

Aclaris Therapeutics, Inc.
Form 10-Q
November 06, 2018
Table of Contents

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, 2018

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	(I.R.S. Employer
Incorporation or Organization)	Identification No.)
640 Lee Road, Suite 200	
Wayne, PA	19087
(Address of principal executive offices)	(Zip Code)

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

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

N/A

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

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

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

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

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on November 5, 2018 was 40,936,191.

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> <u>Statements</u>	2
<u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u> <u>Balance Sheet as</u> <u>of September 30,</u> <u>2018 and</u> <u>December 31,</u> <u>2017</u>	2
<u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u> <u>Statement 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, 2018 and</u> <u>2017</u>	3
<u>Unaudited</u> <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>2018</u>	4

<u>Unaudited</u> <u>Condensed</u> <u>Consolidated</u> <u>Statement of Cash</u> <u>Flows for the nine</u> <u>months ended</u> <u>September 30,</u> <u>2018 and 2017</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>	23
<u>Item 3.</u> <u>Quantitative and</u> <u>Qualitative</u> <u>Disclosures about</u> <u>Market Risk</u>	43
<u>Item 4. Controls</u> <u>and Procedures</u>	43
<u>PART II. OTHER</u> <u>INFORMATION</u>	
<u>Item 1. Legal</u> <u>Proceedings</u>	44
<u>Item 1A. Risk</u> <u>Factors</u>	44
<u>Item 2.</u> <u>Unregistered Sales</u> <u>of Equity</u> <u>Securities and Use</u> <u>of Proceeds</u>	51
<u>Item 6. Exhibits</u>	52

Table of Contents

Part I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET

(Unaudited)

(In thousands, except share and per share data)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,590	\$ 20,202
Marketable securities	107,681	173,655
Accounts receivable, net	1,033	481
Inventory	1,044	—
Prepaid expenses and other current assets	9,171	5,883
Total current assets	145,519	200,221
Marketable securities	—	14,997
Property and equipment, net	4,409	2,159
Intangible assets	7,292	7,349
Goodwill	18,504	18,504
Other assets	452	279
Total assets	\$ 176,176	\$ 243,509
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 13,735	\$ 7,822
Accrued expenses	8,545	4,940
Total current liabilities	22,280	12,762
Contingent consideration	5,244	4,378
Other liabilities	1,775	558
Deferred tax liability	549	549
Total liabilities	29,848	18,247
Stockholders' Equity:		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at September 30, 2018 and December 31, 2017	—	—

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

Common stock, \$0.00001 par value; 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 30,991,060 and 30,856,505 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively

Additional paid in capital	—	—
	400,066	384,943
Accumulated other comprehensive loss	(116)	(246)
Accumulated deficit	(253,622)	(159,435)
Total stockholders' equity	146,328	225,262
Total liabilities and stockholders' equity	\$ 176,176	\$ 243,509

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

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
ESKATA product sales, net	\$ 510	\$ —	\$ 2,043	\$ —
Contract research	1,118	684	3,379	684
Other revenue	—	—	1,000	—
Total revenue, net	1,628	684	6,422	684
Cost of revenue	1,193	453	3,341	453
Gross profit	435	231	3,081	231
Operating expenses:				
Research and development	15,931	10,864	43,472	26,601
Sales and marketing	11,380	3,557	35,030	7,183
General and administrative	6,574	4,566	20,955	13,428
Total operating expenses	33,885	18,987	99,457	47,212
Loss from operations	(33,450)	(18,756)	(96,376)	(46,981)
Other income, net	710	564	2,189	1,392
Net loss	\$ (32,740)	\$ (18,192)	\$ (94,187)	\$ (45,589)
Net loss per share, basic and diluted	\$ (1.06)	\$ (0.63)	\$ (3.04)	\$ (1.68)
Weighted average common shares outstanding, basic and diluted	30,982,192	28,834,808	30,938,026	27,180,244
Other comprehensive income:				
Unrealized gain on marketable securities, net of tax of \$0	\$ 65	\$ 63	\$ 111	\$ 7
Foreign currency translation adjustments	7	(10)	19	149
Total other comprehensive income	72	53	130	156
Comprehensive loss	\$ (32,668)	\$ (18,139)	\$ (94,057)	\$ (45,433)

The accompanying notes are an integral part of these condensed consolidated 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 Comprehensive	Accumulated	Total
	Shares	Value	Paid in Capital	Loss	Deficit	Stockholders' Equity
Balance at December 31, 2017	30,856,505	\$ —	\$ 384,943	\$ (246)	\$ (159,435)	\$ 225,262
Exercise of stock options and vesting of RSUs	134,555	—	24	—	—	24
Unrealized gain on marketable securities	—	—	—	111	—	111
Foreign currency translation adjustment	—	—	—	19	—	19
Stock-based compensation expense	—	—	15,099	—	—	15,099
Net loss	—	—	—	—	(94,187)	(94,187)
Balance at September 30, 2018	30,991,060	\$ —	\$ 400,066	\$ (116)	\$ (253,622)	\$ 146,328

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

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (94,187)	\$ (45,589)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	921	221
Stock-based compensation expense	15,099	10,130
Change in fair value of contingent consideration	866	—
Changes in operating assets and liabilities:		
Accounts receivable	(552)	—
Inventory	(1,044)	—
Prepaid expenses and other assets	(3,461)	(4,331)
Accounts payable	5,932	3,130
Accrued expenses	2,863	(14)
Net cash used in operating activities	(73,563)	(36,453)
Cash flows from investing activities:		
Purchases of property and equipment	(1,210)	(658)
Acquisition of Confluence, net of cash acquired	—	(9,647)
Purchases of marketable securities	(112,344)	(120,496)
Proceeds from sales and maturities of marketable securities	193,427	96,674
Net cash provided by (used in) investing activities	79,873	(34,127)
Cash flows from financing activities:		
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	19,311
Proceeds from issuance of common stock in connection with public offering, net of issuance costs	—	80,918
Capital lease payments	(499)	—
Proceeds from the exercise of employee stock options	577	235
Net cash provided by financing activities	78	100,464
Net increase in cash and cash equivalents	6,388	29,884
Cash and cash equivalents at beginning of period	20,202	30,171
Cash and cash equivalents at end of period	\$ 26,590	\$ 60,055
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	\$ 102	\$ 20
Fair value of stock issued in connection with Confluence acquisition	\$ —	\$ 9,675

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

Property and equipment obtained pursuant to capital lease financing arrangements	\$ 2,076	\$ —
Offering costs included in accounts payable	\$ 20	\$ 107

