Aclaris Therapeutics, Inc. Form 10-Q August 08, 2017 <u>Table of Contents</u>

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 Q

(Mark one)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

to

For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

Commission File Number 001-37581

Aclaris Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware46-0571712(State or Other Jurisdiction of(I.R.S. EmployerIncorporation or Organization)Identification No.)101 Lindenwood Drive, Suite 40019355Malvern, PA19355(Address of principal executive offices)(Zip Code)

Edgar Filing: Aclaris Therapeutics, Inc. - Form 10-Q

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

N/A

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
(,,,,,,	Emerging growth company

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

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

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on August 7, 2017 was 26,736,517.

ACLARIS THERAPEUTICS, INC.

INDEX TO FORM 10-Q

PAGE

<u>PART I.</u> <u>FINANCIAL</u> <u>INFORMATION</u>

<u>Item 1. Financial</u> 2 <u>Statements</u>

Unaudited Condensed Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016

3

2

Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2017 and 2016

Unaudited

4

5

<u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u> <u>Statement of</u> <u>Stockholders'</u> <u>Equity for the six</u> <u>months ended June</u> <u>30, 2017</u>

<u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u>

Statements of Cash Flows for the six months ended June 30, 2017 and 2016	
Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3. Quantitative and Qualitative Disclosures about Market Risk	31
Item 4. Controls and Procedures	31
<u>PART II. OTHER</u> INFORMATION	
Item 1. Legal Proceedings	32
<u>Item 1A. Risk</u> Factors	32
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	33
Item 6. Exhibits	33
<u>Signatures</u> Exhibit Index	34 35

Part I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,708	\$ 30,171
Marketable securities	137,789	107,051
Prepaid expenses and other current assets	5,254	1,334
Total current assets	175,751	138,556
Marketable securities		36,912
Property and equipment, net	938	481
Deferred offering costs	99	116
Other assets	20	20
Total assets	\$ 176,808	\$ 176,085
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,848	\$ 2,845
Accrued expenses	2,521	3,378
Total current liabilities	8,369	6,223
Other liabilities	295	372
Total liabilities	8,664	6,595
Stockholders' Equity:		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at June 30, 2017 and December 31, 2016 Common stock, \$0.00001 par value; 100,000,000 shares authorized at June 30, 2017 and December 31, 2016; 26,736,517 and 26,059,181 shares issued	—	_
and outstanding at June 30, 2017 and December 31, 2016, respectively		
Additional paid-in capital	286,619	260,671

Edgar Filing: Aclaris Therapeutics, Inc. - Form 10-Q

Accumulated other comprehensive loss	(166)	(269)
Accumulated deficit	(118,309)	(90,912)
Total stockholders' equity	168,144	169,490
Total liabilities and stockholders' equity	\$ 176,808	\$ 176,085

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

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ende	ed
	2017	2016	2017	2016
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	7,965	9,836	15,737	19,371
General and administrative	7,330	3,153	12,488	6,757
Total operating expenses	15,295	12,989	28,225	26,128
Loss from operations	(15,295)	(12,989)	(28,225)	(26,128)
Other income, net	457	118	828	218
Net loss	\$ (14,838)	\$ (12,871)	\$ (27,397)	\$ (25,910)
Net loss per share, basic and diluted	\$ (0.56)	\$ (0.62)	\$ (1.04)	\$ (1.27)
Weighted average common shares				
outstanding, basic and diluted	26,594,854	20,663,088	26,339,250	20,417,301
Other comprehensive loss:				
Unrealized (loss) gain on marketable				
securities, net of tax of \$0	\$ (4)	\$ 14	\$ (56)	\$ 156
Foreign currency translation adjustments	87	(16)	159	(6)
Total other comprehensive income (loss)	83	(2)	103	150
Comprehensive loss	\$ (14,755)	\$ (12,873)	\$ (27,294)	\$ (25,760)

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

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF

STOCKHOLDERS' EQUITY

(UNAUDITED)

(In thousands, except share data)

	Common Sto	ock Par	Additional Paid in	Accumulated Other Comprehensiv	veAccumulated	Total Stockholders'
	Shares	Value	Capital	Loss	Deficit	Equity
Balance at December 31, 2016 Issuance of common stock under the at-the-market sales	26,059,181	\$	\$ 260,671	\$ (269)	\$ (90,912)	\$ 169,490
agreement, net of offering costs						
of \$691	635,000		19,311			19,311
Exercise of stock options and						
vesting of restricted stock units	42,336		180			180
Unrealized loss on marketable securities	_		_	(56)		(56)
Foreign currency translation						
adjustment				159		159
Stock-based compensation						
expense			6,457			6,457
Net loss					(27,397)	(27,397)
Balance at June 30, 2017	26,736,517	\$ —	\$ 286,619	\$ (166)	\$ (118,309)	\$ 168,144

