

Aclaris Therapeutics, Inc.
Form 10-Q
November 03, 2016
Table of Contents

DeferredTaxAssetsOther

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 Q

(Mark one)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____

Commission File Number 001-37581

Aclaris Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	46-0571712
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
101 Lindenwood Drive, Suite 400 Malvern, PA	19355
(Address of principal executive offices)	(Zip Code)

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

N/A

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

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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Securities Exchange Act of 1934:

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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 November 2, 2016 was 21,432,907.

Table of Contents

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>	
<u>Unaudited</u>	2
<u>Condensed</u>	
<u>Consolidated</u>	
<u>Balance Sheets as</u>	
<u>of September 30,</u>	
<u>2016 and</u>	
<u>December 31,</u>	
<u>2015</u>	
<u>Unaudited</u>	3
<u>Condensed</u>	
<u>Consolidated</u>	
<u>Statements of</u>	
<u>Operations and</u>	
<u>Comprehensive</u>	
<u>Loss for the three</u>	
<u>and nine months</u>	
<u>ended September</u>	
<u>30, 2016 and</u>	
<u>2015</u>	
<u>Unaudited</u>	4
<u>Condensed</u>	
<u>Consolidated</u>	
<u>Statement of</u>	
<u>Stockholders'</u>	
<u>Equity for the nine</u>	
<u>months ended</u>	
<u>September 30,</u>	
<u>2016</u>	

<u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u> <u>Statements of</u> <u>Cash Flows for the</u> <u>nine months ended</u> <u>September 30,</u> <u>2016 and 2015</u>	5
<u>Notes to</u> <u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u> <u>Financial</u> <u>Statements</u>	6
<u>Item 2.</u> <u>Management’s</u> <u>Discussion and</u> <u>Analysis of</u> <u>Financial</u> <u>Condition and</u> <u>Results of</u> <u>Operations</u>	19
<u>Item 3.</u> <u>Quantitative and</u> <u>Qualitative</u> <u>Disclosures about</u> <u>Market Risk</u>	30
<u>Item 4. Controls</u> <u>and Procedures</u>	30
<u>PART II. OTHER</u> <u>INFORMATION</u>	
<u>Item 1. Legal</u> <u>Proceedings</u>	31
<u>Item 1A. Risk</u> <u>Factors</u>	31
<u>Item 2.</u> <u>Unregistered Sales</u> <u>of Equity</u> <u>Securities and Use</u> <u>of Proceeds</u>	36
<u>Item 6. Exhibits</u>	37

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

<u>Signatures</u>	38
<u>Exhibit Index</u>	39

Table of Contents

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, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,796	\$ 9,851
Marketable securities	66,246	75,017
Prepaid expenses and other current assets	1,548	1,656
Total current assets	85,590	86,524
Marketable securities	—	7,170
Property and equipment, net	461	360
Other assets	20	22
Total assets	\$ 86,071	\$ 94,076
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,774	\$ 810
Accrued expenses	2,817	745
Total current liabilities	4,591	1,555
Other liabilities	358	—
Total liabilities	4,949	1,555
Stockholders' Equity:		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.00001 par value; 100,000,000 shares authorized at September 30, 2016 and December 31, 2015; 21,423,995 and 20,157,503 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Additional paid in capital	160,613	135,503

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

Accumulated other comprehensive loss	(54)	(149)
Accumulated deficit	(79,437)	(42,833)
Total stockholders' equity	81,122	92,521
Total liabilities and stockholders' equity	\$ 86,071	\$ 94,076

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

2

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30, 2016	2015	September 30, 2016	2015
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	7,162	9,407	26,533	12,937
General and administrative	3,650	1,233	10,407	2,928
Total operating expenses	10,812	10,640	36,940	15,865
Loss from operations	(10,812)	(10,640)	(36,940)	(15,865)
Other income, net	118	8	336	16
Net loss	(10,694)	(10,632)	(36,604)	(15,849)
Accretion of convertible preferred stock	—	(1,020)	—	(2,353)
Net loss attributable to common stockholders	\$ (10,694)	\$ (11,652)	\$ (36,604)	\$ (18,202)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.50)	\$ (5.12)	\$ (1.76)	\$ (8.44)
Weighted average common shares outstanding, basic and diluted	21,415,871	2,274,617	20,752,590	2,155,685
Other comprehensive (loss) income:				
Unrealized (loss) gain on marketable securities, net of tax of \$0	(12)	1	144	7
Foreign currency translation adjustments	(43)	—	(49)	—
Total other comprehensive (loss) income	(55)	1	95	7
Comprehensive loss	\$ (10,749)	\$ (10,631)	\$ (36,509)	\$ (15,842)

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

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF

STOCKHOLDERS' EQUITY

(UNAUDITED)

(In thousands, except share data)

	Common Stock	Par	Additional	Accumulated	Other	Accumulated	Total
	Shares	Value	Paid in	Comprehensive	Loss	Deficit	Stockholders'
			Capital	Loss			Equity
Balance at December 31, 2015	20,157,503	\$ —	\$ 135,503	\$ (149)	\$ (42,833)		\$ 92,521
Issuance of common stock in connection with Vixen acquisition	159,420	—	2,355	—	—		2,355
Issuance of common stock in connection with private placement, net of offering costs of \$1,453	1,081,082	—	18,547	—	—		18,547
Exercise of stock options	25,990	—	14	—	—		14
Unrealized gain on marketable securities	—	—	—	144	—		144
Foreign currency translation adjustment	—	—	—	(49)	—		(49)
Stock-based compensation expense	—	—	4,194	—	—		4,194
Net loss	—	—	—	—	(36,604)		(36,604)
Balance at September 30, 2016	21,423,995	\$ —	\$ 160,613	\$ (54)	\$ (79,437)		\$ 81,122