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

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. In July 2015, Aclaris Therapeutics International Limited (“ATIL”) was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. In March 2016, Vixen Pharmaceuticals, Inc. (“Vixen”) became a wholly-owned subsidiary of Aclaris Therapeutics, Inc., and in September 2018, Vixen was dissolved. In August 2017, Aclaris Life Sciences, Inc. (formerly known as Confluence Life Sciences, Inc.) (“Confluence”) was acquired by Aclaris Therapeutics, Inc. and became a wholly-owned subsidiary thereof (see Note 3). Aclaris Therapeutics, Inc., ATIL, Vixen and Confluence are referred to collectively as the “Company.” The Company is a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. The Company’s lead drug, ESKATA (hydrogen peroxide) Topical Solution, 40% (w/w) (“ESKATA”), is a proprietary high concentration formulation of hydrogen peroxide that the Company is commercializing as an office-based prescription treatment for raised seborrheic keratosis (“SK”), a common non malignant skin tumor. The Company submitted a New Drug Application (“NDA”) for ESKATA to the U.S. Food and Drug Administration (“FDA”) in February 2017, and it was approved in December 2017. The Company launched ESKATA in May 2018. In October 2018, the Company entered into a definitive agreement to acquire the worldwide rights to a second commercial product, RHOFADE (see Note 15).

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, 2018, the Company had cash, cash equivalents and marketable securities of \$134,271 and an accumulated deficit of \$253,622. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, the Company had never generated any revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing of the Company’s drug candidates, 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 condensed consolidated financial statements of the Company include the accounts of the operating parent company, Aclaris Therapeutics, Inc., and its wholly-owned subsidiaries, ATIL, Confluence and Vixen. All significant intercompany transactions have been eliminated.

Table of Contents

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, research and development expenses, contingent consideration and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2018, the condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, the condensed consolidated statement of stockholders' equity for the nine months ended September 30, 2018, and the condensed consolidated statement of cash flows for the nine months ended September 30, 2018 and 2017 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements contained in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 12, 2018 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, 2018, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and its cash flows for the nine months ended September 30, 2018 and 2017. The condensed consolidated balance sheet data as of December 31, 2017 was derived from audited financial statements but does not include all disclosures required by GAAP. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2018 and 2017 are unaudited. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, 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, 2017 included in the Company's annual report on Form 10-K filed with the SEC on March 12, 2018.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2017 included in the Company's annual report on Form 10-K filed with the SEC on March 12, 2018. Since the date of such financial statements, there have been no changes to the Company's significant

accounting policies other than those noted below.

In February 2017, the Company paid a \$2,000 Prescription Drug User Fee Act (“PDUFA”) fee to the FDA in conjunction with the filing of its NDA for ESKATA. The Company requested a waiver and refund of this PDUFA fee, which was approved by the FDA in December 2017, and was received by the Company in January 2018.

Revenue Recognition

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

Table of Contents

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

ESKATA Product Sales

The Company sells ESKATA to McKesson Specialty Care Distribution (“McKesson”) which resells ESKATA to healthcare providers, group purchasing organizations (“GPOs”) and hospitals. The Company has entered into an agreement directly with one GPO, and may enter into additional agreements directly with other GPOs and corporate accounts, that provide for discounted pricing in the form of volume-based rebates and chargebacks, and administrative fees. The Company does not accept product returns.

The Company recognizes revenue from sales of ESKATA at the point when control has transferred to the customer, which generally occurs when McKesson takes delivery of the product. The Company includes estimates for variable consideration, including rebates, chargebacks and administrative fees, as a reduction of revenue when it is recognized. Estimates of variable consideration include reserves for rebates, chargebacks and administrative fees related to units remaining in the distribution channel at McKesson. The Company considers all relevant factors when estimating variable consideration including the terms of current contracts, market trends, industry data and forecasted buying patterns as available and appropriate.

The Company has determined that its arrangement with McKesson, its only direct customer, does not include a financing component since payment terms under the agreement do not exceed one year. The Company expenses incremental costs of contracts with direct and indirect customers, which generally include sales commissions, in the period they are incurred.

Contract Research

The Company earns revenue from the provision of laboratory services to clients through Confluence, its wholly-owned subsidiary. Laboratory service revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis and are generally billed on a monthly basis in arrears for services rendered. Revenue related to these contracts is generally recognized as the laboratory services are performed, based upon the rates specified in the contracts. Under ASC Topic 606, the Company elected to apply the “right to invoice”

practical expedient when recognizing laboratory service revenue. The Company recognizes laboratory service revenue in the amount to which it has the right to invoice.

The Company has also received revenue from grants under the Small Business Innovation Research program of the National Institutes of Health (“NIH”). During the nine months ended September 30, 2018, the Company, through Confluence, its wholly-owned subsidiary, had two active grants from NIH which were related to early-stage research. As of September 30, 2018, there are no remaining funds available to the Company under the grants. The Company recognizes revenue related to grants as amounts become reimbursable under each grant, which is generally when research is performed, and the related costs are incurred.

Inventory

Inventory includes the third-party cost of manufacturing and assembly of the finished product form of ESKATA, quality control and other overhead costs. Inventory is stated at the lower of cost or net realizable value. Inventory is

Table of Contents

adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. The Company had \$1,044 and \$0 of inventory as of September 30, 2018 and December 31, 2017, respectively, which was comprised solely of finished goods.

Contingent Consideration

The Company initially recorded the contingent consideration related to future potential payments based upon the achievement of certain development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. For example, if the timing of the development of an acquired drug candidate, or the size of potential commercial opportunities related to an acquired drug, differ from the Company's assumptions, then the fair value of contingent consideration would be adjusted accordingly. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in the Company's condensed consolidated statement of operations.

Recently Issued Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. The Company is evaluating the impact of ASU 2018-15 on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing disclosure requirements. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. The Company is evaluating the impact of ASU 2018-13 on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with nonemployees

except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 is effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year, and early adoption is permitted. The Company is evaluating the impact of ASU 2018-07 on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. The Company adopted the provisions of this standard on January 1, 2018, the impact of which on its consolidated financial statements was not significant.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Under this ASU, entities should recognize revenue in an amount that reflects the consideration to which they expect to be entitled to in exchange for goods and services provided. ASU 2014-09 is effective for annual reporting periods beginning after

Table of Contents

December 15, 2017. The Company adopted the provisions of this standard on January 1, 2018, using the modified retrospective transition method. The Company did not recognize any transition adjustments as a result of adopting ASU 2014-09 and, accordingly, comparative information has not been restated for the periods reported.

