within a contract with a customer to identify the performance obligations, and to determine if they are distinct. The Company recognizes the revenue that is allocated to each distinct performance obligation when (or as) that performance obligation is satisfied. The Company only recognizes revenue when collection of the consideration it is entitled to under a contract with a customer is probable.

#### Contract Research

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

#### Other Revenue

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

*Milestone Payments* — At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the amount allocated to the license of intellectual property. Milestone payments that are not within the control of the Company or the counterparty, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

# **Intangible Assets**

Intangible assets include both definite-lived and indefinite-lived assets. Definite-lived intangible assets consist of a drug discovery technology platform the Company acquired through the acquisition of Confluence. Definite-lived intangible assets are amortized over their estimated useful life based on the pattern over which the intangible assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the straight-line method of amortization is used. Indefinite-lived intangible assets consist of an in-process research and development ("IPR&D") drug candidate acquired through the acquisition of Confluence. IPR&D assets are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. The cost of IPR&D is either amortized over its estimated useful life beginning when the underlying drug candidate is approved and launched commercially or expensed immediately if development of the drug candidate is abandoned.

Definite-lived intangible assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment at least annually, which the Company performs during the fourth quarter, or when indicators of an impairment are present. The Company recognizes impairment losses when and to the extent that the estimated fair value of an intangible asset is less than its carrying value.

#### Leases

Leases represent a company's right to use an underlying asset and a corresponding obligation to make payments to a lessor for the right to use those assets. The Company evaluates leases at their inception to determine if they are an

operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows are substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease.

The Company recognizes assets and liabilities for leases at their inception based upon the present value of all payments due under the lease. The Company uses an implicit interest rate to determine the present value of finance leases, and its incremental borrowing rate to determine the present value of operating leases. The Company determines incremental borrowing rates by referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. The Company recognizes expense for operating and finance leases on a straight-line basis over the term of each lease, and interest expense related to finance leases is recognized over the lease term based on the effective interest method. The Company includes estimates for any residual value guarantee obligations under its leases in lease liabilities recorded on its condensed consolidated balance sheet.

Right-of-use assets are included in other assets and property and equipment, net on the Company's condensed consolidated balance sheet for operating and finance leases, respectively. Obligations for lease payments are included in current portion of lease liabilities and other liabilities on the Company's condensed consolidated balance sheet for both operating and finance leases.

# **Contingent Consideration**

The Company initially recorded a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon the achievement of certain development, regulatory and commercial milestones, as well as future projected sales performance, at its estimated fair value on the date of acquisition. The ultimate amount of future payments, if any, is based on criteria such as sales performance and the achievement of certain regulatory and sales milestones. The Company estimates the fair value of the contingent consideration liability related to the achievement of regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The Company estimates the fair value of the contingent consideration liability associated with sales milestones and royalties by estimating future sales levels, assigning an achievement probability and discounting the associated cash payments to their present values using a creditrisk-adjusted interest rate. Significant assumptions used in the Company's estimates include the probability of success of both achieving regulatory milestones and commencing commercialization, which are based upon an asset's current stage of development and ranged between 4% and 15%. The Company evaluates fair value estimates of contingent consideration liabilities on a periodic basis. Any change in fair value reflects new information about the likelihood of the payment of the contingent consideration and the passage of time. For example, if the timing of the development of an acquired drug candidate, or the size of potential commercial opportunities related to an acquired drug candidate, differ from the Company's assumptions, then the fair value of contingent consideration would be adjusted accordingly. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in the Company's condensed consolidated statement of operations.

#### **Concentration of Credit Risk and of Significant Suppliers**

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

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

## **Recently Issued Accounting Pronouncements**

In November 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The Company adopted this standard as of January 1, 2020, the impact of which on its consolidated financial statements was not significant.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. The Company adopted this standard as of January 1, 2020, the impact of which on its consolidated financial statements was not significant.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing disclosure requirements. The Company adopted this standard as of January 1, 2020, the impact of which on its consolidated financial statements was not significant.

#### 3. Fair Value of Financial Assets and Liabilities

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

		September 30, 2020				
(In thousands)	Level 1	Level 2	Level 3	Total		
Assets:						
Cash equivalents	\$ 19,444	\$ 3,029	\$ —	\$ 22,473		
Marketable securities	_	29,834	_	29,834		
Total assets	\$ 19,444	\$ 32,863	\$ —	\$ 52,307		
		-				
Liabilities:						
Acquisition-related contingent consideration	\$ —	\$ —	\$ 4,061	\$ 4,061		
Total liabilities	<u>\$ —</u> \$ —	\$ —	\$ 4,061	\$ 4,061		
			er 31, 2019			
(In thousands)	Level 1	December 12	er 31, 2019 Level 3	Total		
Assets:		Level 2	Level 3			
Assets: Cash equivalents	Level 1 \$ 21,277			Total \$ 21,277		
Assets:		Level 2	Level 3			
Assets: Cash equivalents		Level 2 \$ —	Level 3	\$ 21,277		
Assets: Cash equivalents Marketable securities	\$ 21,277	Level 2 \$ — 39,078	Level 3 \$	\$ 21,277 39,078		
Assets: Cash equivalents Marketable securities	\$ 21,277	Level 2 \$ — 39,078	Level 3 \$	\$ 21,277 39,078		
Assets: Cash equivalents Marketable securities	\$ 21,277	Level 2 \$ — 39,078	Level 3 \$	\$ 21,277 39,078		
Assets: Cash equivalents Marketable securities Total assets	\$ 21,277	Level 2 \$ — 39,078	Level 3 \$	\$ 21,277 39,078		
Assets: Cash equivalents Marketable securities Total assets Liabilities:	\$ 21,277 — \$ 21,277	Level 2 \$ — 39,078	Level 3	\$ 21,277 39,078 \$ 60,355		

Total marketable securities

As of September 30, 2020 and December 31, 2019, the Company's cash equivalents consisted of a money market fund, which was valued based upon Level 1 inputs, and corporate debt securities, which were valued based upon Level 2 inputs. The Company's marketable securities consisted of investments with maturities of more than three months and included commercial paper and corporate debt, asset-backed and U.S. government agency debt securities, which were valued based upon Level 2 inputs. In determining the fair value of its Level 2 investments, the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. Quarterly, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of the quoted prices provided. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to quoted prices obtained from the third-party pricing service. During the nine months ended September 30, 2020 and 2019, there were no transfers between Level 1, Level 2 and Level 3. The increase in contingent consideration of \$2.4 million during the nine months ended September 30, 2020 was primarily due to updates to the Company's assumptions as a result of the successful completion of a Phase 1 clinical trial for ATI-450 and the submission and allowance of an Investigational New Drug Application for ATI-1777.

As of September 30, 2020 and December 31, 2019, the fair value of the Company's available for sale marketable securities by type of security was as follows:

	September 30, 2020						
(In thousands)  Marketable securities:	Amortized Cost	Unre	ross alized ain	Unr	ross ealized Loss	_	Fair Value
Corporate debt securities	\$ 2,649	\$	_	\$	_	\$	2,649
Commercial paper	20,469		_		_		20,469
Asset-backed securities	4,166		2		_		4,168
U.S. government agency debt securities	2,547		1		_		2,548
Total marketable securities	\$ 29,831	\$	3	\$		\$	29,834
		De	cembe	r 31, 2	019		
(In thousands)	Amortized Cost	Gro Unrea Ga	lized	Unre	oss alized oss		Fair Value
Marketable securities:							
Corporate debt securities	\$ 7,815	\$	2	\$	_	\$	7,817
Commercial paper	15,129				_		15,129
	,						
Asset-backed securities	8,004		4		_		8,008

\$ 39,074

(3)

39,078

# 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)		tember 30, 2020	December 31, 2019		
Computer equipment	\$	1,317	\$	1,315	
Finance lease right-of-use assets		435		435	
Lab equipment		1,331		1,250	
Furniture and fixtures		647		647	
Leasehold improvements		1,127		889	
Property and equipment, gross		4,857		4,536	
Accumulated depreciation		(2,937)		(2,066)	
Property and equipment, net	\$	1,920	\$	2,470	

Depreciation expense was \$0.3 million for each of the three months ended September 30, 2020 and 2019, and \$0.9 million for each of the nine months ended September 30, 2020 and 2019.

# 5. Intangible Assets

Intangible assets consisted of the following:

		Gross	Cost	<b>Accumulated Amortization</b>				
	Remaining	September 30,	December 31,	September 30,	December 31,			
(In thousands, except years)	Life (years)	2020	2019	2020	2019			
Other intangible assets	6.8	751	751	238	181			
IPR&D	na	6,629	6,629	_	_			
Total intangible assets	3	\$ 7,380	\$ 7,380	\$ 238	\$ 181			

As of September 30, 2020, estimated future amortization expense is as follows:

		Ending
(In thousands)	Dece	mber 31,
2020	\$	18
2021		75
2022		75
2023		75
2024		75
Thereafter		195
Total	\$	513

# 6. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	September 30, 2020		De	cember 31, 2019
Employee compensation expenses	\$	2,516	\$	3,321
Research and development expenses		671		2,857
Other		629		1,543
Total accrued expenses	\$	3,816	\$	7,721

#### 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 provides for \$11.0 million in term loans, of which the Company borrowed the entire amount on March 30, 2020. The Loan and Security Agreement is secured by substantially all of the assets of the Company other than intellectual property. 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.