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

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (36,604)	\$ (15,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	80	57
Stock-based compensation expense	4,194	243
Non-cash charges related to Vixen acquisition	2,784	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	110	(764)
Accounts payable	915	(491)
Accrued expenses	1,990	572
Net cash used in operating activities	(26,531)	(16,232)
Cash flows from investing activities:		
Purchases of property and equipment	(170)	(375)
Purchases of marketable securities	(33,747)	(13,002)
Proceeds from sales and maturities of marketable securities	49,832	5,914
Net cash provided by (used in) investing activities	15,915	(7,463)
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 redeemable convertible preferred stock, net of issuance costs	—	39,864
Proceeds from the exercise of employee stock options	14	—
Payment of deferred offering costs	—	(1,507)
Net cash provided by financing activities	18,561	38,357
Net increase in cash and cash equivalents	7,945	14,662
Cash and cash equivalents at beginning of period	9,851	10,757
Cash and cash equivalents at end of period	\$ 17,796	\$ 25,419
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	\$ 13	\$ 19
Accretion of convertible preferred stock to redemption value	\$ —	\$ 1,764
Fair value of stock issued in connection with Vixen acquisition	\$ 2,355	\$ —
Deferred offering costs included in accounts payable	\$ —	\$ 436

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

5

Table of Contents

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 clinical stage specialty pharmaceutical company focused on identifying, developing and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. The Company’s lead drug candidate, A-101, is a proprietary high concentration hydrogen peroxide topical solution that is being developed as a prescription treatment for seborrheic keratosis (“SK”), a common non-malignant skin tumor. The Company has completed three Phase 2 clinical trials and is currently conducting three Phase 3 clinical trials of A-101 in patients with SK.

Initial Public Offering

On October 6, 2015, the Company’s registration statement on Form S-1 relating to its initial public offering of its common stock (the “IPO”) was declared effective by the Securities and Exchange Commission (“SEC”). The Company’s common stock began trading on the NASDAQ Global Select Market on October 7, 2015. The IPO closed on October 13, 2015, and 5,000,000 shares of common stock were sold at a price to the public of \$11.00 per share, for aggregate gross proceeds of \$55,000. In addition, upon the closing of the IPO, all of the Company’s outstanding convertible preferred stock was converted into an aggregate total of 11,677,076 shares of common stock.

On October 12, 2015, the underwriters of the IPO exercised in full their option to purchase additional shares, and on October 13, 2015, the Company sold 750,000 additional shares of common stock at a price to the public of \$11.00 per share, for aggregate gross proceeds of \$8,250.

The Company paid underwriting discounts and commissions of \$4,428 to the underwriters in connection with the IPO, including the underwriters’ exercise of their option to purchase additional shares. In addition, the Company incurred expenses of \$2,272 in connection with the IPO. The net offering proceeds received by the Company, after deducting

underwriting discounts, commissions and offering expenses, were \$56,550.

Private Placement

On June 2, 2016, pursuant to a securities purchase agreement with certain accredited investors dated May 27, 2016, the Company closed a private placement in which it sold an aggregate of 1,081,082 shares of common stock at a price of \$18.50 per share, for gross proceeds of \$20,000. The Company incurred placement agent fees of \$1,300 and expenses of \$153 in connection with the private placement. The net offering proceeds received by the Company, after deducting placement agent fees and transaction expenses, were \$18,547.

Table of Contents

Reverse Stock Split

On September 24, 2015, the Company effected a 1 for 3.45 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's then-outstanding convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in these condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

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 September 30, 2016, the Company had cash, cash equivalents and marketable securities of \$84,042 and an accumulated deficit of \$79,437. 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. 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 September 30, 2016, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015, the condensed consolidated statement of stockholders' equity for the nine months ended September 30, 2016, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015 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 SEC on March 23, 2016 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, 2016, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015 and its cash flows for the nine months ended September 30, 2016 and 2015. The condensed consolidated balance sheet data as of December 31, 2015 was derived from audited financial statements but does not include all disclosures required by accounting

Table of Contents

principles generally accepted in the United States. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2016 and 2015 are unaudited. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, 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, 2015 included in the Company's annual report on Form 10-K filed with the SEC on March 23, 2016.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2015 included in the Company's annual report on Form 10-K filed with the SEC on March 23, 2016. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Assets Held for Sale

In order for an asset to be classified as held for sale there must be an active program to market the asset, and it must be probable the asset will be disposed of within one year. The carrying value of an asset held for sale is reported at the lower of its carrying value or its fair value less costs to sell. No additional depreciation expense is recognized once an asset is classified as held for sale. All current and historical balance sheet information for the Company's assets held for sale is included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets. As of September 30, 2016 and December 31, 2015, \$216 in assets were classified as held for sale.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments-Credit Losses (Topic 326). This ASU introduces a new model for recognizing credit losses on financial instruments based upon estimated expected credit losses. ASU 2016-13 will apply to loans, accounts receivable, financial assets measured at amortized cost and at fair value through other comprehensive income, loan commitments and certain off-balance sheet credit exposures. ASU 2016-13 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those years, and early adoption will be permitted. The Company is assessing the potential impact of ASU 2016-13 on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. This ASU requires all tax effects of share-based payment settlements to be recorded through the income statement. Currently, tax benefits in excess of compensation cost, or “windfalls”, are recorded in equity, and tax deficiencies, or “shortfalls”, are recorded to equity to the extent of previous windfalls, and then to the income statement. In addition, under the new guidance, companies will be permitted to make a policy election to recognize the impact of forfeitures either when they occur, or on an estimated basis. Finally, this update simplifies withholding requirements to allow companies to withhold up to an employee’s maximum tax rate without resulting in liability classification for the award. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, and early adoption is permitted. The Company has adopted the provisions of this standard early, the impact of which on its consolidated financial statements was not significant.