3. Acquisition of Confluence

In August 2017, the Company acquired Confluence, at which time, Confluence became a wholly-owned subsidiary of the Company. The Company gave aggregate consideration with a fair value of \$24,322 to the equity holders of Confluence. The Company also agreed to pay the Confluence equity holders contingent consideration of up to \$80,000, based upon the achievement of certain development, regulatory and commercial milestones, including \$2,500 of which may be paid in shares of the Company's common stock upon the achievement of a specified development milestone. In addition, the Company has agreed to pay the Confluence equity holders specified future royalty payments calculated as a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product.

The following table summarizes the fair value of total consideration given to the Confluence equity holders in connection with the acquisition:

Cash consideration paid	\$ 10,269
Aclaris common stock issued	9,675
Contingent consideration	4,378
Total fair value of consideration to Confluence equity holders	\$ 24,322

The Company accounted for the acquisition of Confluence as a business combination using the acquisition method of accounting. Under the acquisition method of accounting, the assets acquired and liabilities assumed in this transaction were recorded at their respective fair values on the date of acquisition using assumptions that are subject to change. The Company finalized the purchase price allocation for the acquisition of Confluence in the second quarter of 2018.

The following supplemental unaudited pro forma information presents the Company's financial results, for the periods presented, as if the acquisition of Confluence had occurred on January 1, 2017. This supplemental unaudited pro forma financial information has been prepared for comparative purposes only, and is not necessarily indicative of what actual results would have been had the acquisition of Confluence occurred on January 1, 2017, nor is this information indicative of future results.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ 1,628	\$ 1,063	\$ 6,422	\$ 3,366
Gross profit	435	298	3,081	1,102
Total operating expenses	33,885	18,736	99,457	48,122
Net loss	(32,740)	(17,875)	(94,187)	(45,627)

The supplemental unaudited pro forma financial results for the three and nine months ended September 30, 2017 include adjustments to exclude \$997 and \$1,351, respectively, of acquisition-related expenses, as well as \$217 and \$888, respectively, to exclude revenue billed to the Company by Confluence. The supplemental unaudited pro forma financial results for the three and nine months ended September 30, 2017 also include an adjustment for amortization expense related to the other intangible asset acquired.

Table of Contents

4. Fair Value of Financial Assets and Liabilities

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

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 24,583	\$ —	\$ —	\$ 24,583
Marketable securities	—	107,681	—	107,681
Total Assets	\$ 24,583	\$ 107,681	\$ —	\$ 132,264

Liabilities:				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 5,244	\$ 5,244
Total liabilities	\$ —	\$ —	\$ 5,244	\$ 5,244

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 19,339	\$ —	\$ —	\$ 19,339
Marketable securities	—	188,652	—	188,652
Total Assets	\$ 19,339	\$ 188,652	\$ —	\$ 207,991

Liabilities:				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 4,378	\$ 4,378
Total liabilities	\$ —	\$ —	\$ 4,378	\$ 4,378

As of September 30, 2018 and December 31, 2017, the Company's cash equivalents consisted of investments with maturities of less than three months and included a money market fund, which was valued based upon Level 1 inputs, and commercial paper which was valued based upon Level 2 inputs. In determining the fair value of its Level 2 investments the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. On a quarterly basis, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of those quoted prices. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to the quoted prices obtained from the third-party pricing service. During the three and nine months ended September 30, 2018 and the year ended December 31, 2017, there were no transfers between Level 1, Level 2 and Level 3. The change in contingent consideration related to acquisition of Confluence of \$866 during the nine months ended September 30, 2018 was the result of updates to the Company's

assumptions related to drug discovery research on the soft-JAK inhibitors acquired as part of the acquisition, which progressed more quickly than originally planned.

Table of Contents

The following tables present the fair value of the Company's available for sale marketable securities by type of security:

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 16,088	\$ —	\$ (23)	\$ 16,065
Commercial paper	51,691	—	—	51,691
Asset-backed securities	16,009	—	(8)	16,001
U.S. government agency debt securities	23,952	—	(28)	23,924
Total marketable securities	\$ 107,740	\$ —	\$ (59)	\$ 107,681

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 37,401	\$ —	\$ (68)	\$ 37,333
Commercial paper	85,202	—	—	85,202
Asset-backed securities	16,708	—	(13)	16,695
U.S. government agency debt securities	49,511	—	(89)	49,422
Total marketable securities	\$ 188,822	\$ —	\$ (170)	\$ 188,652

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2018	December 31, 2017
Computer equipment	\$ 1,338	\$ 650
Fleet vehicles	2,076	—
Manufacturing equipment	562	511
Lab equipment	928	721
Furniture and fixtures	524	327

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

Leasehold improvements	326	430
Property and equipment, gross	5,754	2,639
Accumulated depreciation	(1,345)	(480)
Property and equipment, net	\$ 4,409	\$ 2,159

Depreciation expense was \$366 and \$103 for the three months ended September 30, 2018 and 2017, respectively, and \$865 and \$208 for the nine months ended September 30, 2018 and 2017, respectively.

Table of Contents

6. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2018	December 31, 2017
Employee compensation expenses	\$ 4,219	\$ 3,010
Sales and marketing expenses	833	39
Research and development expenses	1,900	627
Capital leases, current portion	591	142
Professional fees	336	108
Payable to NST	—	590
Other	666	424
Total accrued expenses	\$ 8,545	\$ 4,940

7. Stockholders' Equity

Preferred Stock

As of September 30, 2018 and December 31, 2017, 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, 2018 or December 31, 2017.

Common Stock

As of September 30, 2018 and December 31, 2017, 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. The

Company did not declare any dividends through September 30, 2018.

At-The-Market Equity Offering

In November 2016, the Company entered into an at-the-market sales agreement with Cowen and Company, LLC (“Cowen”) to sell the Company’s securities under a shelf registration statement filed in November 2016. In October 2018, the Company terminated the at-the-market sales agreement with Cowen. During the nine months ended September 30, 2018, the Company did not issue any shares of common stock under the at-the-market sales agreement. As of September 30, 2018, the Company had issued and sold an aggregate of 635,000 shares of common stock under the at-the-market sales agreement at a weighted average price per share of \$31.50, for aggregate gross proceeds of \$20,003. The Company has incurred expenses of \$691 in connection with the shares issued under the at-the-market sales agreement.