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

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Six Months E June 30,	Inded
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (27,397)	\$ (25,910)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	105	48
Stock-based compensation expense	6,457	2,576
Non-cash charges related to Vixen acquisition		2,784
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,897)	30
Accounts payable	3,161	2,493
Accrued expenses	(1,168)	1,353
Net cash used in operating activities	(22,739)	(16,626)
Cash flows from investing activities:		
Purchases of property and equipment	(388)	(106)
Purchases of marketable securities	(41,534)	(11,282)
Proceeds from sales and maturities of marketable securities	47,652	31,430
Net cash provided by investing activities	5,730	20,042
Cash flows from financing activities:		
Proceeds from issuance of common stock in connection with private placement, net		
of issuance costs		18,547
Proceeds from issuance of common stock under the at-the-market sales agreement,		
net of issuance costs	19,311	
Proceeds from the exercise of employee stock options	235	1
Net cash provided by financing activities	19,546	18,548
Net increase in cash and cash equivalents	2,537	21,964
Cash and cash equivalents at beginning of period	30,171	9,851
Cash and cash equivalents at end of period	\$ 32,708	\$ 31,815
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	\$ 190	\$ 18
Fair value of stock issued in connection with Vixen acquisition	\$ —	\$ 2,355

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

ACLARIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share data)

1. Organization and Nature of Business

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. On July 17, 2015, Aclaris Therapeutics International Limited ("ATIL") was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. On March 24, 2016, Vixen Pharmaceuticals, Inc. ("Vixen") became a wholly-owned subsidiary of Aclaris Therapeutics, Inc. (see Note 11). Aclaris Therapeutics, Inc., together with ATIL and Vixen, are referred to collectively as the "Company". The Company is a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. The Company's lead drug candidate, A-101 40% Topical Solution, is a proprietary high concentration formulation of hydrogen peroxide topical solution that the Company is developing as a prescription treatment for seborrheic keratosis ("SK"), a common non malignant skin tumor. The Company has completed three Phase 3 clinical trials of A-101 40% Topical Solution in patients with SK, and in February 2017 submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA"). The NDA was accepted by the FDA in May 2017 and the Prescription Drug User Fee Act ("PDUFA") target action date for the completion of the FDA's review of the NDA is December 24, 2017.

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. At June 30, 2017, the Company had cash, cash equivalents and marketable securities of \$170,497 and an accumulated deficit of \$118,309. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of the Company's products will require significant additional financing. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The financial statements include the consolidated accounts of the Company and its wholly-owned subsidiaries, ATIL and Vixen. All intercompany transactions have been eliminated.

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 and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2017, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2017 and 2016, the condensed consolidated statement of stockholders' equity for the six months ended June 30, 2017, and the condensed consolidated statements of cash flows for the six months ended June 30, 2017 and 2016 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 March 15, 2017 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2017, the results of its operations and comprehensive loss for the three and six months ended June 30, 2017 and 2016 and its cash flows for the six months ended June 30, 2017 and 2016. The condensed consolidated balance sheet data as of December 31, 2016 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 six months ended June 30, 2017 and 2016 are unaudited. The results for the three and six months ended June 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, 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, 2016 included in the Company's annual report on Form 10-K filed with the SEC on March 15, 2017.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2016 included in the Company's annual report on Form 10-K filed with the SEC on March 15, 2017. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies other than noted immediately below.

In February 2017, the Company paid a \$2.0 million PDUFA fee to the FDA in conjunction with the filing of its NDA for A-101 40% Topical Solution. The Company has requested a waiver and refund of this PDUFA fee from the FDA, and the amount has been recorded in prepaid expenses and other current assets on the Company's condensed consolidated balance sheet.

Recently Issued Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. The Company is assessing the potential impact of ASU 2017-01 on its consolidated financial statements.

3. Fair Value of Financial Assets and Liabilities

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

	June 30, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 23,596	\$ 6,993	\$ —	\$ 30,589
Marketable securities		137,789		137,789
Total	\$ 23,596	\$ 144,782	\$ —	\$ 168,378

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 11,522	\$ 12,691	\$ —	\$ 24,213
Marketable securities		143,963	—	143,963
Total	\$ 11,522	\$ 156,654	\$ —	\$ 168,176

As of June 30, 2017 and December 31, 2016, the Company's cash equivalents consisted of investments with maturities of less than three months and included a money market fund, which was valued based upon Level 1 inputs, and commercial paper and asset-backed 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. On a quarterly basis, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of those quoted prices. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to the quoted prices obtained from the third-party pricing 30, 2017 and the year ended December 31, 2016, there were no transfers between Level 1, Level 2 and Level 3.