Table of Contents

3. Fair Value of Financial Assets and Liabilities

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

	Fair Value Measurements as of September 30, 2016			
	Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 11,378	\$ 1,401	\$ —	\$ 12,779
Marketable securities	—	66,246	—	66,246
Total	\$ 11,378	\$ 67,647	\$ —	\$ 79,025

	Fair Value Measurements as of December 31, 2015			
	Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 8,810	\$ 250	\$ —	\$ 9,060
Marketable securities	—	82,187	—	82,187
Total	\$ 8,810	\$ 82,437	\$ —	\$ 91,247

As of September 30, 2016 and December 31, 2015, 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 asset-backed securities. 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, 2016 and the year ended December 31, 2015, there were no transfers between Level 1, Level 2 and Level 3.

As of September 30, 2016 and December 31, 2015, 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

	September 30, 2016			
	Amortized	Gross	Gross	Fair
	Cost	Unrealized	Unrealized	Value
		Gain	Loss	
Marketable securities:				
Corporate debt securities	\$ 36,963	\$ —	\$ (14)	\$ 36,949
Commercial paper	11,975	—	—	11,975
Asset-backed securities	8,299	2	—	8,301
U.S. government agency debt securities	9,019	3	(1)	9,021
Total marketable securities	\$ 66,256	\$ 5	\$ (15)	\$ 66,246

Table of Contents

	December 31, 2015		Gross Unrealized Loss	Fair Value
	Amortized Cost	Gross Unrealized Gain		
Marketable securities:				
Corporate debt securities	\$ 46,270	\$ —	\$ (125)	\$ 46,145
Commercial paper	9,789	—	—	9,789
Asset-backed securities	6,234	—	(14)	6,220
U.S. government agency debt securities	20,048	—	(15)	20,033
Total marketable securities	\$ 82,341	\$ —	\$ (154)	\$ 82,187

As of September 30, 2016 and December 31, 2015, the Company's investments in corporate debt securities had credit ratings of A and above and remaining maturities of less than 12 months and less than 15 months, respectively.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2016	December 31, 2015
Computer equipment	\$ 340	\$ 262
Manufacturing equipment	131	101
Furniture and fixtures	112	39
Property and equipment, gross	583	402
Less: Accumulated depreciation	(122)	(42)
Property and equipment, net	\$ 461	\$ 360

Depreciation expense was \$32 for each of the three months ended September 30, 2016 and 2015, and was \$80 and \$57 for the nine months ended September 30, 2016 and 2015, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following:

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

	September 30, 2016	December 31, 2015
Research and development expenses	\$ 1,489	\$ 123
Employee-related expenses	1,088	—
Licensing fees	—	250
Vixen contract payable	100	—
Professional fees	37	283
Other	103	89
Total accrued expenses	\$ 2,817	\$ 745

Table of Contents

6. Stockholders' Equity

Preferred Stock

As of September 30, 2016 and December 31, 2015, 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 September 30, 2016 or December 31, 2015.

Common Stock

As of September 30, 2016 and December 31, 2015, 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, 2016.

7. Stock Based Awards

2012 Equity Compensation Plan

Upon the 2015 Equity Incentive Plan (the "2015 Plan"), described below, becoming effective, no further grants may be made under the 2012 Equity Compensation Plan, as amended and restated (the "2012 Plan").

The Company granted a total of 1,140,524 stock options under the 2012 Plan, of which 1,075,667 were outstanding as of September 30, 2016 and all of which were outstanding as of December 31, 2015. 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.

2015 Equity Incentive Plan

On September 15, 2015, the Company's board of directors adopted and on September 16, 2015, the Company's stockholders approved the 2015 Plan, which became effective in connection with the IPO in October 2015. The 2015 Plan provides for the grant of incentive stock options, nonstatutory 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, 2016, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 806,300 shares. As of September 30, 2016, 1,608,205 shares remained available for grant under the 2015 Plan.

Table of Contents

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, 2016 and 2015 were as follows:

	Nine Months Ended September 30,	
	2016	2015
Risk-free interest rate	1.41 %	1.73 %
Expected term (in years)	6.5	6.2
Expected volatility	96.60 %	96.65 %
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, 2016 through September 30, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2015	1,738,524	\$ 13.23	9.51	\$ 24,722
Granted	222,528	20.10		
Exercised	(25,990)	0.55		
Forfeited and canceled	(67,561)	15.69		
Outstanding as of September 30, 2016	1,867,501	\$ 14.13	8.80	\$ 22,921
	1,867,501	\$ 14.13	8.80	\$ 22,921

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

Options vested and expected to vest as of
September 30, 2016

Options exercisable as of September 30, 2016	384,223	(1)	\$ 5.54	8.07	\$ 7,713
--	---------	-----	---------	------	----------

(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 September 30, 2016.

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2016 was \$15.83 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.

Table of Contents

Restricted Stock Units

The following table summarizes RSU activity from January 1, 2016 through September 30, 2016:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2015	53,800	\$ 28.68
Granted	37,200	20.32
Vested	—	—
Forfeited and cancelled	(2,000)	28.68
Outstanding as of September 30, 2016	89,000	\$ 25.19

The Company did not grant RSUs during the nine months ended September 30, 2015.

Stock Based Compensation

The following table summarizes stock based compensation expense recorded by the Company for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 623	\$ 47	\$ 1,577	\$ 74
General and administrative	995	111	2,617	169
	\$ 1,618	\$ 158	\$ 4,194	\$ 243

As of September 30, 2016, the Company had unrecognized stock based compensation expense for stock options and RSUs of \$16,483 and \$1,884, respectively, which is expected to be recognized over weighted average periods of 3.14 years and 3.36 years, respectively.