Public Offerings of Common Stock

In August 2017, the Company entered into an underwriting agreement pursuant to which the Company issued and sold 3,747,602 shares of common stock under a registration statement on Form S-3, including the underwriters’ partial exercise of their option to purchase additional shares. The shares of common stock were sold to the public at a price of \$23.02 per share, for gross proceeds of \$86,270. The Company paid underwriting discounts and commissions of \$5,176 to the underwriters and incurred expenses of \$176 in connection with this public offering. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and offering expenses, were \$80,918.

Table of Contents

In October 2018, the Company consummated a second public offering of shares of common stock (see Note 15).

8. Stock Based Awards

2017 Inducement Plan

In July 2017, the Company's board of directors adopted the 2017 Inducement Plan (the "2017 Inducement Plan"). The 2017 Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The only employees eligible to receive grants of awards under the 2017 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq listing rules, generally including individuals who were not previously an employee or director of the Company. Under the terms of the 2017 Inducement Plan upon adoption, the Company may grant up to 1,000,000 shares of common stock pursuant to nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, and other stock awards. The shares of common stock underlying any awards that expire, or are otherwise terminated, settled in cash or repurchased by the Company under the 2017 Inducement Plan will be added back to the shares of common stock available for issuance under the 2017 Inducement Plan. As of September 30, 2018, 22,471 shares of common stock were available for grant under the 2017 Inducement Plan.

2015 Equity Incentive Plan

In September 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (the "2015 Plan"), and on September 16, 2015, the Company's stockholders approved the 2015 Plan. The 2015 Plan became effective in connection with the Company's initial public offering in October 2015. Beginning at the time the 2015 Plan became effective, no further grants may be made under the Company's 2012 Equity Compensation Plan, as amended and restated (the "2012 Plan"). The 2015 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, 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, 2018, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 1,234,260 shares. As of September 30, 2018, 1,718,918 shares remained available for grant under the 2015 Plan.

2012 Equity Compensation Plan

Upon the 2015 Plan becoming effective, no further grants can be made under the 2012 Plan. The Company granted stock options to purchase a total of 1,140,524 shares under the 2012 Plan, of which 951,905 and 984,720 were outstanding as of September 30, 2018 and December 31, 2017, respectively. Stock options granted under the 2012 Plan vest over four years and expire after ten years. As required, the exercise price for the stock options granted under the 2012 Plan was not less than the fair value of the shares of common stock underlying the awards as determined by the Company as of the date of grant.

Table of Contents

Stock Option Valuation

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

	Nine Months Ended September 30,			
	2018		2017	
Risk-free interest rate	2.65	%	1.89	%
Expected term (in years)	6.3		6.2	
Expected volatility	96.56	%	93.84	%
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, 2018 through September 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	3,328,757	\$ 20.69	8.28	\$ 19,812
Granted	1,397,900	21.25		
Exercised	(59,450)	9.70		
Forfeited and cancelled	(343,854)	24.82		
Outstanding as of September 30, 2018	4,323,353	\$ 20.69	8.10	\$ 7,634
Options vested and expected to vest as of September 30, 2018	4,323,353	\$ 20.69	8.10	\$ 7,634
Options exercisable as of September 30, 2018	1,543,159	(1) \$ 15.70	7.00	\$ 6,785

(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, 2018.

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2018 was \$16.75 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, 2018 through September 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2017	283,553	\$ 27.02
Granted	419,160	21.12
Vested	(106,202)	26.89
Forfeited and cancelled	(54,883)	23.76
Outstanding as of September 30, 2018	541,628	\$ 22.81

Stock Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of revenue	\$ 194	\$ 130	\$ 560	\$ 130
Research and development	1,433	1,332	4,916	3,853
Sales and marketing	760	480	2,687	1,260
General and administrative	2,320	1,731	6,936	4,887
Total stock-based compensation expense	\$ 4,707	\$ 3,673	\$ 15,099	\$ 10,130

As of September 30, 2018, the Company had unrecognized stock based compensation expense for stock options and RSUs of \$40,938 and \$10,222, respectively, which is expected to be recognized over weighted average periods of 2.73 years and 3.10 years, respectively.

9. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	\$ (32,740)	\$ (18,192)	\$ (94,187)	\$ (45,589)
Denominator:				
Weighted average shares of common stock outstanding	30,982,192	28,834,808	30,938,026	27,180,244
Net loss per share, basic and diluted	\$ (1.06)	\$ (0.63)	\$ (3.04)	\$ (1.68)

The Company's potentially dilutive securities, which included stock options and RSUs, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential shares of common stock excluded from the calculation of diluted

Table of Contents

net loss per share for the three and nine months ended September 30, 2018 and 2017. All share amounts presented in the table below represent the total number outstanding as of September 30, 2018 and 2017.

	September 30,	
	2018	2017
Options to purchase common stock	4,323,353	3,242,831
Restricted stock unit awards	541,628	294,331
Total potential shares of common stock	4,864,981	3,537,162

10. Commitments and Contingencies

Agreements for Office Space

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

In November 2016, the Company entered into a lease agreement with a third party for additional office space in Malvern, Pennsylvania with a term ending in November 2019. The Company also occupies office and laboratory space in St. Louis, Missouri under the terms of an agreement which it entered into in January 2018 and which expires in December 2018.

Rent expense was \$204 and \$110 for the three months ended September 30, 2018 and 2017, respectively, and was \$682 and \$284 for the nine months ended September 30, 2018 and 2017, respectively. The Company recognizes rent expense on a straight-line basis over the term of the lease and has accrued for rent expense incurred but not yet paid.

Capital Leases

Laboratory Equipment

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

Fleet Vehicles

The Company leases automobiles for its sales force and other field-based employees under the terms of a master lease agreement with a third party. The lease term for each automobile begins on the date the Company takes delivery and continues for a period of four years. The Company has accounted for the automobile leases as capital leases in its condensed consolidated financial statements.

Table of Contents

As of September 30, 2018, future minimum payments under operating and capital lease agreements were as follows:

Year Ending December 31,	
2018	\$ 312
2019	1,100
2020	1,037
2021	1,054
2022	791
Thereafter	531
Total	\$ 4,825

11. Related Party Transactions

In August 2013, the Company entered into a sublease agreement with NeXeption, Inc. ("NeXeption"), which was subsequently assigned to NST Consulting, LLC, a wholly-owned subsidiary of NST, LLC. In November 2017, the Company terminated the sublease with NST Consulting, LLC effective March 31, 2018. The Company paid \$590 to NST Consulting, LLC, which amount represented accelerated rent payments. Total net payments made under the sublease during the nine months ended September 30, 2018 and 2017 were \$570 and \$231, 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 November 2017, the Company terminated the NST Services Agreement effective December 31, 2017.