As of June 30, 2017 and December 31, 2016, the fair value of the Company's available for sale marketable securities by type of security was as follows:

Edgar Filing: Aclaris Therapeutics, Inc. - Form 10-Q

	June 30, 2017		Gross	
	Amortized Cost	Gross Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 38,318	\$ —	\$ (25)	\$ 38,293
Commercial paper	34,098			34,098
Asset-backed securities	25,938		(21)	25,917
U.S. government agency debt securities	39,539		(58)	39,481
Total marketable securities	\$ 137,893	\$ —	\$ (104)	\$ 137,789

	December 31, 2016			
		Gross	Gross	
	Amortized	Unrealized	Unrealized	Fair
	Cost	Gain	Loss	Value
Marketable securities:				
Corporate debt securities	\$ 51,352	\$ —	\$ (59)	\$ 51,293
Commercial paper	20,463			20,463
Asset-backed securities	28,692	6	(1)	28,697
U.S. government agency debt securities	43,505	8	(3)	43,510
Total marketable securities	\$ 144,012	\$ 14	\$ (63)	\$ 143,963

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	June 30,	December 31,
	2017	2016
Computer equipment	\$ 530	\$ 310
Manufacturing equipment	478	149
Furniture and fixtures	125	115
Leasehold improvements	33	33
Property and equipment, gross	1,166	607
Accumulated depreciation	(228)	(126)
Property and equipment, net	\$ 938	\$ 481

Depreciation expense was \$55 and \$27 for the three months ended June 30, 2017 and 2016, respectively, and \$105 and \$48 for the six months ended June 30, 2017 and 2016, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following:

	June 30,	December 31,
	2017	2016
Research and development expenses	\$ 1,187	\$ 1,166
Employee compensation expenses	1,074	1,732
Vixen contract payable	100	100
Professional fees	100	77
Other	60	303
Total accrued expenses	\$ 2,521	\$ 3,378

6. Stockholders' Equity

Preferred Stock

As of June 30, 2017 and December 31, 2016, the Company's amended and restated certificate of incorporation authorized the Company to issue 10,000,000 shares of undesignated preferred stock. No shares of preferred stock were outstanding as of June 30, 2017 or December 31, 2016.

Common Stock

As of June 30, 2017 and December 31, 2016, 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 June 30, 2017.

At-The-Market Equity Offering

On November 2, 2016, the Company entered into an at-the-market sales agreement with Cowen and Company, LLC to sell the Company's securities under a shelf registration statement filed in November 2016. During the three months ended June 30, 2017, the Company issued and sold 635,000 shares of common stock under the at-the-market sales agreement. The shares were sold at a weighted average price per share of \$31.50, for aggregate gross proceeds of \$20.0 million. As of June 30, 2017, the Company had issued and sold an aggregate of 635,000 shares of common stock under the at-the-market sales agreement, for aggregate gross proceeds of \$20.0 million.

7. Stock Based Awards

2015 Equity Incentive Plan

On September 15, 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (the "2015 Plan"), and on September 16, 2015, 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, beginning on January 1, 2016 and 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 31 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, 2017, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 1,042,367 shares. As of June 30, 2017, 1,533,599 shares remained available for grant under the 2015 Plan.

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 1,003,647 and 1,049,667 were outstanding as of June 30, 2017 and December 31, 2016, respectively. Stock options granted under the 2012 Plan vest over four years and expire after ten years. As required, the exercise price for the stock options granted under the 2012 Plan was not less than the fair value of common shares as determined by the Company as of the date of grant.

Stock Option Valuation

The weighted average assumptions the Company used to estimate the fair value of stock options granted were as follows:

	Six Months Ended				
	June 30,				
	2017	2016			
Risk-free interest rate	1.93 %	1.44 %			
Expected term (in years)	6.0	6.6			
Expected volatility	94.09 %	96.90 %			
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 from January 1, 2017 through June 30, 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2016	2,702,350	\$ 18.94	9.05	\$ 24,434
Granted	135,000	27.19		
Exercised	(36,738)	6.40		
Forfeited and cancelled	(27,546)	(17.55)		
Outstanding as of June 30, 2017	2,773,066	\$ 19.53	8.64	\$ 23,461
Options vested and expected to vest as of				
June 30, 2017	2,773,066	\$ 19.53	8.64	\$ 23,461
Options exercisable as of June 30, 2017	736,308 (1)) \$ 11.02	7.99	\$ 12,043

(1) All options granted under the 2012 Plan are exercisable immediately, subject to a repurchase right in the Company's favor that lapses as the option vests. This amount reflects the number of shares under options that were vested, as opposed to exercisable, as of June 30, 2017.

The weighted average grant date fair value of stock options granted during the six months ended June 30, 2017 was \$20.81 per share.

The intrinsic value of a stock option is calculated as the difference between the exercise price of the stock option and the fair value of the underlying common stock, and cannot be less than zero.