Table of Contents

8. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders is summarized in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	\$ (10,694)	\$ (10,632)	\$ (36,604)	\$ (15,849)
Accretion of redeemable convertible preferred stock	—	(1,020)	—	(2,353)
Net loss attributable to common stockholders	\$ (10,694)	\$ (11,652)	\$ (36,604)	\$ (18,202)
Denominator:				
Weighted average shares of common stock outstanding	21,415,871	2,730,427	20,752,590	2,730,427
Less: Weighted average shares of unvested restricted common stock outstanding	—	(455,810)	—	(574,742)
Weighted average common shares outstanding used in calculating net loss per share attributable to common stockholders, basic and diluted	21,415,871	2,274,617	20,752,590	2,155,685
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.50)	\$ (5.12)	\$ (1.76)	\$ (8.44)

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 attributable to common stockholders is the same. The following table presents potential common shares excluded from the calculation of diluted net loss per share attributable to common stockholders for both the three and nine months ended September 30, 2016 and 2015. All share amounts presented in the table below represent the total number outstanding as of September 30.

	2016	2015
Stock options to purchase common stock	1,867,501	1,140,524
Restricted stock unit awards	89,000	—
Unvested restricted common stock	—	399,757
Convertible preferred stock (as converted to common stock)	—	11,677,076
	1,956,501	13,217,357

9. Commitments and Contingencies

Sublease

In August 2013, the Company entered into a sublease agreement with a related party (see Note 10) for its office space with a term ending on November 30, 2016. As part of an amendment to the sublease agreement entered into in December 2014, the Company increased the amount of office space to be subleased and agreed to new monthly terms commencing in January 2015. On August 14, 2015, the Company further amended its sublease agreement to increase the square footage of the space and to extend the term of the lease to November 2019. Effective December 1, 2015, the Company further amended its sublease agreement to increase the square footage and agreed to new monthly sublease terms. Rent expense under operating leases was \$66 and \$34 for the three months ended September 30, 2016 and 2015, respectively, and was \$178 and \$86 for the nine months ended September 30, 2016 and 2015, respectively. The

Table of Contents

Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not yet paid.

As of September 30, 2016, future minimum lease payments under the sublease were as follows:

Years Ending December 31,	
2016	\$ 65
2017	263
2018	268
2019	251
2020	—
Total	\$ 847

10. Related Party Transactions

In August 2013, the Company entered into a sublease agreement with NeXeption, Inc. ("NeXeption"), which was subsequently amended in December 2014 and August 2015. 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. 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 September 30, 2016 and 2015 were \$64 and \$44, respectively, and during the nine months ended September 30, 2016 and 2015 were \$179 and \$97, 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 January 2015 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 and November 2015 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.

Table of Contents

During the three and nine months ended September 30, 2016 and 2015, amounts included in the consolidated statement of operations for the NST Services Agreement are summarized in the following table:

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Services provided by NST Consulting, LLC	\$ 79	\$ 105	\$ 237	\$ 358
Services provided to NST Consulting, LLC	(15)	(69)	(45)	(186)
General and administrative expense, net	\$ 64	\$ 36	\$ 192	\$ 172
Services provided by NST Consulting, LLC	\$ 60	\$ —	\$ 181	\$ —
Services provided to NST Consulting, LLC	(21)	(63)	(63)	(190)
Research and development expense, net	\$ 39	\$ (63)	\$ 118	\$ (190)
Services provided by NST Consulting, LLC	\$ 139	\$ 105	\$ 418	\$ 358
Services provided to NST Consulting, LLC	(36)	(132)	(108)	(376)
Total, net	\$ 103	\$ (27)	\$ 310	\$ (18)
Payments made to NST	\$ 88	\$ (2)	\$ 263	\$ 13

The Company did not have any open invoices payable to NST Consulting, LLC under the NST Services Agreement as of either September 30, 2016 or December 31, 2015.

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 one-time milestone payment of \$300 upon the dosing of the first subject with A-101 in the Company's Phase 3 clinical trial. The payment was recorded as general and administrative expense during the nine months ended September 30, 2016.

Under the finder's services agreement, the Company is obligated to make an additional milestone payment of \$1,000 upon the submission of an NDA for A-101 and regulatory milestones and 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.

Table of Contents

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.

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 nine months ended September 30, 2016. Additionally, the Company will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred.

Table of Contents

12. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three and nine months ended September 30, 2016 and 2015 due to the Company's conclusion that a valuation allowance is required.

Table of Contents

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;
- 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-

Table of Contents

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, 2015, which are included in our 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 23, 2016.

Overview

We are a clinical-stage specialty pharmaceutical company focused on identifying, developing and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Our lead drug candidate, A-101 Topical Solution, is a proprietary 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. We have completed three Phase 2 clinical trials of A-101 in over 300 patients with SK. In these trials, following one or two applications of A-101, we observed clinically relevant and statistically significant improvements in clearing SK lesions on the face, trunk and extremities of the body. In the first quarter of 2016, we initiated two multi-center, double-blind Phase 3 clinical trials and one open label Phase 3 clinical trial of A-101 in patients with SK. We completed enrollment of the Phase 3 clinical trials of A-101 for SK in the third quarter of 2016, and expect to report results in the fourth quarter of 2016. If the results of these trials are favorable, we plan to submit a New Drug Application, or NDA, for A-101 for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in the first quarter of 2017 and a Marketing Authorization Application to the European Medicines Agency in mid-2017.