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, and three of the Company's executive officers are and have been members of entities affiliated with NST, LLC.

During the three and nine months ended September 30, 2018 and 2017, amounts included in the condensed consolidated statement of operations and comprehensive loss for the NST Services Agreement are summarized in the following table:

	Three Months Ended September 30, 2018 2017		Nine Months Ended September 30, 2018 2017	
Services provided by NST Consulting, LLC	\$ —	\$ 49	\$ —	\$ 161
Services provided to NST Consulting, LLC	—	—	—	(18)
General and administrative expense, net	\$ —	\$ 49	\$ —	\$ 143
Net payments made to NST Consulting, LLC	\$ —	\$ 35	\$ —	\$ 218

The Company had a net amount payable of \$0 and \$570 to NST Consulting, LLC under the NST Services Agreement as of September 30, 2018 and December 31, 2017, respectively.

Table of Contents

12. Agreements Related to Intellectual Property

License, Development and Commercialization Agreement – Cipher Pharmaceuticals Inc.

In April 2018, the Company entered into an exclusive license agreement with Cipher Pharmaceuticals Inc. (“Cipher”) for the rights to obtain regulatory approval of and commercialize A-101 40% Topical Solution in Canada for the treatment of SK. Under the agreement, Cipher is responsible for obtaining marketing approval in Canada for A-101 40% Topical Solution. The Company will supply Cipher with finished product, and, if regulatory approval is obtained, Cipher will be responsible for distribution and commercialization of A-101 40% Topical Solution in Canada. Additionally, Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada. The Company received an up-front payment of \$1,000 upon signing of the agreement with Cipher, which is included in other revenue on the Company’s condensed consolidated statement of operations for the nine months ended September 30, 2018. The Company can earn aggregate payments of \$1,000 upon the achievement of specified development milestones, and aggregate payments of \$1,750 upon the achievement of specified commercial milestones under the terms of the agreement with Cipher. Cipher will also be required to pay the Company a low double-digit percentage royalty on net sales of A-101 40% Topical Solution in Canada. The term of the agreement expires on the later of the expiration of applicable patents in Canada or the 15th anniversary of the first commercial sale of licensed product in Canada.

Assignment Agreement – Estate of Mickey Miller and

Finder’s Services Agreement – KPT Consulting, LLC

In August 2012, the Company entered into an assignment agreement with the Estate of Mickey Miller (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. Under the terms of the finder’s services agreement, the Company made a milestone payment of \$1,000 upon the achievement of specified regulatory milestones in April 2017 and a milestone payment of \$1,500 upon the achievement of specified commercial milestones in May 2018. The payments were recorded as general and administrative expenses in the Company’s condensed consolidated statement of operations.

Under the finder’s services agreement, the Company is obligated to make an additional milestone payment of \$3,000 upon the achievement of a specified commercial milestone. 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. During the nine months ended September 30, 2018, the Company incurred an aggregate expense of \$82 related to royalty payments under these agreements. 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.

13. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three and nine months ended September 30, 2018 and 2017 due to the Company's conclusion that a valuation allowance was required for those periods.

Table of Contents

14. Segment Information

The Company has two reportable segments, dermatology therapeutics and contract research. The dermatology therapeutics segment is focused on identifying, developing and commercializing innovative therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. The Company's lead drug, ESKATA, is a proprietary formulation of high-concentration hydrogen peroxide topical solution that the Company is commercializing as an office-based prescription treatment for raised SKs, a common non-malignant skin tumor, and which is distributed by a wholesaler. The contract research segment earns revenue from the provision of laboratory services to clients through Confluence, the Company's wholly-owned subsidiary. Laboratory service revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis. Corporate and other includes general and administrative expenses as well as eliminations of intercompany transactions. The Company does not report balance sheet information by segment since it is not reviewed by the chief operating decision maker, and all of the Company's tangible assets are held in the United States.

The Company's results of operations by segment for the three and nine months ended September 30, 2018 and 2017 are summarized in the tables below:

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Three Months Ended September 30, 2018				
Revenue, net	\$ 510	\$ 3,225	\$ (2,107)	\$ 1,628
Cost of revenue	126	2,823	(1,756)	1,193
Research and development	15,931	—	—	15,931
Sales and marketing	11,366	14	—	11,380
General and administrative	—	566	6,008	6,574
Loss from operations	\$ (26,913)	\$ (178)	\$ (6,359)	\$ (33,450)

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Three Months Ended September 30, 2017				
Revenue, net	\$ —	\$ 1,212	\$ (528)	\$ 684
Cost of revenue	—	893	(440)	453
Research and development	10,864	—	—	10,864
Sales and marketing	3,555	2	—	3,557
General and administrative	72	196	4,298	4,566
Loss from operations	\$ (14,491)	\$ 121	\$ (4,386)	\$ (18,756)

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Nine Months Ended September 30, 2018				
Revenue, net	\$ 3,043	\$ 8,779	\$ (5,400)	\$ 6,422
Cost of revenue	278	7,564	(4,501)	3,341
Research and development	43,472	—	—	43,472

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

Sales and marketing	34,996	34	—	35,030
General and administrative	—	1,557	19,398	20,955
Loss from operations	\$ (75,703)	\$ (376)	\$ (20,297)	\$ (96,376)

20

Table of Contents

Nine Months Ended September 30, 2017	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	\$ —	\$ 1,212	\$ (528)	\$ 684
Cost of revenue	—	893	(440)	453
Research and development	26,601	—	—	26,601
Sales and marketing	7,181	2	—	7,183
General and administrative	223	195	13,010	13,428
Loss from operations	\$ (34,005)	\$ 122	\$ (13,098)	\$ (46,981)

Foreign Subsidiary

The Company's wholly-owned subsidiary, ATIL, was formed and operates in the United Kingdom. ATIL is utilized for research and development, regulatory and administrative functions and had \$38 and \$175 of net assets, composed principally of cash, as of September 30, 2018 and December 31, 2017, respectively.