Restricted Stock Units

The following table summarizes RSU activity from January 1, 2017 through June 30, 2017:

		Weighted
		Average
		Grant
		Date
	Number	Fair Value
	of Shares	Per Share
Outstanding as of December 31, 2016	219,614	\$ 27.43
Granted	13,167	28.50
Vested	(7,799)	20.26
Forfeited and cancelled	(2,096)	25.08
Outstanding as of June 30, 2017	222,886	\$ 27.76

Stock Based Compensation

The following table summarizes stock based compensation expense recorded by the Company:

	Three Months Ended		Six Months	Six Months Ended	
	June 30,		June 30,		
	2017	2016	2017	2016	
Research and development	\$ 1,304	\$ 533	\$ 2,521	\$ 954	
General and administrative	2,000	821	3,936	1,622	
Total stock-based compensation expense	\$ 3,304	\$ 1,354	\$ 6,457	\$ 2,576	

As of June 30, 2017, the Company had unrecognized stock based compensation expense for stock options and RSUs of \$31,174 and \$4,794, respectively, which is expected to be recognized over weighted average periods of 3.02 years and 2.62 years, respectively.

8. Net Loss per Share

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

	Three Months En June 30, 2017	nded 2016	Six Months Ende June 30, 2017	ed 2016
Numerator: Net loss Denominator: Weighted average shares of common	\$ (14,838)	\$ (12,871)	\$ (27,397)	\$ (25,910)
stock outstanding Net loss per share, basic and diluted	26,594,854 \$ (0.56)	20,663,088 \$ (0.62)	26,339,250 \$ (1.04)	20,417,301 \$ (1.27)

The Company's potentially dilutive securities, which included stock options, RSUs, preferred stock and shares of restricted common stock that were issued but not yet vested, 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 common shares outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential common shares excluded from the calculation of diluted net loss per share for both the three and six months ended June 30, 2017 and 2016. All share amounts presented in the table below represent the total number outstanding as of June 30, 2017 and 2016.

	June 30, 2017	2016
Stock options to purchase common stock	2,773,066	1,913,419
Restricted stock unit awards	222,886	85,000
Total potential common shares	2,995,952	1,998,419

9. Commitments and Contingencies

Agreements for Office Space

In August 2013, the Company entered into a sublease agreement with a related party (see Note 10), which was subsequently amended and restated in March 2014, for its office space with a term ending on November 30, 2016. The Company further amended the terms of this sublease agreement in December 2014, August 2015, February 2016 and October 2016 to increase the square footage of the space being subleased and/or agree to new sublease terms. The August 2015 amendment extended the term of the lease to November 2019.

In November 2016, the Company entered into a lease agreement with a third party for additional office space in the same building as its headquarters with a term beginning in February 2017 and ending in November 2019.

Rent expense was \$90 and \$60 for the three months ended June 30, 2017 and 2016, respectively, and was \$174 and \$112 for the six months ended June 30, 2017 and 2016, respectively. The Company recognizes rent expense on a straight-line basis over the term of the lease and has accrued for rent expense incurred but not yet paid.

As of June 30, 2017, future minimum lease payments under these agreements were as follows:

Year Ending December 31,	
2017	\$ 178
2018	363
2019	339
2020	
2021	
Thereafter	
Total	\$ 880

10. Related Party Transactions

In August 2013, the Company entered into a sublease agreement with NeXeption, Inc. ("NeXeption"), which was subsequently amended and restated in March 2014 and further amended in December 2014. In August 2015, pursuant to an Assignment and Assumption Agreement, NeXeption, Inc. assigned all interests, rights, duties and obligations under the sublease to NST Consulting, LLC, a wholly-owned subsidiary of NST, LLC. Following the Assignment and Assumption Agreement, the sublease was further amended in August 2015, February 2016 and October 2016. Mr. Stephen Tullman, the chairman of the Company's board of directors, was an executive officer of NeXeption and is also the manager of NST Consulting, LLC and NST, LLC. Total payments made under the sublease during the three months ended June 30, 2017 and 2016 were \$50 and \$56, respectively, and during the six months ended June 30, 2017 and 2016 were \$124 and \$115, respectively.

In February 2014, the Company entered into a services agreement with NST, LLC (the "NST Services Agreement"), pursuant to which NST, LLC provided certain pharmaceutical development, management and other administrative services to the Company. Under the same agreement, the Company also provided services to another company under common control with the Company and NST, LLC and was reimbursed by NST, LLC for those services. In addition to Mr. Tullman's role as manager of NST, LLC, several of the Company's executive officers are members of NST, LLC.

The NST Services Agreement was amended in December 2014 pursuant to which NST, LLC assigned all interests, rights, duties and obligations under the NST Services Agreement to NST Consulting, LLC. Under the NST Services Agreement, as amended, NST Consulting, LLC provides services to the Company and the Company provides services to another company under common control with the Company and NST Consulting, LLC. The NST Services Agreement was further amended in August 2015, November 2015, January 2016, December 2016 and May 2017 to adjust the amount of services the Company is obligated to provide to NST Consulting, LLC and the amount of services NST Consulting, LLC is obligated to provide to the Company. The Company may offset any payments owed by the Company to NST Consulting, LLC against payments that are owed by NST Consulting, LLC to the Company for the provision of personnel, including consultants, to the Company.