We are also developing A-101 as a prescription treatment for common warts, also known as verruca vulgaris, and A-102, a proprietary gel dosage form of hydrogen peroxide, as a prescription treatment for SK and common warts. We recently completed a Phase 2 clinical trial 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 score and in complete clearance of common warts in patients treated with the 45% concentration of A-101 compared to placebo. Based on these results, we plan to continue the development of the 45% concentration of A-101 as a treatment for common warts.

We have also in-licensed the exclusive, worldwide rights to inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions. We plan to develop these JAK inhibitors, ATI-50001 and ATI-50002, as potential treatments for hair loss associated with an autoimmune skin disease known as alopecia areata, or AA, and potentially for other dermatological conditions, as well as other JAK inhibitor compounds. We submitted an investigational new drug application, or IND, to the FDA for ATI-50001 in October 2016 and intend to commence a proof-of-concept trial for this drug candidate in the first half of 2017. We intend to submit an IND to the FDA for

ATI-50002 and to commence a proof-of-concept trial for this drug candidate in the first half of 2017. We also intend to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated dermatology company.

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 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 \$71.5 million of gross proceeds from sales of our convertible preferred stock, net proceeds of \$56.6 million from our initial public offering, or IPO, in October 2015, and net proceeds of \$18.5 million from a private placement of our common stock in June 2016. We do not expect to generate significant revenue unless and until we obtain marketing approval for and commercialize A-101 for the treatment of SK or one of our other current or future drug candidates.

Table of Contents

Since our inception, we have incurred significant operating losses. Our net loss was \$20.6 million for the year ended December 31, 2015 and \$36.6 million for the nine months ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of \$79.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical development and clinical trials, and seek regulatory 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 and do not expect to generate any revenue from the sale of products in the near future.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with the discovery and development of our drug candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigator sites and consultants that conduct our clinical trials and preclinical studies;

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

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.

Table of Contents

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 and long-term toxicology studies. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, complete Phase 3 clinical trials of A-101 in patients with SK, and conduct other clinical trials and prepare regulatory filings for A-101 and 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 other 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 patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may not succeed in achieving regulatory 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, commercial, finance, and legal functions, including stock-based compensation, patent filing and prosecution costs and professional fees for market research, legal, auditing and tax services, travel expenses, recruiting expenses, facility related costs, 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 stock exchange listing and SEC requirements, accounting and investor relations costs, director compensation, and director and officer insurance premiums associated with being a public company. Additionally, if and when we believe regulatory approval of a drug candidate appears likely, we anticipate

Table of Contents

payroll and other expenses will increase as a result of our preparation for commercial operations related to the sales and marketing of that 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, 2015 included in our 2015 Annual Report on Form 10-K filed with the SEC on March 23, 2016.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

Three Months Ended		Change
2016	September 30, 2015	

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

	(In thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	7,162	9,407	(2,245)
General and administrative	3,650	1,233	2,417
Total operating expenses	10,812	10,640	172
Loss from operations	(10,812)	(10,640)	(172)
Other income, net	118	8	110
Net loss	\$ (10,694)	\$ (10,632)	\$ (62)

Research and Development Expenses

Research and development expenses were \$7.2 million for the three months ended September 30, 2016, compared to \$9.4 million for the three months ended September 30, 2015. The decrease of \$2.2 million was primarily driven by an \$8.0 million upfront payment made to Rigel for the ATI-50001 and ATI-50002 JAK inhibitor drugs in the three months ended September 30, 2015, for which there was no similar transaction in the three months ended September 30, 2016. Excluding the payment to Rigel, research and development expenses increased \$5.7 million, primarily driven by a \$2.3 million increase in costs associated with the development of A-101 for the treatment of SK, a \$0.1 million

Table of Contents

increase in costs related to the development of A-101 for the treatment of common warts, an increase of \$1.9 million in preclinical development expenses related to the JAK inhibitor technology, an increase of \$0.6 million in payroll-related expenses due to increased headcount and an increase of \$0.6 million in stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses were \$3.7 million for the three months ended September 30, 2016, compared to \$1.2 million for the three months ended September 30, 2015. The increase of \$2.4 million was primarily attributable to increases of \$0.6 million in payroll-related expenses due to increased headcount, \$0.9 million in higher stock-based compensation expense, \$0.3 million in professional fees associated with being a public company, and a \$0.3 million increase in market research expenses related to pre-commercial activities for A-101.

Other Income, Net

The increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our IPO in October 2015 and our private placement in June 2016.

Comparison of Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	26,533	12,937	13,596
General and administrative	10,407	2,928	7,479
Total operating expenses	36,940	15,865	21,075
Loss from operations	(36,940)	(15,865)	(21,075)
Other income, net	336	16	320
Net loss	\$ (36,604)	\$ (15,849)	\$ (20,755)

Research and Development Expenses

Research and development expenses were \$26.5 million for the nine months ended September 30, 2016, compared to \$12.9 million for the nine months ended September 30, 2015. The increase of \$13.6 million was primarily attributable to an \$8.7 million increase in costs associated with the development of A-101 for the treatment of SK, an increase of \$4.9 million in preclinical development expenses related to the JAK inhibitor technology, a \$0.7 million increase in costs related to the development of A-101 for the treatment of common warts, an increase of \$1.6 million in payroll-related expenses due to increased headcount, and an increase of \$1.5 million in stock-based compensation expense. The increases noted above were partially offset by a decrease of \$4.6 million in licensing expenses as we incurred \$3.4 million of expenses associated with the Vixen acquisition in the nine months ended September 30, 2016, compared to \$8.0 million of expense resulting from the upfront payment made to Rigel for the ATI-50001 and ATI-50002 JAK inhibitor drugs during the nine months ended September 30, 2015.