Intersegment Revenue

Revenue for the contract research segment includes \$2,107 and \$528 for services performed on behalf of the dermatology therapeutics segment for the three months ended September 30, 2018 and 2017, respectively, and \$5,400 and \$528 for services performed on behalf of the dermatology therapeutics segment for the nine months ended September 30, 2018 and 2017, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

15. Subsequent Events

Asset Purchase Agreement – Allergan Sales, LLC

On October 15, 2018, the Company entered into an Asset Purchase Agreement (“APA”) with Allergan Sales, LLC (“Allergan”). Pursuant to the APA, the Company has agreed to acquire the worldwide rights to RHOFADÉ (oxymetazoline hydrochloride) cream, 1%, which includes an exclusive license to certain intellectual property for RHOFADÉ, as well as additional intellectual property (the “Acquisition”). The Company expects the transaction to close before the end of 2018.

Pursuant to the APA, the Company is required to pay Allergan cash consideration of \$65,000, including \$58,500 to be paid at closing and \$6,500 to be placed in escrow, plus the book value of specified lots of Allergan's inventory of RHOFAD, which is estimated to be approximately \$1,000. The Company has also agreed to pay Allergan a one-time payment of \$5,000 upon the achievement of a specified development milestone related to the potential development of an additional dermatology product. In addition, the Company has agreed to pay Allergan specified royalties, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFAD, have expired or, if later, ten years from the closing date of the Acquisition. In addition, the Company has agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of the Company's management team, including Neal Walker, Frank Ruffo, Christopher Powala and Stuart Shanler, as well as Stephen Tullman, the chairman of the Company's board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these entities, these individuals may be entitled to receive a portion of the potential future payments payable by the Company.

Table of Contents

The APA contains customary representations and warranties, pre-closing covenants and indemnities. The closing of the Acquisition is subject to the satisfaction or waiver of a number of customary closing conditions in the APA, including, among others, the receipt of regulatory approval, the absence of certain governmental restraints and the absence of a material adverse effect on the Company or the RHOFAD assets.

The APA may be terminated prior to the closing date by mutual written agreement of the Company and Allergan. In addition, the APA may be terminated by either the Company or Allergan in certain circumstances, including if the Acquisition has not closed by July 15, 2019, or if the other party has breached any representation, warranty, covenant, obligation or agreement such that certain of the conditions to closing cannot be satisfied.

Loan and Security Agreement – Oxford Finance LLC

On October 15, 2018, the Company and its wholly owned subsidiaries Confluence Discovery Technologies, Inc. and Aclaris Life Sciences, Inc. (together, the “Borrowers”) entered into a Loan and Security Agreement (“Loan Agreement”) with Oxford Finance LLC, a Delaware limited liability company (“Oxford”). The Loan Agreement provides for up to \$65,000 in term loans (the “Term Loan Facility”). Of the \$65,000, the Company borrowed \$30,000 on October 31, 2018. The remaining \$35,000 will become available to be borrowed beginning on the closing date of the Acquisition and ending on the earlier of March 31, 2019 or an event of default. Should the Borrowers not draw all of the Term Loan Facility, or if the Borrowers repay the entirety of the amount drawn during the applicable draw timeframe, the Borrowers will be required to pay a non-utilization fee equal to 1.0% of the undrawn portion of the Term Loan Facility.

The Loan Agreement provides for interest only payments through November 1, 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 1, 2021 and continuing through the maturity date of October 1, 2023. All unpaid principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan Agreement provides for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate, as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus 6.25%. The Loan Agreement also provides for a final payment fee equal to 5.75% of the original principal amount of the term loans drawn under the Term Loan Facility, which final payment is due on October 1, 2023 or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

The Borrowers have the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of (i) 3% of the original principal amount of the aggregate term loans drawn for any prepayment prior to the first anniversary of the Funding Date (as defined in the Loan Agreement), (ii) 2% of the original principal amount of the aggregate term loans drawn for any prepayment between the first and second anniversaries of the Funding Date or (iii) 1% of the original principal amount of the aggregate term loans drawn for any prepayment after the second anniversary of the Funding Date but before October 1, 2023. The Borrowers also have the option to prepay the term loans in part, once in a three-month period, of an amount of \$2,000 or greater, subject to the same prepayment fees

and other specified limitations.

The Term Loan Facility is secured by substantially all of the Borrowers' assets, except that the collateral does not include the Borrowers' intellectual property. However, the Borrowers have agreed not to encumber any of their intellectual property. The Loan Agreement contains customary representations, warranties and covenants by the Borrowers. The Loan Agreement also contains specified financial covenants related to minimum consolidated future revenues of the Borrowers.

October 2018 Public Offering

On October 17, 2018, the Company entered into an underwriting agreement pursuant to which the Company issued and sold 9,941,750 shares of common stock under registration statements on Form S-3, including the underwriters' full exercise of their option to purchase additional shares. The shares of common stock were sold to the public at a price of \$10.75 per share, for gross proceeds of \$106,874. The Company paid underwriting discounts and commissions of \$6,412 to the underwriters in connection with the offering.

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. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item 1A, "Risk Factors," in our Annual Report on Form 10-K in Part I, Item 1A, "Risk Factors," and in our other filings with the Securities and Exchange Commission, or SEC. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes for the year ended December 31, 2017, which are included in our 2017 Annual Report on Form 10-K filed with the SEC, on March 12, 2018.

Overview

We are a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. Our lead product ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, is a proprietary formulation of high-concentration hydrogen peroxide topical solution that has been approved by the U.S. Food and Drug Administration, or FDA, as an office-based prescription treatment for raised seborrheic keratosis, or SK, a common non-malignant skin tumor. The FDA approved our New Drug Application, or NDA, for ESKATA for the treatment of raised SKs in December 2017. We also submitted a Marketing Authorization Application, or MAA, for ESKATA in select countries in the European Union in July 2017. We are also developing another high-concentration formulation of hydrogen peroxide, A-101 45% Topical Solution, as a prescription treatment for common warts, also known as verruca vulgaris. Additionally, in 2015, we in-licensed exclusive, worldwide rights to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, or AA, vitiligo and androgenetic alopecia, or AGA, also known as male or female pattern baldness. In 2016, we acquired additional intellectual property rights for the development and commercialization of certain JAK inhibitors for specified dermatological conditions. We have also entered into an agreement to acquire RHOFADÉ (oxymetazoline hydrochloride) cream, 1% and additional intellectual property from Allergan Sales, LLC, or Allergan, as described further below under "— Recent Developments." RHOFADÉ is approved for the topical treatment of persistent facial

erythema, or redness, associated with rosacea in adults. We intend to continue to in-license or acquire additional drug candidates and technologies to build a fully integrated dermatology company.