During the three and six months ended June 30, 2017 and 2016, amounts included in the consolidated statement of operations and comprehensive loss for the NST Services Agreement are summarized in the following table:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Services provided by NST Consulting, LLC	\$ 56	\$ 79	\$ 112	\$ 158
Services provided to NST Consulting, LLC	(7)	(15)	(18)	(30)
General and administrative expense, net	\$ 49	\$ 64	\$ 94	\$ 128
Services provided by NST Consulting, LLC Services provided to NST Consulting, LLC Research and development expense, net	\$ — — \$ —	\$ 60 (21) \$ 39	\$ — — \$ —	\$ 121 (42) \$ 79
Services provided by NST Consulting, LLC Services provided to NST Consulting, LLC Total, net	\$ 56 (7) \$ 49	\$ 139 (36) \$ 103	\$ 112 (18) \$ 94	\$ 279 (72) \$ 207
Net payments made to NST	\$ 47	\$ 117	\$ 182	\$ 175

The Company had \$4 and \$91 payable to NST Consulting, LLC under the NST Services Agreement as of June 30, 2017 and December 31, 2016, respectively.

11. Agreements Related to Intellectual Property

Assignment Agreement and Finder's Services Agreement

In August 2012, the Company entered into an assignment agreement with the Estate of Mickey Miller, or the Miller Estate, under which the Company acquired some of the intellectual property rights covering A-101. In connection with obtaining the assignment of the intellectual property from the Miller Estate, the Company also entered into a separate finder's services agreement with KPT Consulting, LLC. In February 2016, under the terms of the assignment agreement and the finder's services agreement, the Company made a milestone payment of \$300 upon the dosing of the first human subject with A-101 40% Topical Solution in the Company's Phase 3 clinical trial. In April 2017, the Company made an additional milestone payment of \$1,000 upon the achievement of specified regulatory milestones. The payments were recorded as general and administrative expenses in the Company's consolidated statement of operations.

Under the finder's services agreement, the Company is obligated to make additional milestone payments of up to \$4,500 upon the achievement of specified commercial milestones. Under each of the assignment agreement and the finder's services agreement, the Company is also obligated to pay royalties on sales of A-101 or related products, at low single-digit percentages of net sales, subject to reduction in specified circumstances. The Company has not made any royalty payments to date under either agreement. Both agreements will terminate upon the expiration of the last pending, viable patent claim of the patents acquired under the assignment agreement, but no sooner than 15 years from the effective date of the agreements.

Stock Purchase Agreement with Vixen Pharmaceuticals, Inc. and License Agreement with Columbia University

On March 24, 2016, the Company entered into a stock purchase agreement (the "Vixen Agreement") with Vixen, JAK1, LLC, JAK2, LLC and JAK3, LLC (together with JAK1, LLC and JAK2, LLC, the "Selling Stockholders") and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the representative of the Selling Stockholders. Pursuant to the Vixen Agreement, the Company acquired all shares of Vixen's capital stock from the Selling Stockholders (the "Vixen Acquisition"). Following the Vixen Acquisition, Vixen became a wholly-owned subsidiary of the Company. Pursuant to the Vixen Agreement, the Company paid \$600 upfront and issued an aggregate of 159,420 shares of the Company's common stock to the Selling Stockholders. The Company is obligated to make annual payments of \$100 on March 24th of each year, through March 24, 2022, with such amounts being creditable against specified future payments that may be paid under the Vixen Agreement.

The Company is obligated to make aggregate payments of up to \$18,000 to the Selling Stockholders upon the achievement of specified pre-commercialization milestones for three products in the United States, the European Union and Japan, and aggregate payments of up to \$22,500 upon the achievement of specified commercial milestones. With respect to any commercialized products covered by the Vixen Agreement, the Company is obligated to pay low single-digit royalties on 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 the Company sublicenses any of Vixen's patent rights and know-how acquired pursuant to the Vixen Agreement, the Company will be obligated to pay a portion of any consideration the Company receives from such sublicenses in specified circumstances.

As a result of the transaction with Vixen, the Company became party to the Exclusive License Agreement, by and between Vixen and the Trustees of Columbia University in the City of New York ("Columbia"), dated as of December 31, 2015 (the "License Agreement"). Under the License Agreement, the Company is obligated to pay Columbia an annual license fee of \$10, subject to specified adjustments for patent expenses incurred by Columbia and creditable against any royalties that may be paid under the License Agreement. The Company is also obligated to pay up to an aggregate of \$11,600 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 the Company sublicenses any of Columbia's patent rights and know-how acquired pursuant to the License Agreement, it will be obligated to pay Columbia a portion of any consideration received from such sublicenses in specified circumstances. The royalties, as determined on a country-by-country and product-by-product basis, are payable until the date that all of the patent rights for that product have expired, the expiration of any market exclusivity period granted by a regulatory body or, in specified circumstances, ten years from the first commercial sale of such product. The License Agreement terminates on the date of expiration of all royalty obligations thereunder unless earlier terminated by either party for a material breach, subject to a specified cure period. The Company may also terminate the License Agreement without cause at any time upon advance written notice to Columbia.