Table of Contents

General and Administrative Expenses

General and administrative expenses were \$10.4 million for the nine months ended September 30, 2016, compared to \$2.9 million for the nine months ended September 30, 2015. The increase of \$7.5 million was primarily attributable to increases of \$1.6 million in payroll-related expenses due to increased headcount, \$2.5 million in stock-based compensation expense, \$0.4 million in legal and patent expenses related to the Vixen acquisition, \$1.5 million in professional fees associated with being a public company, a \$0.7 million increase in market research expenses related to pre-commercial activities for A-101, and a \$0.3 million one-time milestone payment made during the nine months ended September 30, 2016 pursuant to the finder's services agreement related to A-101.

Other Income, Net

The increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our IPO in October 2015 and our private placement in June 2016.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have financed our operations since inception through \$71.5 million of gross proceeds from sales of our convertible preferred stock, net proceeds of \$56.6 million from our IPO in October 2015, and net proceeds of \$18.5 million from our private placement in June 2016.

As of September 30, 2016, we had cash, cash equivalents and marketable securities of \$84.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to 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 over the next five years, other than our sublease obligations and contingent obligations under acquisition and intellectual property licensing agreements, each of which are described below.

Initial Public Offering

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

On October 13, 2015, we closed our IPO in which we sold 5,750,000 shares of common stock at a price to the public of \$11.00 per share, for aggregate gross proceeds of \$63.3 million. We paid underwriting discounts and commissions of \$4.4 million, and we also incurred expenses of \$2.3 million in connection with the IPO. As a result, the net offering proceeds to us, after deducting underwriting discounts and commissions and expenses, were \$56.6 million.

Private Placement

On June 2, 2016, we closed a private placement in which we sold an aggregate of 1,081,082 shares of common stock at a price of \$18.50 per share, for gross proceeds of \$20.0 million. We incurred placement agent fees of \$1.3 million, and expenses of \$0.2 million in connection with the private placement. As a result, the net offering proceeds to us, after deducting placement agent fees and transaction expenses, were \$18.5 million.

Table of Contents

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended	
	September 30,	
	2016	2015
	(In thousands)	
Net cash used in operating activities	\$ (26,531)	\$ (16,232)
Net cash provided by (used in) investing activities	15,915	(7,463)
Net cash provided by financing activities	18,561	38,357
Net increase in cash and cash equivalents	\$ 7,945	\$ 14,662

Operating Activities

During the nine months ended September 30, 2016, operating activities used \$26.5 million of cash, primarily resulting from our net loss of \$36.6 million partially offset by cash provided by changes in our operating assets and liabilities of \$3.0 million and by non-cash adjustments of \$7.1 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2016 consisted primarily of a \$2.9 million increase in accounts payable and accrued expenses. The increase in accounts payable and accrued expenses was primarily due to expenses incurred, but not yet paid, in connection with our Phase 3 clinical trials for A-101 and the timing of vendor invoicing and payments.

During the nine months ended September 30, 2015, operating activities used \$16.2 million of cash, primarily resulting from our net loss of \$15.8 million and cash used by changes in our operating assets and liabilities of \$0.7 million. Net cash used in changes in our operating assets and liabilities during the nine months ended September 30, 2015 consisted primarily of a \$0.8 million increase in prepaid expenses and other current assets and a \$0.5 million decrease in accounts payable, which were partially offset by a \$0.6 million increase in accrued expenses. The increase in prepaid expenses and other current assets was primarily due to prepayments for clinical trial expenses. The decrease in accounts payable was due to the timing of vendor invoicing and payments. The increase in accrued expenses was due to an increase in accruals for personnel costs related to annual bonuses, which were paid in December 2015, as well as an increase in accruals for IPO-related expenses.

Investing Activities

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

During the nine months ended September 30, 2016, investing activities provided \$15.9 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$49.8 million, partially offset by purchases of marketable securities of \$33.7 million and purchases of equipment of \$0.2 million.

During the nine months ended September 30, 2015, investing activities used \$7.5 million of cash, consisting of purchases of marketable securities of \$13.0 million, and purchases of equipment of \$0.4 million, partially offset by proceeds from sales and maturities of marketable securities of \$5.9 million.

Financing Activities

During the nine months ended September 30, 2016, financing activities provided \$18.6 million of cash primarily from the private placement of 1,081,082 shares of our common stock in June 2016.

During the nine months ended September 30, 2015, financing activities provided \$38.4 million of cash as a result of \$39.9 million in proceeds from the issuance of Series C convertible preferred stock, partially offset by \$1.5 million of payments for IPO costs.

Table of Contents

Funding Requirements

We plan to focus in the near term on the development, regulatory approval and potential commercialization of A-101 for the treatment of SK. We anticipate we will incur net losses for the next several years as we complete clinical development of A-101 for the treatment of SK and continue research and development of A-101 for the treatment of common warts, A-102 for the treatment of SK and common warts and ATI-50001 and ATI-50002 for the treatment of AA, and potentially for other dermatological conditions, as well as for development of other JAK inhibitor compounds. In addition, we plan to continue to invest in discovery efforts to explore additional drug candidates, potentially build commercial capabilities and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our drug candidate arising out of our current clinical trials when we expect, or at all.

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

As a publicly traded company, we have incurred and will continue to incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and the NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that were not applicable to us prior to our IPO. We expect ongoing compliance with these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that our existing cash, cash equivalents and marketable securities are sufficient to fund our operating expenses and capital expenditure requirements for a period greater than 12 months from September 30, 2016 based on our current operating assumptions, including the completion of our three Phase 3 clinical trials for A-101 for the treatment of SK, the submission of our NDA with the FDA for the approval of A-101 for the treatment of SK in the United States and the completion of our Phase 2 clinical trials for A-101 for the treatment of common warts. These assumptions may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to commercialize A-101 for the treatment of SK, if we receive regulatory approval, and to pursue in-licenses or acquisitions of other drug candidates. If we receive regulatory approval for A-101 for the treatment of SK, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. 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. If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations and the pursuit of our growth strategy.