The term loan repayment schedule provides for interest only payments beginning April 1, 2020 and continuing through March 1, 2022, followed by 24 consecutive equal monthly installments of principal, plus monthly payments of accrued interest, starting on April 1, 2022 and continuing through the maturity date of March 1, 2024. All outstanding principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 2% and (ii) 6.75%.

The Loan and Security Agreement includes a final payment fee equal to 5% of the original principal amount borrowed. The Company has the option to prepay the outstanding balance of the term loans in full, subject to a prepayment premium of (i) 3% of the original principal amount borrowed for any prepayment on or prior to the first anniversary of March 30, 2020, (ii) 2% of the original principal amount borrowed for any prepayment after the first anniversary and on or before the second anniversary of March 30, 2020 or (iii) 1% of the original principal amount borrowed for any prepayment after the second anniversary of March 30, 2020 but before March 1, 2024.

# 8. Stockholders' Equity

#### **Preferred Stock**

As of September 30, 2020 and December 31, 2019, the Company's amended and restated certificate of incorporation authorized the Company to issue 10,000,000 shares of undesignated preferred stock. There were no shares of preferred stock outstanding as of September 30, 2020 or December 31, 2019.

#### **Common Stock**

As of September 30, 2020 and December 31, 2019, the Company's amended and restated certificate of incorporation authorized the Company to issue 100,000,000 shares of \$0.00001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to any preferential dividend rights of any series of preferred stock that may be outstanding. No dividends have been declared through September 30, 2020.

# Warrants

In connection with the Loan and Security Agreement with SVB, the Company issued the Warrant to SVB. The Warrant has 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 Warrant will terminate, if not earlier exercised, on the earlier of March 29, 2030 and the closing of certain merger or other transactions in which the consideration is cash, stock of a publicly-traded acquirer or a combination thereof. 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.

#### **Equity Purchase Agreement with Lincoln Park Capital Fund, LLC**

In August 2020, the Company entered into the Purchase Agreement with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park, at its discretion, up to \$15.0 million of shares of its common stock over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 121,584 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of the Company's common stock on the effective date of the Purchase Agreement resulting in an aggregate fair value of \$0.3 million. As of September 30, 2020, the Company had not sold any shares of its common stock to Lincoln Park under the Purchase Agreement.

#### 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, 2020, the number of shares of common stock that may be issued under the 2015 Plan was increased by 1,451,997 shares. As of September 30, 2020, 2,212,858 shares remained available for grant 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 443,000 stock options and 29,062 RSUs outstanding as of September 30, 2020 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 609,628 and 745,735 were outstanding as of September 30, 2020 and December 31, 2019, respectively. Stock options granted under the 2012 Plan vested over four years and expire after ten years.

# **Stock Option Valuation**

The weighted average assumptions the Company used to estimate the fair value of stock options granted during the nine months ended September 30, 2020 and 2019 were as follows:

	Nine Months September	
	2020	2019
Risk-free interest rate	0.87 %	2.27 %
Expected term (in years)	6.1	6.2
Expected volatility	85.19 %	101.70 %
Expected dividend yield	0 %	0 %

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

# **Stock Options**

The following table summarizes stock option activity for the nine months ended September 30, 2020:

(In thousands, except share and per share data and years)	Number of Shares	P	Veighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	I	ggregate ntrinsic Value
Outstanding as of December 31, 2019	3,102,221	\$	20.33	6.6	\$	148
Granted	734,800		1.30			
Exercised	_		_			_
Forfeited and cancelled	(736,258)		22.01			
Outstanding as of September 30, 2020	3,100,763	\$	15.42	6.5	\$	1,143
Options vested and expected to vest as of September 30, 2020	3,100,763	\$	15.42	6.5	\$	1,143
Options exercisable as of September 30, 2020	1,960,821	\$	18.84	5.3	\$	330

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2020 was \$0.93 per share.

# **Restricted Stock Units**

The following table summarizes RSU activity for the nine months ended September 30, 2020:

(In thousands, except share and per share data)	Number of Shares	A Gra Fa	eighted verage ant Date ir Value er Share	ggregate ntrinsic Value
Outstanding as of December 31, 2019	3,592,915	\$	4.62	
Granted	1,168,805		1.36	
Vested	(1,764,629)		3.27	\$ 2,404
Forfeited and cancelled	(688,734)		4.77	
Outstanding as of September 30, 2020	2,308,357	\$	3.95	

# **Stock-Based Compensation**

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

	Т	hree Mo Septen	-			nths Ended nber 30,
(In thousands)		2020		2019	2020	2019
Cost of revenue	\$	216	\$	25	\$ 728	\$ 454
Research and development		437		1,418	2,192	4,733
General and administrative		1,288		2,581	5,783	7,707
Total stock-based compensation expense	\$	1,941	\$	4,024	\$ 8,703	\$ 12,894

As of September 30, 2020, the Company had unrecognized stock-based compensation expense for stock options and RSUs of \$5.6 million and \$6.7 million, respectively, which is expected to be recognized over weighted average periods of 1.4 years and 2.0 years, respectively.

# 10. Net Loss per Share

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

		Three Mor Septem	 		Nine Mon Septem	 
(In thousands, except for share and per share data)		2020	2019		2020	2019
Numerator:						
Net loss	\$	(10,659)	\$ (55,319)	\$	(37,842)	\$ (142,760)
Denominator:						
Weighted average shares of common stock						
outstanding	4	2,802,582	 1,364,387	4	12,187,140	 1,296,377
Net loss per share, basic and diluted	\$	(0.25)	\$ (1.34)	\$	(0.90)	\$ (3.46)

The Company's potentially dilutive securities, which included stock options, RSUs and warrants, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following table presents potential shares of common stock excluded from the calculation of diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2020 and 2019. All share amounts presented in the table below represent the total number outstanding as of September 30, 2020 and 2019.

	Septem	ber 30,
	2020	2019
Options to purchase common stock	3,100,763	3,573,394
Restricted stock unit awards	2,308,357	1,635,638
Warrants issued to SVB	460,251	_
Total potential shares of common stock	5,869,371	5,209,032

#### 11. Leases

#### **Operating Leases**

Agreements for Office Space

In November 2017, the Company entered into a sublease agreement with Auxilium Pharmaceuticals, LLC (the "Sublandlord") pursuant to which it subleases 33,019 square feet of office space for its headquarters in Wayne, Pennsylvania. The sublease has a term that runs through October 2023. If for any reason the lease between Chesterbrook Partners, LP (the "Landlord") and Sublandlord is terminated or expires prior to October 2023, the Company's sublease will automatically terminate.

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:

	•	mber 30, 020	December 31, 2019		
(In thousands)		020	 2019		
Operating Leases:					
Gross cost	\$	5,240	\$ 5,213		
Accumulated amortization		(948)	(480)		
Other assets	\$	4,292	\$ 4,733		
Current portion of lease liabilities	\$	582	\$ 526		
Other liabilities		3,052	3,548		
Total operating lease liabilities	\$	3,634	\$ 4,074		

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled \$0.3 million for each of the three months ended September 30, 2020 and 2019, and \$0.8 million and \$0.6 million for the nine months ended September 30, 2020 and 2019, respectively.

# **Finance Leases**

Laboratory Equipment

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

#### 12. Related Party Transactions

# Mallinckrodt plc

In April 2018, Bryan Reasons was appointed to the Company's board of directors. Subsequently, in March 2019, Mr. Reasons became the Chief Financial Officer of Mallinckrodt plc. Prior to Mr. Reasons joining Mallinckrodt plc, the Company entered into a master services agreement with a subsidiary ("Mallinckrodt") of Mallinckrodt plc in November 2018, pursuant to which Confluence provides laboratory services to Mallinckrodt in the ordinary course of business. Mr. Reasons was not involved in the negotiation or execution of the agreement, but may be deemed to have an interest in the ongoing transactions based on his employment as an executive officer of Mallinckrodt plc. During the nine months ended September 30, 2020 and 2019, the Company invoiced Mallinckrodt for \$0.3 million and \$0.1 million, respectively, under

the master services agreement. As of September 30, 2020, the Company had no outstanding accounts receivable balance from Mallinckrodt. Mr. Reasons had no financial interest in these transactions.

#### 13. Agreements Related to Intellectual Property

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

In October 2019, the Company sold RHOFADE to 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 \$0.5 million and \$0 during the nine months ended September 30, 2020 and 2019, respectively. Royalty income is included in other revenue on the condensed consolidated statements of operations and comprehensive loss. EPI Health has also agreed to pay the Company potential sales milestone payments of up to \$20.0 million in the aggregate upon the achievement of specified levels of net sales of products covered by the asset purchase agreement, and 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the disposition in any territory outside of the United States, subject to specified exceptions.

# Agreement and Plan of Merger - Confluence

In August 2017, the Company entered into an Agreement and Plan of Merger, pursuant to which it acquired Confluence (the "Confluence Agreement"). In November 2018, the Company achieved a development milestone specified in the Confluence Agreement, as a result of which the Company paid the former Confluence equity holders \$2.5 million in cash and issued them 253,208 shares of its common stock with a fair value of \$2.2 million. Under the Confluence Agreement, the Company also agreed to pay the former Confluence equity holders aggregate remaining contingent consideration of up to \$75.0 million based upon the achievement of specified regulatory and commercial milestones. In addition, the Company agreed to pay the former Confluence equity holders future royalty payments calculated as a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. In addition, 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.