Edgar Filing: Aclaris Therapeutics, Inc. - Form 10-Q

The Company accounted for the transaction with Vixen as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in Accounting Standards Codification Topic 805, Business Combinations. The Company concluded the transaction with Vixen did not meet the definition of a business because the transaction principally resulted in the acquisition of the License Agreement. The Company did not acquire tangible assets, processes, protocols or operating systems. In addition, at the time of the transaction, there were no activities being conducted related to the licensed patents. The Company expensed the acquired intellectual property as of the acquisition date on the basis that the cost of intangible assets purchased from others for use in research and development activities, and that have no alternative future uses, are expensed at the time the costs are incurred. Accordingly, the Company recorded the \$600 upfront payment, the fair value of the shares of common stock issued of \$2,355, and the present value of the six non-contingent annual payments as research and development expense in the six months ended June 30, 2016. Additionally, the Company will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred.

12. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three and six months ended June 30, 2017 and 2016 due to the Company's conclusion that a valuation allowance is required.

13. Subsequent Events

On August 3, 2017, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Confluence Life Sciences, Inc., a Delaware corporation ("Confluence"), Aclaris Life Sciences, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub"), and Fortis Advisors LLC, as representative of the holders of Confluence equity. The Merger Agreement provided for Merger Sub to merge with and into Confluence (the "Merger"), with Confluence surviving as a wholly owned subsidiary of the Company. The Merger with Confluence will add small molecule drug discovery and preclinical development capabilities, which the Company expects will allow it to bring early-stage research and development activities in-house that the Company currently outsources to third parties. The Company expects to account for the acquisition of Confluence as a business combination.

Pursuant to the Merger Agreement, the Company was to pay holders of Confluence's capital stock and options to purchase Confluence's common stock (collectively, the "Confluence Equityholders"), upfront consideration of \$20,000 consisting of \$10,000 in cash and \$10,000 in shares of the Company's common stock, subject to adjustments for working capital, debt and transaction expenses. On the closing date, the Company paid \$8,697 and issued 314,572 shares to the Confluence Equityholders and deposited \$1,000 in cash and 34,955 shares into escrow as required by the Merger Agreement.

The Company has also agreed to pay the Confluence Equityholders contingent consideration of up to \$80,000, based upon the achievement of certain development, regulatory and commercial milestones set forth in the Merger Agreement. Of the contingent consideration, \$2,500 may be paid in shares of the Company's common stock upon the achievement of a specified development milestone. In addition, the Company has agreed to pay the Confluence Equityholders specified 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 Merger Agreement to a third party, the Company will be obligated to pay the Confluence Equityholders a portion of any incremental consideration (in excess of the development and milestone payments described above) that the Company receives from such sales, licenses or

transfers in specified circumstances.

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 due to a number of factors, including risks related to:

- · our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials and regulatory approval of protocols for future clinical trials;
- the difficulties in obtaining and maintaining regulatory approval of our drug candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop, manufacture and commercialize our drug candidates;
- · our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our drug candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- $\cdot \,$ the rate and degree of market acceptance of any of our drug candidates;
- · obtaining and maintaining intellectual property protection for our drug candidates and our proprietary technology;
- · the successful development of our commercialization capabilities, including sales and marketing capabilities;

- · recently enacted and future legislation and regulation regarding the healthcare system;
 - the success of competing therapies and products that are or become available; and
- the performance of third parties, including contract research organizations and third-party manufacturers.

These and other factors that could cause or contribute to these differences are described in this Quarterly Report on Form 10-Q in Part II – Item 1A, "Risk Factors," and under similar captions in our other filings with the Securities and Exchange Commission. Statements made herein are as of the date of the filing of this Form 10-Q with the Securities and Exchange Commission 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-

18

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, 2016, which are included in our 2016 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 15, 2017.

Overview

We are a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. Our lead drug candidate, A-101 40% Topical Solution, is a proprietary formulation of high-concentration hydrogen peroxide topical solution that we are developing as a prescription treatment for seborrheic keratosis, or SK, a common non-malignant skin tumor. In the first quarter of 2016, we initiated two multi-center, randomized, double blinded, vehicle-controlled Phase 3 clinical trials and one open-label Phase 3 clinical trial of A-101 40% Topical Solution in patients with SK. In November 2016, we announced positive top-line results from the two pivotal Phase 3 clinical trials, which are summarized below. Based on these results, we submitted a New Drug Application, or NDA, for A-101 40% Topical Solution for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in February 2017, and the NDA was accepted by the FDA in May 2017. The Prescription Drug User Fee Act, or PDUFA, target action date for the completion of the FDA's review of the NDA is December 24, 2017. We also submitted a Marketing Authorization Application, or MAA, in the European Union in July 2017. We are also developing A-101 45% Topical Solution as a prescription treatment for common warts, also known as verruca vulgaris. Additionally, in 2015, we in-licensed exclusive, worldwide rights to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, or AA, vitiligo and androgenetic alopecia, or AGA. In 2016, we acquired additional intellectual property rights for the development and commercialization of certain JAK inhibitors for specified dermatological conditions. We intend to continue to in-license or acquire additional drug candidates and technologies to build a fully integrated dermatology company.