We may raise additional capital through the sale of equity or convertible debt securities. In such an event, your 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, development and commercialization of pharmaceutical drugs, we are unable to precisely estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the drug candidates we pursue;
- the scope, progress, results and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical trials;

Table of Contents

- the timing of, and the costs involved in, obtaining regulatory approvals for our drug candidates;
- the cost of manufacturing our drug candidates and any drugs we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
 - the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future drug candidates, if any.

Contractual Obligations and Commitments

We sublease office space in Malvern, Pennsylvania under an operating sublease agreement with a term through November 2019 that, as amended, requires future rental payments of \$0.1 million during the three months ending December 31, 2016, an aggregate of \$0.5 million during the years ending December 31, 2017 and 2018, and \$0.3 million during the year ending December 31, 2019.

Under the assignment agreement pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of A-101 or 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, we have agreed to make a payment of \$1.0 million upon the submission of an NDA for A-101. We have also agreed to make aggregate payments of up to \$4.5 million upon the achievement of specified commercial milestones. In addition, we have agreed to pay royalties on sales of A-101 or related products at a low single-digit percentage of net sales, as defined in the agreement.

Under a commercial supply agreement with a third party, we have agreed to pay a termination fee of up to \$0.4 million in the event we terminate the agreement without cause or the third party terminates the agreement for cause.

Under a license agreement with Rigel that we entered into in August 2015, we have agreed to make aggregate payments of up to \$80.0 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional \$10.0 million to Rigel upon the achievement of a second set of development milestones. 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 commercial license agreement with other third parties that we entered into in November 2015, we have agreed to make aggregate payments of up to \$2.35 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. We will pay an annual maintenance fee of \$50,000, to be credited against any milestone fees or royalties paid in each calendar year. With respect to any products we commercialize under the agreement, we will pay tiered royalties at a low to mid-single-digit percentage of annual net sales, subject to specified reductions, as determined on a country-by-country and product-by-product basis, until the date that all of the patent rights for that product have expired, or in specified countries under specified circumstances, ten years from the first commercial sale of such product.

Under a stock purchase agreement with Vixen Pharmaceuticals, Inc., or Vixen, that we entered into in March 2016, we have agreed to make aggregate payments of up to \$18.0 million upon the achievement of specified pre-commercialization milestones for three products covered by Vixen 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

Table of Contents

products covered by the Vixen patent rights. We will pay an annual fee of \$100,000, to be credited against any specified future payments made in each year. With respect to any products we commercialize under the agreement, we will pay royalties at 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.

Under a license agreement with the Trustees of Columbia University in the City of New York, or Columbia University, that we became party to as a result of the stock purchase agreement with Vixen, we are 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 University patent rights and/or know-how, and royalties at a sub-single-digit percentage of annual net sales of products covered by Columbia University patent rights and/or know-how, subject to specified adjustments. 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.

We enter into contracts in the normal course of business with CROs 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 Jumpstart Our Business Startups Act of 2012 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. 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 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 do not expect our operating results or cash flows to be affected significantly by the effect of a change in market interest rates on our investments.

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, 2016, 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 Controls Over Financial Reporting

There have not been any changes in our internal controls over financial reporting during our fiscal quarter ended September 30, 2016 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. 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 for the specified risk factors related to our intellectual property described 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, 2015, filed with the SEC on March 23, 2016.

If we are unable to obtain and maintain patent protection for our drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drug candidates may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates.

The patent prosecution process is expensive and time-consuming, however, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are

Table of Contents

prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications that we own or license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Even if our patent applications that we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drugs in a non-infringing manner. For example, the patent applications that we exclusively license from Columbia University that are primarily directed to methods of treating hair loss disorders with JAK inhibitors may not issue or may issue with claims directed to the use of specific JAK inhibitors, which may not be relevant to the JAK inhibitors we intend to commercialize or the JAK inhibitors that our competitor's may commercialize.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Our issued U.S. patents, with claims directed to treatment of SK and acrochordons with A-101, are scheduled to expire in 2022. Certain issued U.S. patents relating to our JAK inhibitors, ATI-50001 and ATI-50002, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to our JAK inhibitors, are scheduled to expire in 2030. The issued U.S. patent that we exclusively licensed from Columbia University with claims directed to the use of a third party JAK inhibitor for the treatment of hair loss disorders, including AA and androgenetic alopecia, or AGA, and inducing hair growth, expires in 2031. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds

Table of Contents

that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties. For instance, we are aware of third parties that have marketed high-concentration hydrogen peroxide solutions over the internet for the treatment of SK. These parties do not appear to have regulatory authority, and we have not authorized them in any way to market these products. However, to date we have refrained from seeking to enforce our intellectual property rights against these third parties due to the transient nature of their activities. With respect to ATI-50001 and ATI-50002, if we do not elect to exercise our first right to do so, Rigel may enforce the licensed patents relating to ATI-50001 and ATI-50002 against any infringing third party in the field of dermatology. In addition, Rigel has the first right, but not the obligation, to enforce the licensed patents relating to ATI-50001 and ATI-50002 against any infringing party outside of the field of dermatology. With respect to the licensed patents from JAKPharm and Key Organics, if we do not elect to exercise our first right to do so, JAKPharm and Key Organics may enforce the licensed patents relating to an infringement of the licensed JAK compounds against any infringing third party in the field of dermatology. In addition, JAKPharm and Key Organics has the right to enforce the licensed patents relating to an infringement of the licensed JAK compounds against any infringing party outside of the field of dermatology. With respect to the licensed patents from Columbia University, Columbia University has the first right to initiate, control and defend any proceedings related to the validity, enforceability or infringement of the licensed patent rights and in doing so, has no obligation to assert more than one licensed patent in one jurisdiction against a third party. With respect to the licensed patents from Columbia University, if Columbia University does not elect to exercise its first right to do so, we may enforce the licensed patent rights relating to an infringement of the licensed patent rights against any infringing third party.