# License and Collaboration Agreement - Rigel Pharmaceuticals, Inc.

In August 2015, the Company entered into an exclusive, worldwide license and collaboration agreement with Rigel Pharmaceuticals, Inc. ("Rigel") for the development and commercialization of products containing two specified JAK inhibitors, which the Company refers to as ATI-501 and ATI-502. Under the agreement, the Company agreed to make aggregate payments of up to \$80.0 million upon the achievement of specified development milestones. In September 2019, the Company made a milestone payment of \$4.0 million to Rigel upon the achievement of a specified development milestone. With respect to any products the Company commercializes under the agreement, the Company will pay Rigel quarterly tiered royalties on its annual net sales of each product at a high single-digit percentage of annual net sales, subject to specified reductions, 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 countries under specified circumstances, ten years from the first commercial sale of such product.

In connection with an amendment of the agreement with Rigel in October 2019, the Company paid Rigel an amendment fee of \$1.5 million in three installments of \$0.5 million in each of January 2020, April 2020 and July 2020. In addition, the parties modified certain other development milestones, and the Company agreed to increase the potential payments payable upon the achievement of such milestones from \$10.0 million to \$10.5 million in the aggregate.

# 14. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the nine months ended September 30, 2020 and 2019 due to the Company's conclusion that a valuation allowance was required for those periods.

# **15. Discontinued Operations**

The components of loss from discontinued operations as reported in the Company's condensed consolidated statement of operations were as follows:

		Three Mor Septem					nths Ended nber 30,			
(In thousands, except share and per share data)		2020		2019		2020		2019		
Revenues:						_				
Product sales, net	\$		\$	4,977	\$		\$	13,734		
Total revenue, net		_		4,977		_		13,734		
Costs and expenses:										
Cost of revenue				1,118				4,396		
Research and development		_		132		1		522		
Sales and marketing		_		5,897		283		22,388		
General and administrative		_		960		1		2,724		
Intangible asset impairment		_		27,638				27,638		
Amortization of definite-lived intangible		_		1,107		_		4,426		
Total costs and expenses				36,852		285		62,094		
Loss from discontinued operations		_		(31,875)		(285)		(48,360)		
Other expense, net		_		(306)				(306)		
Net loss from discontinued operations	\$	_	\$	(32,181)	\$	(285)	\$	(48,666)		
Net loss from discontinued operations per share, basic										
and diluted	\$		\$	(0.78)	\$	(0.01)	\$	(1.18)		
Weighted average common shares outstanding, basic	-									
and diluted	42	2,802,582	4	1,364,387	4	2,187,140		11,296,377		

The following table presents the details of product sales, net included in discontinued operations:

		ree Mo Septem	 	N	Nine Moi Septen	 
(In thousands)	2	020	2019	2	2020	2019
ESKATA	\$		\$ (32)	\$		\$ 312
RHOFADE		_	5,009		_	13,422
Total product sales, net	\$		\$ 4,977	\$		\$ 13,734

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

(In thousands)	-	ember 30, 2020	ember 31, 2019
Accounts receivable, net	\$		\$ 4,966
Discontinued operations - current assets	\$		\$ 4,966
Accounts payable	\$	1,070	\$ 1,705
Accrued expenses		2,230	2,452
Discontinued operations - current liabilities	\$	3,300	\$ 4,157

The Company relied on Allergan Sales, LLC ("Allergan") to distribute RHOFADE on its behalf during 2019 pursuant to the terms of a transition services agreement. Accounts receivable, net as of December 31, 2019 related to amounts invoiced by Allergan for sales of RHOFADE.

The following table presents certain non-cash items related to discontinued operations, which are included in the Company's condensed consolidated statement of cash flows:

	Nine Mo	nths	Ended
	 Septer	mber	30,
(In thousands)	 2020		2019
Depreciation and amortization	\$ 	\$	302
Stock-based compensation expense	_		102
Intangible asset impairment charge	_		27,638
Loss on disposal of property and equipment	_		391
Total non-cash items	\$ 	\$	28,433

# 16. Segment Information

The Company has two reportable segments, therapeutics and contract research. The therapeutics segment is focused on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases. The contract research segment earns revenue from the provision of laboratory services to clients through Confluence, the Company's wholly-owned subsidiary. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis. Corporate and other includes general and administrative expenses as well as eliminations of intercompany transactions. The Company does not report balance sheet information by segment since it is not reviewed by the chief operating decision maker, and all of the Company's tangible assets are held in the United States.

The Company's results of operations by segment for the three and nine months ended September 30, 2020 and 2019 are summarized in the tables below:

(In thousands)			C	ontract	$\mathbf{C}$	orporate		Total
Three Months Ended September 30, 2020		erapeutics		esearch		nd Other		ompany
Total revenue	\$	118	\$	3,015	\$	(1,684)	\$	1,449
Cost of revenue		_		2,765		(1,576)		1,189
Research and development		6,973		_		(107)		6,866
General and administrative				672		3,187		3,859
Loss from operations	\$	(6,855)	\$	(422)	\$	(3,188)	\$	(10,465)
Loss from discontinued operations	\$	_	\$	_	\$	_	\$	_
				ontract		orporate		Total
Three Months Ended September 30, 2019		erapeutics		<u>esearch</u>		ıd Other		ompany
Total revenue	\$	_	\$	2,943	\$	(1,960)	\$	983
Cost of revenue		_		2,724		(1,898)		826
Research and development		16,245		_		(62)		16,183
General and administrative		_		956		5,882		6,838
Loss from operations	\$	(16,245)	\$	(737)	\$	(5,882)		(22,864)
Loss from discontinued operations	\$	(30,915)	\$	_	\$	(1,266)	\$	(32,181)
				ontract		orporate	_	Total
Nine Months Ended September 30, 2020		erapeutics	R	esearch	aı	nd Other		ompany
Total revenue	The	erapeutics 529	R	esearch 10,079		(5,706)		<b>ompany</b> 4,902
Total revenue Cost of revenue		529	R	esearch	aı	(5,706) (5,386)		4,902 3,847
Total revenue Cost of revenue Research and development			R	10,079 9,233	aı	(5,706) (5,386) (320)		4,902 3,847 22,775
Total revenue Cost of revenue Research and development General and administrative	\$	529 — 23,095 —	\$	10,079 9,233 — 2,112	\$	(5,706) (5,386) (320) 13,520	\$	4,902 3,847 22,775 15,632
Total revenue Cost of revenue Research and development General and administrative Loss from operations	\$	529 — 23,095 — (22,566)	\$ \$	10,079 9,233	\$ \$	13,520 (13,520)	\$	ompany 4,902 3,847 22,775 15,632 (37,352)
Total revenue Cost of revenue Research and development General and administrative	\$	529 — 23,095 —	\$	10,079 9,233 — 2,112	\$	(5,706) (5,386) (320) 13,520	\$	4,902 3,847 22,775 15,632
Total revenue Cost of revenue Research and development General and administrative Loss from operations	\$	529 — 23,095 — (22,566)	\$ \$	10,079 9,233 — 2,112	\$ \$	13,520 (13,520)	\$	ompany 4,902 3,847 22,775 15,632 (37,352)
Total revenue Cost of revenue Research and development General and administrative Loss from operations	\$	529 — 23,095 — (22,566)	\$ \$ \$	esearch 10,079 9,233 — 2,112 (1,266)	\$ \$ \$	10 Other (5,706) (5,386) (320) (13,520) (13,520) (1)	\$	ompany 4,902 3,847 22,775 15,632 (37,352) (285)
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations	\$ \$	529 — 23,095 — (22,566) (284)	\$ \$ \$	esearch 10,079 9,233 2,112 (1,266) Contract	\$ \$ \$	d Other (5,706) (5,386) (320) 13,520 (13,520) (1) orporate	\$ \$	0mpany 4,902 3,847 22,775 15,632 (37,352) (285)
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019	\$ \$ \$	529 — 23,095 — (22,566)	\$ \$ \$ CR	esearch 10,079 9,233 2,112 (1,266) contract esearch	\$ \$ \$ C	d Other (5,706) (5,386) (320) 13,520 (13,520) (1) orporate ad Other	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019 Total revenue	\$ \$	529 23,095 (22,566) (284)	\$ \$ \$ CR	esearch 10,079 9,233 2,112 (1,266) contract esearch 11,940	\$ \$ \$	d Other (5,706) (5,386) (320) 13,520 (13,520) (1) orporate d Other (8,808)	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total ompany 3,132
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019 Total revenue Cost of revenue	\$ \$ \$	529 23,095 — (22,566) (284) erapeutics	\$ \$ \$ CR	esearch 10,079 9,233 2,112 (1,266) contract esearch	\$ \$ \$ C	od Other (5,706) (5,386) (320) 13,520 (13,520) (1) orporate d Other (8,808) (8,556)	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total ompany 3,132 3,028
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019 Total revenue Cost of revenue Research and development	\$ \$ \$	529 23,095 (22,566) (284)	\$ \$ \$ CR	esearch 10,079 9,233 2,112 (1,266) sontract esearch 11,940 11,584	\$ \$ \$ C	od Other (5,706) (5,386) (320) 13,520 (13,520) (1)  orporate d Other (8,808) (8,556) (251)	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total ompany 3,132 3,028 53,334
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019 Total revenue Cost of revenue Research and development General and administrative	\$ \$ \$	529 23,095 (22,566) (284) erapeutics — 53,585	\$ \$ \$ CR	esearch 10,079 9,233 2,112 (1,266) contract esearch 11,940	\$ \$ \$ C	od Other (5,706) (5,386) (320) 13,520 (13,520) (1) orporate d Other (8,808) (8,556)	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total ompany 3,132 3,028 53,334 21,771
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019 Total revenue Cost of revenue Research and development General and administrative Goodwill impairment	\$ \$ \$ \$ \$ \$ \$ \$	529 23,095 (22,566) (284) erapeutics 53,585 18,504	\$ \$ \$ C R \$	esearch 10,079 9,233 — 2,112 (1,266) — (ontract esearch 11,940 11,584 — 2,069	\$ \$ \$ C an \$	d Other (5,706) (5,386) (320) 13,520 (13,520) (1) orporate d Other (8,808) (8,556) (251) 19,702	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total ompany 3,132 3,028 53,334 21,771 18,504
Total revenue Cost of revenue Research and development General and administrative Loss from operations Loss from discontinued operations  Nine Months Ended September 30, 2019 Total revenue Cost of revenue Research and development General and administrative	\$ \$ \$	529 23,095 (22,566) (284) erapeutics — 53,585	\$ \$ \$ CR	esearch 10,079 9,233 2,112 (1,266) sontract esearch 11,940 11,584	\$ \$ \$ C	od Other (5,706) (5,386) (320) 13,520 (13,520) (1)  orporate d Other (8,808) (8,556) (251)	\$ \$ \$	4,902 3,847 22,775 15,632 (37,352) (285) Total ompany 3,132 3,028 53,334 21,771