In November 2016, we completed two pivotal Phase 3 clinical trials of A-101 40% Topical Solution in a combined 937 patients who each had a total of four target SK lesions located on the face, trunk and extremities. Each trial met all primary and secondary endpoints for that trial, achieving clinically and statistically significant clearance of SK lesions. Additionally, we completed an open-label safety trial of A-101 40% Topical Solution in November 2016, in which we enrolled 147 patients. Across all three clinical trials, there were no treatment-related serious adverse events among patients treated with A-101 40% Topical Solution, and the most common adverse events reported were nasopharyngitis and sinusitis which were determined to be unrelated to A-101 40% Topical Solution. Based on these results, we submitted an NDA for A-101 40% Topical Solution for the treatment of SK to the FDA in February 2017, and the NDA was accepted by the FDA in May 2017. The PDUFA target action date for the completion of the FDA's review of the NDA is December 24, 2017. We also submitted an MAA in the European Union in July 2017. If approved, A-101 40% Topical Solution would become the first FDA-approved medication for the treatment of SK.

We are also developing A-101 45% Topical Solution for the treatment of common warts. Although common warts are generally not harmful and in most cases eventually clear without medical treatment, they may be painful and aesthetically unattractive and are contagious. On an annual basis, 1.9 million people are diagnosed with common warts. Common warts can be removed with slow-acting, over-the-counter products containing salicylic acid. As with SK, cryosurgery is the most frequently used in-office treatment for common warts. No prescription drugs have been approved by the FDA for the treatment of common warts. We completed a Phase 2 clinical trial in August 2016 evaluating 40% and 45% concentrations of A-101 for the treatment of common warts. In this Phase 2 clinical trial, in which 90 patients completed an eight-week treatment period, we observed statistically significant improvements in the mean change in the Physician's Wart Assessment, or PWA, score and in complete clearance of common warts in patients treated with the 45% concentration of A-101 compared to placebo. In June 2017, we commenced two additional Phase 2 clinical trials of A-101 45% Topical Solution to assess the dose frequency in adult and pediatric patients with common warts. We expect to report results from these additional Phase 2 clinical trials in the first half of 2018.

In addition, we are developing the JAK inhibitors, ATI-50001 and ATI-50002, which we in-licensed from Rigel Pharmaceuticals, Inc., or Rigel, as potential treatments for AA. AA is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include total scalp hair loss, known as alopecia totalis, and total hair loss on the scalp and body, known as alopecia universalis. AA affects up to 2.0% of people globally at some point during their lifetime (i.e. incidence) and up to 0.2% of people are affected at any given time (i.e. prevalence) - with two-thirds of affected individuals being 30 years old or younger at the time of disease onset. Treatment options for the less severe, patchy forms of AA include corticosteroids, either topically applied or injected directly into the scalp where the bare patches are located, or the induction of an allergic reaction at the site of hair loss using a topical contact sensitizing agent, an approach known as topical immunotherapy. The same treatment options are utilized for the more severe forms of AA, although utilization of these treatment options for the more severe forms of AA is limited due to limited efficacy, certain side effects, and their impracticality for extensive surface areas. We are developing ATI-50001 as an oral treatment for alopecia totalis and alopecia universalis and ATI-50002 as a topical treatment for patchy AA. We submitted an Investigational New Drug application, or IND, to the FDA for ATI-50001 in October 2016, and we completed a Phase 1 clinical trial to evaluate the pharmacokinetic and pharmacodynamic properties of this drug candidate in the first quarter of 2017. We plan to initiate a Phase 2 clinical trial for ATI-50001, for the treatment of alopecia totalis and alopecia universalis, in the second half of 2017. We submitted an IND to the FDA for ATI-50002, for the treatment of patchy AA, in July 2017, and plan to commence a Phase 2 clinical trial in the second half of 2017. We expect the Phase 2 clinical trials for ATI-50001, for the treatment of alopecia totalis and alopecia universalis, and for ATI-50002, for the treatment of patchy AA, each to take approximately one year to complete. We also plan to develop ATI-50001 and ATI-50002 as potential treatments for vitiligo, a disorder in which white patches of skin appear on different parts of the body. We plan to commence a Phase 2 clinical trial for ATI-50002, for the treatment of vitiligo, in the second half of 2017.