We have been developing our sales, marketing and product distribution capabilities for ESKATA in order to support our commercial launch in the United States, which occurred in May 2018. We have also hired a targeted field sales force of 50 sales representatives which we believe will allow us to reach the approximately 6,000 health care providers in the United States with the highest potential for using ESKATA. In April 2018, we licensed the rights to commercialize A-101 40% Topical Solution in Canada for the treatment of SK to Cipher Pharmaceuticals Inc., or Cipher. Under the terms of the license agreement, we received an up-front payment of \$1.0 million, and may receive additional milestone payments upon the achievement of specified regulatory and commercial milestones, and royalties from the sale of A-101 40% Topical Solution in Canada. Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada.

Table of Contents

We are developing A-101 45% Topical Solution for the treatment of common warts. In June 2017, we commenced two Phase 2 clinical trials, WART-202 and WART-203, of A-101 45% topical solution to assess the dose frequency in adult and pediatric patients with common warts. Both trials evaluated the safety and efficacy of A-101 45% Topical Solution as compared to placebo, or vehicle. The two randomized, double-blind, vehicle-controlled trials were designed to evaluate the effects of dose frequency and to explore additional clinical endpoints that will be further evaluated in a planned Phase 3 development program. We enrolled a total of 316 patients at 34 investigational centers in the United States across both trials. In January 2018, we reported top line results from these two Phase 2 clinical trials of A-101 45% Topical Solution. In March 2018, we reported final results, which included a 3-month drug-free follow-up phase, from the WART-203 clinical trial. In addition, in April 2018, we concluded the WART-202 clinical trial, in which we evaluated a different dosing regimen from the one used in the WART-203 clinical trial. In both of these clinical trials, patients treated with A-101 45% Topical Solution achieved clinically and statistically significant outcomes for the primary, secondary and exploratory endpoints of the trial. Based on the results from these clinical trials, we held an end of Phase 2 meeting with the FDA and we are using a twice-weekly dosing regimen in our Phase 3 pivotal clinical trials of A-101 45% Topical Solution for the treatment of common warts, which we initiated in September 2018. We expect to report data from these two Phase 3 clinical trials in the second half of 2019. In addition, in 2019, we plan to commence an open-label safety extension trial investigating A-101 45% Topical Solution for the treatment of common warts. If the results of these trials are positive, we expect to submit an NDA to the FDA thereafter.

We are developing our JAK inhibitor drug candidate ATI-501, which we licensed from Rigel Pharmaceuticals, Inc., or Rigel, as an oral treatment for AA. AA is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include total scalp hair loss, known as alopecia totalis, or AT, and total hair loss on the scalp and body, known as alopecia universalis, or AU. We submitted an investigational new drug application, or IND, to the FDA for ATI-501 for the treatment of AA in October 2016. Since the filing of the IND, we have conducted several Phase 1 clinical trials to evaluate the pharmacokinetic and pharmacodynamic, or PK/PD, properties of various formulations of ATI-501. Based on the results from these clinical trials, we selected an oral suspension and have initiated a Phase 2 dose-response clinical trial of ATI-501.

We are developing ATI-502, which we also licensed from Rigel, as a topical treatment for AA, vitiligo, AGA and atopic dermatitis. We submitted an IND to the FDA for ATI-502 for the treatment of AA in July 2017. The following table summarizes the status of our ongoing Phase 2 clinical trials of ATI-501 and ATI-502, including their indications, trial objectives and expected timing for initiation and receipt of preliminary results:

P					
Drug Candidate and Name of Trial	Indication	Objective	Patients	Initiation	Preliminary Results Expected
ATI-501 AUAT-201	AA	Dose-ranging	80	Initiated	2H 2019

ATI-502					
AA-201	AA	Dose-ranging	120	Initiated	1H 2019
AA-202	AA	PK/PD	11	Initiated	1H 2018 ¹
AUATB-201	AA (Eyebrow)	Open-label study	12	Initiated	2H 2018
VITI-201	Vitiligo	Open-label study	33	Initiated	2H 2019 ²
AGA-201	AGA	Open-label study	31	Initiated	1H 2019
AD-201	Atopic Dermatitis	Open-label study	30	Initiated	Mid-2019

(1) AA-202 interim data reported in June 2018.

(2) VITI-201 6-month data expected in the first half of 2019 and 12-month data expected in the second half of 2019.

Table of Contents

In August 2017, we acquired Aclaris Life Sciences, Inc. (formerly known as Confluence Life Sciences, Inc.), or Confluence. This acquisition added small molecule drug discovery and preclinical development capabilities that allow us to bring early-stage research and development activities in-house that we previously outsourced to third parties. We also acquired several preclinical drug candidates as part of the acquisition, including additional JAK inhibitors known as “soft” JAK inhibitors, inhibitors of the MK-2 signaling pathway and inhibitors of interleukin-2-inducible T cell kinase, or ITK. We expect to submit an IND to the FDA for ATI-450, an MK-2 inhibitor, in mid-2019, and for our soft-JAK inhibitors in the second half of 2019. We are considering developing ATI-450 for the treatment of rheumatoid arthritis, psoriasis, hidradenitis suppurativa, cryopyrin-associated periodic syndrome (CAPS), and pyoderma gangrenosum. We are considering developing our soft-JAK inhibitors for the treatment of dermatological conditions, including atopic dermatitis, vitiligo and AA. We are considering developing our ITK inhibitors for the treatment of psoriasis, inflammatory dermatoses, and inflammatory bowel disease.

In October, we were issued a U.S. patent with 18 claims directed to an applicator containing a formulation of high concentration hydrogen peroxide and methods of using such an applicator to treat SK, warts and other indications, which is scheduled to expire in 2035.

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 ESKATA for the treatment of raised SKs, building our intellectual property portfolio, developing our supply chain and engaging in other discovery and clinical activities in dermatology. We have primarily financed our operations with sales of our convertible preferred stock, as well as net proceeds from our initial public offering, or IPO, in October 2015, subsequent public offerings, and a private placement of our common stock.

Since our inception, we have incurred significant operating losses. Our net loss was \$94.2 million for the nine months ended September 30, 2018 and \$68.5 million for the year ended December 31, 2017. As of September 30, 2018, we had an accumulated deficit of \$253.6 million. We expect to incur significant expenses and operating losses related to product manufacturing, marketing, sales and distribution over the next several years as we continue to commercialize ESKATA and, following the closing of the acquisition described below, RHOFADÉ. In addition, ESKATA and RHOFADÉ, and our drug candidates if approved, may not achieve commercial success. We also 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. 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. We may also incur expenses in connection with the in-license or acquisition of additional drug candidates. Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. 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.