# **Intersegment Revenue**

Revenue for the contract research segment included \$1.7 million and \$2.0 million for services performed on behalf of the therapeutics segment for the three months ended September 30, 2020 and 2019, respectively, and \$5.7 million and \$8.8 million for the nine months ended September 30, 2020 and 2019, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

# 17. Legal Proceedings

# **Securities Class Action**

On July 30, 2019, plaintiff Linda Rosi ("Rosi") filed a putative class action complaint captioned *Rosi v. Aclaris Therapeutics*, *Inc.*, *et al.* in the U.S. District Court for the Southern District of New York against the Company and certain of its executive officers. The complaint alleges that the defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find

that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired the Company's securities between May 8, 2018 and June 20, 2019.

On September 5, 2019, an additional plaintiff, Robert Fulcher ("Fulcher"), filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc., et al.* in the same court against the same defendants.

On November 6, 2019, the court consolidated the Rosi and Fulcher actions (together, the "Consolidated Securities Action") and appointed Fulcher "lead plaintiff" for the putative class.

On January 24, 2020, Fulcher filed a consolidated amended complaint in the Consolidated Securities Action, naming two additional executive officers as defendants, extending the putative class period to August 12, 2019, and adding allegations concerning, among other things, alleged statements and omissions throughout the putative class period concerning ESKATA's risks, tolerability and effectiveness. The defendants filed a motion to dismiss the consolidated amended complaint on April 17, 2020. Fulcher filed an opposition to the defendants' motion on June 15, 2020, and the defendants filed a reply to such opposition on August 4, 2020. The motion remains under judicial consideration.

The Company and the other defendants dispute plaintiffs' claims in the Consolidated Securities Action and intend to defend the matter vigorously. At this time, the Company cannot reasonably predict the outcome or estimate potential losses, if any, that could result from this matter.

# **Stockholder Derivative Action**

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

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

On December 12, 2019, the court consolidated the Allred and Brown actions under the caption *In re Aclaris Therapeutics*, *Inc. Derivative Litigation* (the "Consolidated Derivative Action") and directed that future derivative cases filed in or transferred to the court arising out of substantially the same transactions or events be similarly consolidated. Thereafter, on January 11, 2020, the court stayed – subject to certain conditions – all deadlines in the Consolidated Derivative Action pending resolution of the defendants' then-anticipated motion to dismiss the Consolidated Securities Action.

The defendants dispute plaintiffs' claims in the Consolidated Derivative Action and intend to defend the matter vigorously. At this time, the Company cannot reasonably predict the outcome or estimate potential losses, if any, that could result from this matter.

## 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 or phrases "would be," "will allow," "intends to," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions, or the negative of such words or phrases, 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, 2019, which are included in our Annual Report on Form 10-K filed with the SEC on February 25, 2020.

# Overview

We are a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. We currently have a pipeline of drug candidates focused on immuno-inflammatory diseases, as well as one product approved by the U.S. Food and Drug Administration, or FDA, that we are not currently distributing, marketing or selling. In September 2019, we announced the completion of a strategic review of our business, as a result of which we refocused our resources on our immuno-inflammatory development programs. 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 drug candidates and ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, our non-marketed FDA-approved product.

# ATI-450, an Investigational Oral MK2 Inhibitor

We submitted an Investigational New Drug Application, or IND, in April 2019 for ATI-450, an investigational oral, novel, small molecule selective mitogen-activated protein kinase-activated protein kinase 2, or MK2, inhibitor compound, for the treatment of rheumatoid arthritis, which was allowed by the FDA in May 2019. MK2 is a key regulator of pro-inflammatory mediators including TNF $\alpha$ , IL1 $\beta$ , IL6, IL8 and other essential pathogenic signals in chronic immuno-inflammatory diseases, as well as in cancer. As an oral drug candidate, we are developing ATI-450 as a potential alternative to injectable anti-TNF/IL1/IL6 biologics for treating certain immuno-inflammatory diseases.

We initiated a Phase 1 single and multiple ascending dose clinical trial in 77 healthy subjects in August 2019. Final data from this trial demonstrated that ATI-450 resulted in marked inhibition of TNF $\alpha$ , IL1 $\beta$ , IL8 and IL6. We also observed that ATI-450 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. ATI-450 was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received ATI-450) observed during the trial were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain, and nausea.

Following the completion of the Phase 1 clinical trial, in March 2020 we initiated a Phase 2a clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in subjects with moderate to severe rheumatoid arthritis. Our planned enrollment for this trial is up to 25 subjects. Due to the COVID-19 pandemic, we temporarily paused enrollment. We resumed enrolling subjects, and the first subject was dosed, in May 2020. Given the

continuing evolution of the COVID-19 pandemic, we modified our anticipated timing for reporting data from this trial to the first half of 2021.

In November 2020, we initiated a Phase 2a open-label, single-arm clinical trial to investigate the safety, tolerability, efficacy and pharmacodynamics of ATI-450 for the maintenance of remission in subjects with cryopyrin-associated periodic syndrome, or CAPS, previously managed with anti-IL1 therapy. Our planned enrollment for this trial is up to 10 subjects. In November 2020, we filed for orphan drug designation for this indication.

We are also supporting an investigator-initiated Phase 2a, randomized, double-blind, placebo-controlled clinical trial to investigate the safety and efficacy of ATI-450, when used in addition to standard of care therapy, as a potential treatment for cytokine release syndrome in approximately 36 hospitalized patients with COVID-19. The primary endpoint in this trial is the proportion of subjects who are free from respiratory failure by day 14. We are providing funding and clinical drug supply to the University of Kansas Medical Center, the sponsor of the trial. The first subject was dosed in August 2020.

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

In June 2020, we submitted an IND for ATI-1777, an investigational topical "soft" Janus kinase, or JAK, 1/3 inhibitor compound, for the treatment of moderate to severe atopic dermatitis. "Soft" JAK inhibitors are designed to be topically applied and active in the skin, but rapidly metabolized and inactivated when they enter the bloodstream, which may result in low systemic exposure.

In October 2020, we initiated a Phase 2a multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to investigate the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate or severe atopic dermatitis. Our planned enrollment for this trial is approximately 42 subjects. The first subject was dosed in October 2020.

# ATI-2138, an Investigational ITJ Inhibitor

We are developing ATI-2138, an investigational oral ITK/TXK/JAK3, or ITJ, inhibitor compound, as a potential treatment for psoriasis and/or inflammatory bowel disease, which are both T-cell mediated autoimmune diseases. The ITJ compound interrupts T cell signaling through the combined inhibition of ITK/TXK/JAK3 pathways in lymphocytes. We expect to file an IND for ATI-2138 in 2021.

# Other Drug Candidates and Non-Marketed FDA-Approved Product

We are pursuing strategic alternatives, including seeking a partner, to further develop, obtain regulatory approval and/or commercialize, as applicable, our drug candidate A-101 45% Topical Solution as a potential treatment for common warts, as well as ATI-501 and ATI-502, our other JAK inhibitor candidates, as potential treatments for alopecia, and ESKATA, our non-marketed FDA-approved product.

#### Financial Overview

Since our inception, we have incurred significant operating losses. Our net loss was \$37.8 million for the nine months ended September 30, 2020 and \$161.4 million for the year ended December 31, 2019. As of September 30, 2020, we had an accumulated deficit of \$491.4 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 or ESKATA. Furthermore, we have incurred and expect to continue to incur significant costs associated with

operating as a public company, including legal, accounting, investor relations and other expenses. As a result, we will need substantial additional funding to support our continuing operations.

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

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

The global outbreak of COVID-19 continues to rapidly evolve. We have implemented a virtual operations strategy, including teleworking and other alternative work arrangements for our employees, intended to protect the health and safety of our employees while enabling us to continue to develop our pipeline of drug candidates and provide contract research services to our clients. We are focused on ensuring the continuity of our operations. In March 2020, we initiated a Phase 2a clinical trial of ATI-450 as a potential treatment for moderate to severe rheumatoid arthritis. Due to the COVID-19 pandemic, we temporarily paused enrollment. We resumed enrolling subjects, and the first subject was dosed, in May 2020. Given the continuing evolution of the COVID-19 pandemic, we modified our anticipated timing for reporting data from this trial to the first half of 2021.