If we breach our license agreement with JAKPharm and Key Organics, it could compromise our development and commercialization efforts for our JAK inhibitors.

In November 2015, we entered into an exclusive license agreement with JAKPharm and Key Organics, which grants us the rights to certain patent rights and other intellectual property owned by them relating to certain novel JAK inhibitors. If we materially breach or fail to perform any provision under this license agreement, including failure to make payments to JAKPharm and Key Organics when due for royalties and failure to use commercially reasonable efforts to develop and commercialize a JAK inhibitor, JAK Pharm and Key Organics have the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed JAKPharm and Key Organics' patent rights and other intellectual property would end. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under the license agreement with JAKPharm and Key Organics.

If we breach our agreement with the selling stockholders of Vixen, it could compromise our development and commercialization efforts for our JAK inhibitors.

In March 2016, we entered into a stock purchase agreement with the stockholders of Vixen, pursuant to which we purchased all of the stock of Vixen and assumed its license agreement with Columbia University. If we fail to use commercially reasonable efforts to develop and commercialize a JAK inhibitor for AA and a JAK inhibitor for AGA, the license agreement with Columbia University will be transferred to the selling stockholders of Vixen following any adverse resolution of any dispute relating thereto. Upon the effective date of such transfer, our right to practice the licensed Columbia University patent rights and know-how would end.

Table of Contents

If we breach our agreement with Columbia University, it could compromise our development and commercialization efforts for our JAK inhibitors.

In March 2016, we assumed a license agreement with Columbia University, which grants us the right under certain patent rights and know-how owned by Columbia University relating to the use of JAK inhibitors to treat hair-loss disorders. If we materially breach or fail to perform any provision under this license agreement, including failure to make payments to Columbia University when due for royalties and failure to use commercially reasonable efforts to develop and commercialize a licensed product, Columbia University has the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed Columbia University patent rights and know-how would end. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights and know-how licensed to us under the license agreement, and, to the extent such patent rights and know-how relate to our JAK inhibitors, it could compromise our development and commercialization efforts for ATI-50001 or ATI-50002 or the novel JAK inhibitors licensed from JAKPharm and Key Organics.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. For example, the use of A-101 for the treatment of SK is currently covered in patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. Our JAK inhibitors being used in the development of ATI-50001 and ATI-50002 are currently covered in patents and applications in the United States, the European Union, and other major foreign markets. Our novel JAK inhibitors licensed from JAKPharm and Key Organics are currently covered in pending applications in the United States, Canada and Europe. Additionally, only one U.S. patent has issued in the patent portfolio licensed from Columbia University, which is directed to the use of a third party JAK inhibitor for the treatment of hair loss disorders and applications are pending in the United States, Europe, Japan and South Korea. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our invention in such countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our drug candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Table of Contents

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates. For example, we exclusively license intellectual property from Rigel in the field of dermatology related to our JAK inhibitors, ATI-50001 and ATI-50002. We also exclusively license intellectual property from JAKPharm and Key Organics in the field of dermatology related to other novel JAK inhibitors and we also exclusively license intellectual property from Columbia University related to the use of JAK inhibitors for the treatment of hair loss disorders. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term and obtaining data exclusivity for our drug candidates, our business may be materially harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, drug candidates and our target indications. Our issued U.S. patents, with claims directed to treatment of SK and acrochordons with A-101, are scheduled to expire in 2022. Certain issued U.S. patents relating to our JAK inhibitors, ATI-50001 and ATI-50002, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to our JAK inhibitors, are scheduled to expire in 2030. The issued U.S. patent relating to the use of our novel JAK inhibitors licensed from JAKPharm and Key Organics is scheduled to expire in 2030. The issued U.S. patent licensed from Columbia University relating to the use of a third party JAK inhibitor for the treatment of hair loss disorders, including AA and

AGA, and inducing hair growth, expires in 2031. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting our drug candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Table of Contents

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to only one patent that covers the approved product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

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

(b) Use of Proceeds from Public Offering of Common Stock

On October 6, 2015, our Registration Statement on Form S-1, as amended (File No. 333-206437) was declared effective in connection with our IPO, pursuant to which we sold 5,750,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of \$11.00 per share. The IPO closed on October 13, 2015, and, as a result, we received net proceeds of \$56.6 million (after underwriters' discounts and commissions of \$4.4 million and additional offering related costs of \$2.3 million). The joint managing underwriters of the offering were Jefferies LLC and Citigroup Global Markets Inc.

No expenses incurred by us in connection with our IPO were paid directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed by us with the Securities and Exchange Commission on October 8, 2015 pursuant to Rule 424(b) of the Securities Act. Through September 30, 2016, we have not used any of the net proceeds, as we have used cash on

hand as of the IPO date to fund the continued research and development of A-101 and our other drug candidates and for working capital and other general corporate purposes.

Table of Contents

Item 6. Exhibits

The exhibits listed on the Exhibit Index hereto are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Table of Contents

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 3, 2016 By: /s/ Neal Walker
Neal Walker
President and Chief Executive Officer
(On behalf of the Registrant)

Date: November 3, 2016 By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(Principal Financial Officer)

Table of Contents

Exhibit Index

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 Commission on October 13, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant’s Current Report on Form 8-K (File No. 001-37581), filed with the Commission on October 13, 2015).
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
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith.

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