In August 2017, we acquired Confluence Life Sciences, Inc. or Confluence. The merger with Confluence will add small molecule drug discovery and preclinical development capabilities which, we expect, will allow us to bring early-stage research and development activities in-house that we currently outsource to third parties. Through the acquisition of Confluence, we also acquired several preclinical product candidates, including additional JAK inhibitors known as "soft" JAK inhibitors, as well as inhibitors of the MK-2 signaling pathway and inhibitors of interleukin-2-inducible T cell kinase, or ITK. At the closing of the acquisition, we paid approximately \$10.0 million and issued 349,527 shares of our common stock to the former equityholders of Confluence, including amounts deposited into escrow. We are obligated to pay up to \$80.0 million to the former Confluence equityholders upon the

Edgar Filing: Aclaris Therapeutics, Inc. - Form 10-Q

achievement of specified development, regulatory and commercial milestones, as well as low single-digit royalties upon net sales of covered products and a portion of any amounts we may receive from the further sale, out-license or transfer of the acquired intellectual property to third parties.

Since our inception in July 2012, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, developing A-101 40% Topical Solution for the treatment of SK, building our intellectual property portfolio, developing our supply chain and engaging in other discovery and clinical

activities in dermatology. Through the date of this report, we have not generated any revenue and have financed our operations with sales of our convertible preferred stock, as well as net proceeds from our initial public offering, or IPO, in October 2015, a private placement of our common stock in June 2016, a follow-on public offering of our common stock in November 2016 and our at-the-market facility with Cowen and Company LLC, or Cowen. We do not expect to generate significant revenue unless and until we obtain marketing approval for and commercialize A-101 40% Topical Solution for the treatment of SK or one of our other current or future drug candidates.

Since our inception, we have incurred significant operating losses. Our net loss was \$48.1 million for the year ended December 31, 2016 and \$27.4 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of \$118.3 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical development and clinical trials, seek marketing approval and pursue commercialization of any approved drug candidate. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional drug candidates. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations 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 and commercialization of one or more of our drug candidates or delay our pursuit of potential in-licenses or acquisitions.

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception.

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 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;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- · outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- · depreciation of manufacturing equipment;
- payments made under agreements with third parties under which we have acquired or licensed intellectual property;
- · expenses relating to regulatory activities, including filing fees paid to regulatory agencies; and
- · laboratory materials and supplies used to support our research activities.

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

21

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, which are included within "Personnel and other costs" in the table below, to specific research and development programs.

The following table summarizes our research and development expenses for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)			
A-101 Topical Solution (40% and 45%)	\$ 1,917	\$ 6,480	\$ 3,280	\$ 9,703
JAK inhibitors	2,331	1,569	4,887	3,008
Vixen acquisition				3,385
Other	51	57	101	90
Total direct research and development expenses	4,299	8,106	8,268	16,186
Personnel and other costs	2,362	1,197	4,948	2,231
Stock-based compensation	1,304	533	2,521	954
Total research and development expenses	\$ 7,965	\$ 9,836	\$ 15,737	\$ 19,371

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 our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, continue to conduct pre-commercial activities related to A-101 40% Topical Solution for the treatment of SK, and conduct clinical trials and prepare regulatory filings for our other drug candidates.

The successful development of our drug candidates is highly uncertain. At this time, 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:

- \cdot the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- \cdot the number of doses patients receive;
- \cdot the duration of patient follow-up; and
- $\cdot\,$ the results of our clinical trials.

Edgar Filing: Aclaris Therapeutics, Inc. - Form 10-Q

Our expenditures are subject to additional uncertainties, including the terms and timing of marketing approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving marketing approval for any of our drug candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify 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. Drug commercialization will take several years and millions of dollars in development costs.

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, travel expenses and recruiting expenses. Other general and administrative expenses include facility-related costs, patent filing and prosecution costs, professional fees for marketing, legal, auditing and tax services, insurance costs, as well as payments made under our related party services agreement and milestone payments under our finder's services agreement.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with NASDAQ and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. Additionally, if and when we believe a marketing approval of a drug candidate appears likely, we anticipate an increase in payroll and other expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that drug candidate.

Other Income, Net

Other income, net consists of interest earned on our cash, cash equivalents and marketable securities, interest expense, 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 GAAP. 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. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. 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. Actual results may differ from these estimates under different assumptions or conditions. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in the footnotes to our audited consolidated financial statements for the year ended December 31, 2016 included in our 2016 Annual Report on Form 10-K filed with the SEC on March 15, 2017.

Recently Issued Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. We are assessing the potential impact of ASU 2017-01 on our consolidated financial statements.

Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2016

	Three Months Ended			
	June 30,			
	2017	2016	Change	
	(In thousands)			
Revenue	\$ —	\$ —	\$ —	
Operating expenses:				
Research and development	7,965	9,836	(1,871)	