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 ATI-450 as a potential treatment for rheumatoid arthritis and CAPS and our trial of ATI-1777 as a potential treatment for moderate to severe atopic dermatitis. 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 geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, stay-at-home orders, social distancing requirements, business closures and supply chain and other disruptions in the United States and other countries, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of the potential impacts on our business, our preclinical and clinical development and regulatory activities.

# **Components of Our Results of Operations**

# Revenue

Contract Research

We earn revenue from the provision of laboratory services to clients through Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence, our wholly-owned subsidiary. 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.

#### **Cost of Revenue**

Cost of revenue consists of the costs incurred in connection with the provision of contract research services to our clients through Confluence. 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 investigative sites and consultants that conduct our clinical trials and preclinical studies, and investigator-initiated trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing active pharmaceutical ingredients and preclinical and clinical trial materials;
- outsourced professional scientific development services;
- medical affairs expenses related to our drug candidates;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- depreciation of manufacturing equipment;
- payments made under agreements with third parties under which we have acquired or licensed intellectual property;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- non-cash charges related to the revaluation of contingent consideration.

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 ATI-450 as a potential treatment for rheumatoid arthritis, CAPS and other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, continue the development of our preclinical compounds, and continue to identify, research 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, investigator sites, regulatory agencies and third parties that manufacture our preclinical and clinical trial materials, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses, to specific research and development programs.

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

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable subjects;
- the number of subjects that ultimately participate in the trials;
- the number of doses subjects receive;
- the impact on the recruitment, enrollment, conduct and timing of our clinical trials due to the COVID-19 pandemic;
- the duration of subject follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the preparation of regulatory filings for our drug candidates, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may obtain unexpected results from our clinical trials or other development activities. We may elect to discontinue, delay or modify the development, including clinical trials, of some drug candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate,

or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

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

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation and travel expenses. 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 and insurance costs. We anticipate that we will incur increased director and officer insurance premiums and legal expenses associated with defending the current lawsuits described in this report.

# Other Expense, Net

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

# **Critical Accounting Policies and Significant Judgments and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and judgments on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. Except as described below, we believe 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, 2019 included in our Annual Report on Form 10-K filed with the SEC on February 25, 2020.

# **Revenue Recognition**

We account for revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers. Under ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

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

#### Contract Research

Revenue related to laboratory services is generally recognized as the laboratory services are performed, based upon the rates specified in the contracts. Under ASC Topic 606, we elected to apply the "right to invoice" practical

expedient when recognizing contract research revenue and as such, recognize revenue in the amount which we have the right to invoice. ASC Topic 606 also provides an optional exemption, which we have elected to apply, from disclosing remaining performance obligations when revenue is recognized from the satisfaction of the performance obligation in accordance with the "right to invoice" practical expedient.

#### **Intangible Assets**

Our intangible assets include both definite-lived and indefinite-lived assets. Our definite-lived intangible assets consist of a drug discovery technology platform acquired through the acquisition of Confluence. Definite-lived intangible assets are amortized over their estimated useful life based on the pattern over which the intangible assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the straight-line method of amortization is used. Our indefinite-lived intangible assets consist of an in-process research and development, or IPR&D, drug candidate also acquired through the acquisition of Confluence. IPR&D assets are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. The cost of IPR&D assets is either amortized over their estimated useful life beginning when the underlying drug candidate is approved and launched commercially or expensed immediately if development of the drug candidate is abandoned.

Definite-lived intangible assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment at least annually, which we perform during the fourth quarter, or when indicators of an impairment are present. We recognize impairment losses when and to the extent that the estimated fair value of an intangible asset is less than its carrying value.

#### Leases

Leases represent a company's right to use an underlying asset and a corresponding obligation to make payments to a lessor for the right to use those assets. We evaluate leases at their inception to determine if they are an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows are substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease.

We recognize assets and liabilities for leases at their inception based upon the present value of all payments due under the lease. We use an implicit interest rate to determine the present value of finance leases, and our incremental borrowing rate to determine the present value of operating leases. We determine incremental borrowing rates by referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. We recognize expense for operating and finance leases on a straight-line basis over the term of each lease, and interest expense related to finance leases is recognized over the lease term based on the effective interest method. We include estimates for any residual value guarantee obligations under our leases in lease liabilities recorded on our condensed consolidated balance sheet

Right-of-use assets are included in other assets and property and equipment, net on our condensed consolidated balance sheet for operating and finance leases, respectively. Obligations for lease payments are included in current portion of lease liabilities and other liabilities on our condensed consolidated balance sheet for both operating and finance leases.

#### **Contingent Consideration**

We initially recorded a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon the achievement of certain development, regulatory and commercial milestones, as well as future projected sales performance, at its estimated fair value on the date of acquisition. The ultimate amount of

future payments, if any, is based on criteria such as sales performance and the achievement of certain regulatory and sales milestones. We estimate the fair value of the contingent consideration liability related to the achievement of regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. We estimate the fair value of the contingent consideration liability associated with sales milestones and royalties by estimating future sales levels, assigning an achievement probability and discounting the associated cash payment amounts to their present values using a credit-risk-adjusted interest rate. Significant assumptions used in our estimates include the probability of success of both achieving regulatory milestones and commencing commercialization, which are based upon an asset's current stage of development and ranged between 4% and 15%. We evaluate fair value estimates of contingent consideration liabilities on a periodic basis. Any change in fair value reflects new information about the likelihood of the payment of the contingent consideration and the passage of time. For example, if the timing of the development of an acquired drug candidate, or the size of potential commercial opportunities related to an acquired drug candidate, differ from our assumptions, then the fair value of contingent consideration would be adjusted accordingly. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in our condensed consolidated statement of operations.

#### **Recently Issued Accounting Pronouncements**

In November 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. We adopted this standard as of January 1, 2020, the impact of which on our consolidated financial statements was not significant.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification, or ASC, 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. We adopted this standard as of January 1, 2020, the impact of which on our consolidated financial statements was not significant.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing disclosure requirements. We adopted this standard as of January 1, 2020, the impact of which on our consolidated financial statements was not significant.

# **Results of Operations**

# Comparison of Three Months Ended September 30, 2020 and 2019

	Thr	ee Months End			
(In thousands)		2020	2019	Change	
Revenues:					
Contract research	\$	1,331	\$ 983	\$ 348	,
Other revenue		118	_	118	)
Total revenue		1,449	983	466	,
Costs and expenses:					
Cost of revenue		1,189	826	363	,
Research and development		6,866	16,183	(9,317	)
General and administrative		3,859	6,838	(2,979)	)
Total costs and expenses		11,914	 23,847	(11,933)	)
Loss from operations		(10,465)	(22,864)	12,399	
Other expense, net		(194)	(274)	80	)
Loss from continuing operations		(10,659)	 (23,138)	12,479	_
Loss from discontinued operations			(32,181)	32,181	
Net loss	\$	(10,659)	\$ (55,319)	\$ 44,660	ı
					_

# Revenue

Contract research revenue was \$1.3 million and \$1.0 million for the three months ended September 30, 2020 and 2019, respectively, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence. Other revenue for the three months ended September 30, 2020 consisted of \$0.1 million of royalties earned on net sales of RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, pursuant to the asset purchase agreement with EPI Health, LLC, or EPI Health.

# **Cost of Revenue**

Cost of revenue was \$1.2 million and \$0.8 million for the three months ended September 30, 2020 and 2019, respectively, and related to providing laboratory services to our clients through Confluence.

# **Research and Development Expenses**

The following table summarizes our research and development expenses:

(In thousands)	Three Months Ended September 30, 2020 2019				Change														
	_																		Change
ATI-450	\$	2,216	\$	2,199	\$ 17														
ATI-1777		694		362	332														
ATI-2138		599		330	269														
Other JAK inhibitors		_		1,881	(1,881)														
A-101 45% Topical Solution		27		2,353	(2,326)														
Other research and development expenses		826		1,009	(183)														
Personnel expenses		1,441		2,631	(1,190)														
Stock-based compensation		437		1,418	(981)														
Development milestone		_		4,000	(4,000)														
Change in contingent consideration		626		_	626														
Total research and development expenses	\$	6,866	\$	16,183	\$ (9,317)														

Research and development expenses for ATI-450 during the three months ended September 30, 2019 primarily consisted of preclinical development activities and activities related to a Phase 1 clinical trial that was completed in January 2020. ATI-450 expenses during the three months ended September 30, 2020 primarily consisted of costs associated with multiple clinical trials, including a Phase 2a trial in subjects with rheumatoid arthritis. Expenses for ATI-1777 were higher during the three months ended September 30, 2020 due to initial activities related to a Phase 2a clinical trial which began enrollment in October 2020. Expenses for ATI-2138 were higher during the three months ended September 30, 2020 primarily due to preclinical development activities to support an IND submission. Expenses related to other JAK inhibitors decreased primarily as a result of the completion of several Phase 2 clinical trials of ATI-501 and ATI-502 during 2019. Expenses related to A-101 45% Topical Solution decreased primarily due to the completion of our Phase 3 clinical trials during 2019. Personnel expenses and stock-based compensation decreased due to lower headcount primarily as a result of the restructuring we announced in September 2019. In September 2019, we made a milestone payment of \$4.0 million to Rigel Pharmaceuticals, Inc., or Rigel, upon the achievement of a development milestone. The change in contingent consideration during the three months ended September 30, 2020 was the result of updates to our assumptions as a result of the submission and allowance of an IND for ATI-1777.

## **General and Administrative Expenses**

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,					
(In thousands)		2020	2019		Change	
Personnel expenses	\$	861	\$	2,397	\$	(1,536)
Professional and legal fees		907		565		342
Facility and support services		362		735		(373)
Other general and administrative expenses		441		560		(119)
Stock-based compensation		1,288		2,581		(1,293)
Total general and administrative expenses	\$	3,859	\$	6,838	\$	(2,979)

Personnel and stock-based compensation expenses decreased primarily due to lower headcount primarily as a result of the restructuring we announced in September 2019. Professional and legal fees included accounting, legal, investor relations and corporate communication costs, as well as legal fees related to patents and current lawsuits described in this report, and were higher primarily as a result of higher legal and accounting fees. Facility and support services included general office expenses, information technology costs and other expenses, and have decreased primarily due to lower information technology costs resulting from lower headcount. Other general and administrative expenses included

travel and insurance costs, and were lower primarily due to reduced travel-related activities in light of the COVID-19 pandemic.

# Other Expense, net

Other expense, net for the three months ended September 30, 2020 was \$0.2 million and primarily included interest expense related to our term loan facility with Silicon Valley Bank, or SVB, which we borrowed in March 2020, as well as interest on our finance leases, partially offset by interest income earned on our cash and investments. Other expense, net for the three months ended September 30, 2019 was \$0.3 million and primarily included interest expense incurred on our debt with Oxford Finance LLC, which we borrowed in October 2018 and repaid in full in October 2019, partially offset by interest income earned on our cash and investments.

# **Loss from Discontinued Operations**

In September 2019, we announced the completion of a strategic review and our decision to refocus on our immuno-inflammatory development programs and to actively seek partners for our commercial products. The condensed consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to our commercial products as discontinued operations (see Note 15 to the condensed consolidated financial statements included in this report for additional information).

# Comparison of Nine Months Ended September 30, 2020 and 2019

	Nin	e Months End		
(In thousands)		2020	 2019	Change
Revenues:				
Contract research	\$	4,373	\$ 3,132	\$ 1,241
Other revenue		529	<u> </u>	529
Total revenue		4,902	3,132	 1,770
Costs and expenses:				
Cost of revenue		3,847	3,028	819
Research and development		22,775	53,334	(30,559)
General and administrative		15,632	21,771	(6,139)
Goodwill impairment		_	18,504	(18,504)
Total costs and expenses		42,254	 96,637	(54,383)
Loss from operations		(37,352)	 (93,505)	56,153
Other expense, net		(205)	(589)	384
Loss from continuing operations		(37,557)	 (94,094)	56,537
Loss from discontinued operations		(285)	(48,666)	48,381
Net loss	\$	(37,842)	\$ (142,760)	\$ 104,918

# Revenue

Contract research revenue was \$4.4 million and \$3.1 million for the nine months ended September 30, 2020 and 2019, respectively, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence. Other revenue during the nine months ended September 30, 2020 consisted of \$0.5 million of royalties earned on net sales of RHOFADE pursuant to the asset purchase agreement with EPI Health.

# **Cost of Revenue**

Cost of revenue was \$3.8 million and \$3.0 million for the nine months ended September 30, 2020 and 2019, respectively, and related to providing laboratory services to our clients through Confluence.

# **Research and Development Expenses**

The following table summarizes our research and development expenses:

	Nine Months Ended September 30,					
(In thousands)	2	020	2019			Change
ATI-450	\$	4,950	\$	5,617	\$	(667)
ATI-1777		2,553		2,733		(180)
ATI-2138		1,753		456		1,297
Other JAK inhibitors		629		10,573		(9,944)
A-101 45% Topical Solution		559		12,216		(11,657)
Other research and development expenses		2,555		4,382		(1,827)
Personnel expenses		5,191		7,890		(2,699)
Stock-based compensation		2,192		4,733		(2,541)
Development milestone		_		4,000		(4,000)
Change in contingent consideration		2,393		734		1,659
Total research and development expenses	\$ 2	2,775	\$	53,334	\$	(30,559)

Research and development expenses for ATI-450 during the nine months ended September 30, 2019 primarily consisted of preclinical development activities and activities related to a Phase 1 clinical trial that was completed in January 2020. ATI-450 expenses during the nine months ended September 30, 2020 primarily consisted of costs associated with multiple clinical trials, including a Phase 2a trial in subjects with rheumatoid arthritis. ATI-450 expenses decreased during the nine months ended September 30, 2020 due to lower preclinical development activities, partially offset by an increase in costs associated with various ongoing clinical trials. Expenses for ATI-1777 were lower during the nine months ended September 30, 2020 primarily due to the completion of preclinical development activities, partially offset by costs associated with initial activities related to a Phase 2a clinical trial which began enrollment in October 2020. Expenses for ATI-2138 were higher during the nine months ended September 30, 2020 primarily due to preclinical development activities to support an IND submission. Expenses related to other JAK inhibitors decreased primarily as a result of the completion of several Phase 2 clinical trials of ATI-501 and ATI-502 during 2019. Expenses related to A-101 45% Topical Solution decreased primarily due to the completion of our Phase 3 clinical trials during 2019. Other research and development expenses, which primarily included expenses for medical affairs activities as well as drug discovery, were lower primarily as a result of lower medical affairs related activities during the nine months ended September 30, 2020 primarily resulting from our clinical trials that were completed during 2019 for A-101 45% Topical Solution, ATI-501 and ATI-502. Personnel expenses and stock-based compensation decreased due to lower headcount primarily as a result of the restructuring we announced in September 2019. In September 2019, we made a milestone payment of \$4.0 million to Rigel upon the achievement of a development milestone. The change in contingent consideration during the nine months ended September 30, 2020 was the result of updates to our assumptions as a result of the completion of a successful Phase 1 clinical trial for ATI-450 and the submission of an IND for ATI-1777, while the change in contingent consideration during the nine months ended September 30, 2019 was the result of updates to our assumptions as a result of the submission and allowance of an IND for ATI-450.

# **General and Administrative Expenses**

The following table summarizes our general and administrative expenses:

	Nine Months Ended September 30,					
(In thousands)		2020		2019	Change	
Personnel expenses	\$	4,130	\$	6,987	\$	(2,857)
Professional and legal fees		2,857		2,982		(125)
Facility and support services		1,294		2,091		(797)
Other general and administrative expenses		1,568		2,004		(436)
Stock-based compensation		5,783		7,707		(1,924)
Total general and administrative expenses	\$	15,632	\$	21,771	\$	(6,139)

Personnel and stock-based compensation expenses decreased primarily due to lower headcount primarily as a result of the restructuring we announced in September 2019. Professional and legal fees included accounting, legal, investor relations and corporate communication costs, as well as legal fees related to patents and current lawsuits described in this report, and were lower year-over-year primarily as a result of lower legal fees. Facility and support services included general office expenses, information technology costs and other expenses, and have decreased primarily due to lower information technology costs resulting from lower headcount. Other general and administrative expenses included travel and insurance costs, and were lower primarily due to reduced travel-related activities in light of the COVID-19 pandemic.

# **Goodwill Impairment**

During the nine months ended September 30, 2019, we performed an interim impairment analysis due to a decline in our stock price. Our impairment analysis noted that our stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, we recorded a goodwill impairment charge of \$18.5 million writing off the full balance of goodwill.

## Other Expense, net

Other expense, net for the nine months ended September 30, 2020 was \$0.2 million and primarily included interest expense related to our term loan facility with SVB which we borrowed in March 2020, as well as interest on our finance leases, partially offset by interest income earned on our cash and investments. Other expense, net for the nine months ended September 30, 2019 was \$0.6 million and primarily included interest expense incurred on our debt with Oxford Finance LLC, which we borrowed in October 2018 and repaid in full in October 2019, partially offset by interest income earned on our cash and investments.

#### **Loss from Discontinued Operations**

In September 2019, we announced the completion of a strategic review and our decision to refocus on our immuno-inflammatory development programs and to actively seek partners for our commercial products. The condensed consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to our commercial products as discontinued operations (see Note 15 to the condensed consolidated financial statements included in this report for additional information).

# **Liquidity and Capital Resources**

Since our inception, we have incurred net losses and negative cash flows from our operations. Prior to our acquisition of Confluence in August 2017, we did not generate any revenue. We have financed our operations over the last several years primarily through sales of our equity securities in public offerings and a private placement transaction. In March 2020, we entered into the Loan and Security Agreement with SVB. In August 2020, we entered into an equity purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park.

As of September 30, 2020, we had cash, cash equivalents, restricted cash and marketable securities of \$55.2 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 term loan facility, lease obligations, and contingent obligations under acquisition and intellectual property licensing agreements, which are summarized below under "Contractual Obligations and Commitments."

# 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 provides for \$11.0 million in term loans, of which we borrowed the entire amount on March 30, 2020. The Loan and Security Agreement is secured by substantially all of our assets other than intellectual property.

The term loan repayment schedule provides for interest only payments beginning April 1, 2020 and continuing through March 1, 2022, followed by 24 consecutive equal monthly installments of principal, plus monthly payments of accrued interest, starting on April 1, 2022 and continuing through the maturity date of March 1, 2024. All outstanding principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 2% and (ii) 6.75%.

The Loan and Security Agreement includes a final payment fee equal to 5% of the original principal amount borrowed. We have the option to prepay the outstanding balance of the term loans in full, subject to a prepayment premium of (i) 3% of the original principal amount borrowed for any prepayment on or prior to the first anniversary of March 30, 2020, (ii) 2% of the original principal amount borrowed for any prepayment after the first anniversary and on or before

the second anniversary of March 30, 2020 or (iii) 1% of the original principal amount borrowed for any prepayment after the second anniversary of March 30, 2020 but before March 1, 2024.

The Loan and Security Agreement contains a customary covenant that limits our ability, subject to specified exceptions, to incur additional indebtedness without the prior written consent of SVB.

#### **Equity Purchase Agreement with Lincoln Park Capital Fund, LLC**

In August 2020, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park, at our discretion, up to \$15.0 million of shares of our common stock over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 121,584 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of our common stock on the effective date of the Purchase Agreement resulting in an aggregate fair value of \$0.3 million. As of September 30, 2020, we had not sold any shares of our common stock to Lincoln Park under the Purchase Agreement.

#### **Cash Flows**

The following table summarizes our cash flows for each of the periods presented:

	<u>N</u>	Nine Months Ended September 30,			
(In thousands)		2020		2019	
Net cash used in operating activities	\$	(29,776)	\$	(76,055)	
Net cash provided by investing activities		8,692		49,241	
Net cash provided by (used in) financing activities		10,543		(307)	
Net decrease in cash, cash equivalents and restricted cash	\$	(10,541)	\$	(27,121)	

#### **Operating Activities**

During the nine months ended September 30, 2020, operating activities used \$29.8 million of cash primarily resulting from our net loss of \$37.8 million, partially offset by non-cash adjustments of \$12.9 million. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2020 consisted of a \$10.9 million net decrease in accounts payable and accrued expenses, which were partially offset by a \$4.8 million decrease in accounts receivable and a \$1.3 million decrease in prepaid expenses and other assets. The net decrease in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of December 31, 2019. The decrease in accounts receivable was primarily the result of cash received from Allergan Sales, LLC, or Allergan, related to sales of RHOFADE made during the year ended December 31, 2019. The decrease in prepaid expenses and other assets was primarily due to amortization of the premiums for our corporate insurance policies, which we expense equally over the policy term. Expenses incurred as of December 31, 2019 and paid during the nine months ended September 30, 2020 primarily included employee annual merit bonuses, as well as expenses related to preclinical development and Phase 1 clinical trial activities for ATI-450, and preclinical development activities for ATI-1777 and ATI-2138. Non-cash expenses of \$12.9 million were composed of stock-based compensation expense of \$8.7 million, a charge of \$2.4 million related to the change in contingent consideration and depreciation and amortization expense of \$1.8 million.

During the nine months ended September 30, 2019, operating activities used \$76.1 million of cash primarily resulting from our net loss of \$142.8 million, partially offset by non-cash adjustments of \$66.0 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2019 consisted of a \$9.9 million increase in accounts payable and accrued expenses and a \$3.9 million decrease in prepaid expenses and other assets, which were partially offset by a \$13.0 million increase in accounts receivable. The increase in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of September 30, 2019, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of September 30, 2019 primarily included sales discounts and allowances related to sales of RHOFADE, as well as expenses related to our Phase 3 clinical trials for A-101 45% Topical Solution, our Phase 2 clinical trials for ATI-501 and ATI-502 and preclinical development

and Phase 1 clinical trial activities for ATI-450. The decrease in prepaid expenses and other assets was due to research and development activities primarily related to preclinical development activities for ATI-450 and ATI-502 which concluded during the nine months ended September 30, 2019, and reduced sales and marketing activities related to our decision to no longer use a sales force to promote RHOFADE in September 2019. In addition, because the annual renewal of our corporate insurance policies occurred in October 2019, the balance of prepaid insurance was minimal as of September 30, 2019. The increase in accounts receivable was primarily the result of sales of RHOFADE during the nine months ended September 2019. Non-cash expenses of \$66.0 million were composed of an intangible asset impairment charge of \$27.6 million, a goodwill impairment charge of \$18.5 million, stock-based compensation expense of \$13.0 million, a charge of \$0.7 million related to the change in contingent consideration and depreciation and amortization expense of \$6.1 million.

#### **Investing Activities**

During the nine months ended September 30, 2020, investing activities provided \$8.7 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$49.0 million, offset by purchases of marketable securities of \$39.9 million and purchases of equipment of \$0.4 million.

During the nine months ended September 30, 2019, investing activities provided \$49.2 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$171.9 million, offset by purchases of marketable securities of \$121.3 million and purchases of equipment of \$1.3 million.

# **Financing Activities**

During the nine months ended September 30, 2020, financing activities provided \$10.5 million of cash and consisted of \$10.9 million of net borrowings pursuant to the Loan and Security Agreement with SVB offset by \$0.1 million of finance lease payments and \$0.2 million of deferred issuance costs.

During the nine months ended September 30, 2019, financing activities used \$0.3 million of cash primarily related to finance lease payments.

# **Funding Requirements**

We anticipate we will incur net losses in the near term as we continue the clinical development of ATI-450 as a potential treatment for rheumatoid arthritis, CAPS and other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, continue the development of our preclinical compounds, and continue to identify, research and develop additional drug candidates. We may not be able to generate revenue from these programs if, among other things, our clinical trials are not successful, the FDA does not approve our drug candidates currently in clinical trials when we expect, or at all, or we are not able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

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

As a publicly traded company, we incur and will continue to incur significant legal, accounting and other 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.

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 ATI-450 and ATI-1777, to develop our preclinical compounds, and to support our discovery efforts. Additional funds may not be available on a

timely basis, on commercially acceptable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital or generate revenue from transactions with third-party partners for the development and/or commercialization of our drug candidates, we may need to substantially curtail our planned operations.

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

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

- the number and development requirements of the drug candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our drug candidates;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the extent to which we in-license or acquire additional drug candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the impact on the timing of our preclinical studies, the recruitment, enrollment, conduct and timing of our clinical trials and our business due to the COVID-19 pandemic;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and earn revenue from such arrangements; and
- the revenue earned from our commercial products as a result of licenses to, or partnerships with, third parties.

# **Contractual Obligations and Commitments**

We occupy space for our headquarters in Wayne, Pennsylvania under a sublease agreement which has a term through October 2023. We occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through June 2029.

We lease laboratory equipment used in our laboratory space in St. Louis, Missouri under two capital lease financing arrangements which have terms through October 2020 and December 2020.

In March 2020, we borrowed \$11.0 million under the Loan and Security Agreement with SVB. Amounts borrowed under the Loan and Security Agreement are subject to interest only through March 2022, after which we will be required to make principal and interest payments through the maturity date of March 2024.

Under the assignment agreement with the Estate of Mickey Miller pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of ESKATA and related products at rates ranging in low single-digit percentages of net sales, as defined in the agreement. Under the related finder's services agreement with KPT Consulting, LLC, we have agreed to make a remaining payment of \$3.0 million upon the achievement of a specified commercial milestone. In addition, we have agreed to pay royalties on sales of ESKATA and related products at a low single-digit percentage of net sales, as defined in the agreement. In August 2019, we voluntarily discontinued the commercialization of ESKATA in the United States and withdrew the marketing authorizations we had previously received for the product in all countries outside of the United States.

Under a license agreement with Rigel Pharmaceuticals, Inc., or Rigel, we have agreed to make remaining aggregate payments of up to \$76.0 million upon the achievement of specified development milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional \$10.5 million to Rigel upon the achievement of a second set of development milestones. In addition, in connection with the amendment of the agreement

in October 2019, we paid Rigel an amendment fee of \$1.5 million in three installments of \$0.5 million in each of January 2020, April 2020 and July 2020. With respect to any products we commercialize under the agreement, we will pay Rigel quarterly tiered royalties on our annual net sales of each product developed using the licensed JAK inhibitors at a high single digit percentage of annual net sales, subject to specified reductions.

Under a stock purchase agreement with the selling stockholders of one of our former subsidiaries, we are obligated to make aggregate payments of up to \$18.0 million upon the achievement of specified pre-commercialization milestones for three products covered by the acquired patent rights in the United States, the European Union and Japan, and aggregate payments of up to \$22.5 million upon the achievement of specified commercial milestones for products covered by the acquired patent rights. We are also obligated to make an annual payment of \$0.1 million through March 2022, which amounts are creditable against any specified future payments that may be paid under the agreement. With respect to any covered products that we commercialize under the agreement, we are obligated to pay 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. If we sublicense any of the patent rights and know-how acquired pursuant to the agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

Under a license agreement with The Trustees of Columbia University in the City of New York, or Columbia, we are obligated to pay an annual license fee of \$10,000, subject to specified adjustments for patent expenses incurred by Columbia and creditable against any royalties that may be paid under the license agreement. We are also obligated to pay up to an aggregate of \$11.6 million upon the achievement of specified commercial milestones, including specified levels of net sales of products covered by Columbia patent rights and/or know-how, and royalties at a sub-single-digit percentage of annual net sales of products covered by Columbia patent rights and/or know-how, subject to specified adjustments. If we sublicense any of Columbia's patent rights and know-how acquired pursuant to the agreement, we will be obligated to pay Columbia a portion of any consideration we receive from such sublicense in specified circumstances.

Under a merger agreement with Confluence, we are obligated to make remaining aggregate payments of up to \$75.0 million upon the achievement of specified regulatory and commercialization milestones. With respect to any covered products we commercialize, we are obligated to pay 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. If we sell, license or transfer any of the intellectual property acquired pursuant to the agreement, we will be obligated to pay a portion of any consideration we receive from such sale, license or transfer in specified circumstances.

We enter into contracts in the normal course of business with CROs and contract manufacturing organizations for clinical trials, preclinical research 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.

# **Off-Balance Sheet Arrangements**

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

#### **Emerging Growth Company Status**

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies. We will cease to be an emerging growth company as of December 31, 2020.

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

Our cash equivalents and marketable securities consist of money market funds, asset-backed securities, commercial paper, corporate debt securities and government agency debt. 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 Loan and Security Agreement with SVB provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 2% and (ii) 6.75%. To the extent that any present or future credit facilities that we enter into are based on a floating interest rate, we will be subject to risks relating to changes in market interest rates. In periods of rising interest rates when we have such debt outstanding, our interest expense would increase. Based upon our debt outstanding of \$11.0 million as of September 30, 2020, a 100 basis-point increase in the interest rate on our loan with SVB would result in \$0.1 million of additional interest expense on an annualized basis.

The uncertainty that exists with respect to the economic impact of the global COVID-19 pandemic has introduced significant volatility in the financial markets during and subsequent to our quarter ended September 30, 2020.

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

# (a) Evaluation of Disclosure Controls and Procedures

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

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

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2020, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level.

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

There have not been any changes in our internal control over financial reporting during our fiscal quarter ended September 30, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### **Item 1. Legal Proceedings**

#### **Securities Class Action**

On July 30, 2019, plaintiff Linda Rosi, or Rosi, filed a putative class action complaint captioned *Rosi v. Aclaris Therapeutics, Inc., et al.* in the U.S. District Court for the Southern District of New York against us and certain of our executive officers. The complaint alleges that the defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired our securities between May 8, 2018 and June 20, 2019.

On September 5, 2019, an additional plaintiff, Robert Fulcher, or Fulcher, filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc.*, *et al.* in the same court against the same defendants.

On November 6, 2019, the court consolidated the Rosi and Fulcher actions, or together, the Consolidated Securities Action, and appointed Fulcher "lead plaintiff" for the putative class.

On January 24, 2020, Fulcher filed a consolidated amended complaint in the Consolidated Securities Action, naming two additional executive officers as defendants, extending the putative class period to August 12, 2019, and adding allegations concerning, among other things, alleged statements and omissions throughout the putative class period concerning ESKATA's risks, tolerability and effectiveness. The defendants filed a motion to dismiss the consolidated amended complaint on April 17, 2020. Fulcher filed an opposition to the defendants' motion on June 15, 2020, and the defendants filed a reply to such opposition on August 4, 2020. The motion remains under judicial consideration.

We and the other defendants dispute plaintiffs' claims in the Consolidated Securities Action and intend to defend the matter vigorously.

#### **Stockholder Derivative Action**

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

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

On December 12, 2019, the court consolidated the Allred and Brown actions under the caption *In re Aclaris Therapeutics*, *Inc. Derivative Litigation*, or the Consolidated Derivative Action, and directed that future derivative cases filed in or transferred to the court arising out of substantially the same transactions or events be similarly consolidated. Thereafter, on January 11, 2020, the court stayed – subject to certain conditions – all deadlines in the

Consolidated Derivative Action pending resolution of the defendants' then-anticipated motion to dismiss the Consolidated Securities Action.

The defendants dispute plaintiffs' claims in the Consolidated Derivative Action and intend to defend the matter vigorously.

In addition, from time to time, we are subject to litigation and claims arising in the ordinary course of business but, except as stated above, we are not currently a party to any material legal proceedings and we are not aware of any 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. Except as noted below, 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, 2019, filed with the SEC on February 25, 2020.

# Risks Related to Our Business, Our Financial Position and Capital Needs

Our business has been adversely impacted and could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could adversely affect our operations, including at our headquarters, which is currently subject to a telework order, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business has been adversely affected by the effects of the recent and evolving COVID-19 pandemic, which was declared by the World Health Organization as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, which, among other things, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. In response to these public health directives and orders, we have implemented a virtual operations strategy, including teleworking and other alternative work arrangements for all employees. The effects of our alternative work arrangement policies may negatively impact productivity, disrupt our business and delay our preclinical drug development and clinical trials and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, executive and similar government orders, and business shutdowns, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Some of our third-party manufacturers which we use for the supply of materials for our drug candidates or other materials necessary to manufacture drug product to conduct preclinical studies and clinical trials are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these studies and trials.

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some subjects may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial

operations. For example, in March 2020, we initiated a Phase 2a clinical trial of ATI-450 as a potential treatment for moderate to severe rheumatoid arthritis. Due to the COVID-19 pandemic, we temporarily paused enrollment. We resumed enrolling subjects, and the first subject was dosed, in May 2020. Given the continuing evolution of the COVID-19 pandemic, we modified our anticipated timing for reporting data from this trial to the first half of 2021.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and impact our ability to make scheduled payments pursuant to our Loan and Security Agreement with SVB. In addition, a recession or market correction resulting from the further spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. 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 geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, stay-at-home orders, social distancing requirements and business closures and supply chain and other disruptions in the United States and other countries, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of the impacts on our business, our preclinical and clinical development and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 25, 2020.

# We may not be able to generate sufficient cash to service our indebtedness, including the Loan and Security Agreement with SVB.

In March 2020, we entered into the Loan and Security Agreement with SVB, pursuant to which we borrowed \$11.0 million. Our obligations under the Loan and Security Agreement are secured by substantially all of our assets except for our intellectual property, and we may not encumber our intellectual property without SVB's prior written consent. The Loan and Security Agreement contains customary representations, warranties and covenants by us, which covenants, among other things, limit our ability, subject to specified exceptions, to convey, sell, lease, transfer, assign or otherwise dispose of our assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; undergo specified change of control events; create, incur, assume or be liable for indebtedness; create, incur, allow or suffer any liens on our property; pay dividends and make other restricted payments; make investments; or enter into any material transactions with our affiliates. Our obligations under the Loan and Security Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial condition. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, including the impact of the COVID-19 pandemic, some of which may be beyond our control. We cannot guarantee that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot guarantee that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the covenants and conditions of the Loan and Security Agreement could result in an event of default, which could result in an acceleration of amounts due under the Loan and Security Agreement. We may

not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and SVB could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business.

# Risks Related to the Development and Potential Commercialization of Our Drug Candidates

Our clinical trials may fail to demonstrate the safety and efficacy of our drug candidates, or serious adverse or unacceptable side effects may be identified during the development of our drug candidates, which could increase our costs or necessitate the abandonment or limitation of the development of our drug candidates or prevent or delay our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates.

If our drug candidates are associated with side effects in clinical trials or have characteristics that are serious or unexpected, our costs could increase or we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for our drug candidates. Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the drug candidate.

Before any potential third-party partners can obtain marketing approvals for the commercial sale of our drug candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our drug candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the drug candidate studied for the target indication.

Additionally, if we or others identify undesirable side effects caused by our drugs, a number of potentially significant negative consequences could result, including:

- we may need to abandon the development or limit the further development of our drug candidates, including in various populations and indications;
- regulatory authorities may withdraw approval to market such product;
- regulatory authorities may require additional warnings on the labels;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients;
- our reputation and physician or patient acceptance of our drug candidates, if approved, may suffer; and
- our ability to pursue strategic alternatives, including identifying and consummating transactions with thirdparty partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates would be harmed.

For example, in June 2020 we announced our support of an investigator-initiated trial of ATI-450 in hospitalized patients with COVID-19. Although the COVID-19 trial is not sponsored by us, the use of ATI-450 in a hospitalized and severely ill patient population may be associated with adverse events and risks that could jeopardize our development of ATI-450 in other populations and indications, including our trials in subjects with rheumatoid arthritis and CAPS.

Any of these events could prevent us from pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize the particular drug candidate and could significantly harm our business, results of operations and prospects.

#### Risks Related to Ownership of Our Common Stock

Exclusive forum provisions in our amended and restated certificate of incorporation and amended and restated bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws provide the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

Our amended and restated certificate of incorporation and amended and restated bylaws further provide any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

# 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	Purchase Agreement, dated as of August 13, 2020, by and between the Registrant and Lincoln Park Capital Fund, LLC. (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 13, 2020).

10.2	Registration Rights Agreement, dated as of August 13, 2020, by and between the Registrant and Lincoln Park Capital Fund, LLC. (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on August 13, 2020).
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

<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.

# **SIGNATURES**

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

ACLARIS THERAPEUTICS, INC.

Date: November 4, 2020 By: /s/ Neal Walker

Neal Walker

President and Chief Executive Officer

(On behalf of the Registrant)

Date: November 4, 2020 By: /s/ Frank Ruffo

Frank Ruffo

Chief Financial Officer (Principal Financial Officer)

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

#### I, Neal Walker, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2020 of Aclaris Therapeutics, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2020

/s/ Neal Walker
Neal Walker
President and 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 September 30, 2020 of Aclaris Therapeutics, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2020

/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, President and Chief Executive Officer of Aclaris Therapeutics, Inc. (the "Company"), and Frank Ruffo, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

- 1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020, 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 4th day of November, 2020.

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

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