Table of Contents

Recent Developments

Acquisition of RHOFADÉ

On October 15, 2018, we entered into an Asset Purchase Agreement, or the APA, with Allergan, pursuant to which we have agreed to acquire the worldwide rights to RHOFADÉ, which includes an exclusive license to certain intellectual property for RHOFADÉ, as well as additional intellectual property. In addition, Allergan has agreed to provide transition support services to us.

Pursuant to the APA, and upon the terms and subject to the conditions thereof, we are required to pay Allergan total cash consideration of \$65.0 million, including \$58.5 million to be paid at the closing and \$6.5 million to be placed in escrow, plus the book value of specified lots of Allergan's inventory of RHOFADÉ, which we estimate to be approximately \$1 million. We have also agreed to pay Allergan a one-time payment of \$5.0 million upon the achievement of a specified development milestone related to the potential development of an additional dermatology product. In addition, we have agreed to pay Allergan specified royalty payments, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFADÉ, have expired or, if later, ten years from the closing date of the acquisition. In addition, we have agreed to assume the rights and obligations of Allergan related to RHOFADÉ, including the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of our management team, including Neal Walker, Frank Ruffo, Christopher Powala and Stuart Shanler, as well as Stephen Tullman, the chairman of our board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these entities, these individuals may be entitled to receive a portion of the potential future payments payable by us.

The completion of the acquisition is subject to the satisfaction or waiver of a number of customary closing conditions in the APA, including the receipt of regulatory approval, the absence of certain governmental restraints and the absence of a material adverse effect on us or the RHOFADÉ business. We expect to close the acquisition in the fourth quarter of 2018.

Allergan received approval from the FDA in January 2017 to market RHOFADÉ for the topical treatment of persistent facial redness associated with rosacea in adults, and the product became commercially available in the United States in May 2017.

Loan and Security Agreement with Oxford

On October 15, 2018, we entered into a Loan and Security Agreement, or the Loan and Security Agreement, with Oxford Finance LLC, or Oxford. The Loan and Security Agreement provides for up to \$65.0 million in term loans. Of the \$65.0 million, we borrowed \$30.0 million on October 31, 2018. The remaining \$35.0 million will become available for draw beginning on the closing date of the RHOFADÉ acquisition and ending on the earlier of March 31, 2019 or an event of default.

October 2018 Public Offering

On October 17, 2018, we entered into an underwriting agreement pursuant to which we issued and sold 9,941,750 shares of common stock, including the underwriters' full exercise of their option to purchase additional shares. The shares of common stock were sold to the public at a price of \$10.75 per share, for gross proceeds of \$106.9 million. We paid underwriting discounts and commissions of \$6.4 million to the underwriters in connection with the offering.

Table of Contents

Components of Our Results of Operations

Revenue

ESKATA Product Sales

We sell ESKATA to McKesson Specialty Care Distribution, or McKesson, which resells ESKATA to healthcare providers, group purchasing organizations, or GPOs, and hospitals. We have entered into an agreement directly with one GPO, and may enter into additional agreements directly with other GPOs and corporate accounts, that provide for discounted pricing in the form of volume-based rebates and chargebacks, and administrative fees. We do not accept product returns.

We recognize revenue from sales of ESKATA at the point when control has transferred to the customer, which generally occurs when McKesson takes delivery of the product. We include estimates for variable consideration, including rebates, chargebacks and administrative fees, as a reduction of revenue when it is recognized. Estimates of variable consideration include reserves for rebates, chargebacks and administrative fees related to units remaining in the distribution channel at McKesson. We consider all relevant factors when estimating variable consideration including the terms of current contracts, market trends, industry data and forecasted buying patterns as available and appropriate.

We determined that our arrangement with McKesson, our only customer, does not include a financing component since payment terms under the agreement do not exceed one year. We expense incremental costs of contracts with direct and indirect customers, which generally includes sales commissions, in the period they are incurred.

Contract Research

We also earn revenue from the provision of laboratory services to clients through Confluence, our wholly-owned subsidiary. Laboratory service revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis and are generally billed on a monthly basis in arrears for services rendered. Revenue related to these contracts is generally recognized as the laboratory services are performed, based upon the rates specified in the contracts. Under ASC Topic 606, we elected to apply the “right to invoice” practical expedient when recognizing laboratory service revenue. We recognize laboratory service revenue in the amount to which we have the right to invoice.

We have also received revenue from grants under the Small Business Innovation Research program of the National Institutes of Health, or NIH. During the nine months ended September 30, 2018, we, through Confluence, our wholly-owned subsidiary, had two active grants from NIH which were related to early-stage research. As of September 30, 2018, there are no remaining funds available to us under the grants. We recognize revenue related to grants as amounts become reimbursable under each grant, which is generally when research is performed, and the related costs are incurred.

Table of Contents

Cost of Revenue

Cost of revenue consists of the cost of manufacturing the finished product form of ESKATA, as well as costs incurred in connection with the provision of contract research services to our clients through Confluence. Cost of revenue primarily includes:

ESKATA Product Sales

- third-party cost of manufacturing and assembly of finished product form of ESKATA;
- depreciation of manufacturing equipment;
- product release and stability testing;
- warehousing and insurance costs; and
- royalty payments.

Contract Research

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

Research and Development Expenses

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

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

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, continue to conduct clinical trials of A-101 45% Topical Solution for the treatment of common warts, and conduct clinical trials and prepare regulatory filings for our other drug candidates. We expense research and development costs as incurred. Our direct research and development expenses primarily consist of external costs including fees paid to CROs, consultants, investigator sites, regulatory agencies and third parties that manufacture our preclinical and clinical trial materials, and are

Table of Contents

tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses, to specific research and development programs.

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

- 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 marketing approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving marketing approval for any of our drug candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some drug candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

Sales and Marketing Expenses

Sales and marketing expenses include salaries and related costs for our field sales force, as well as personnel in our marketing and sales operations functions, including stock-based compensation, travel expenses and recruiting expenses. Sales and marketing expenses also include costs of content development, advertising, sponsorships and attendance at dermatology conferences as well as costs related to developing our direct-to-consumer advertising campaign, which we launched in October 2018.

Additionally, we anticipate significant increases in our sales and marketing expenses as a result of the commercial launch of ESKATA in May 2018 and if we begin selling RHOFADÉ following the expected closing of that acquisition.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance, investor relations and legal functions, including stock-based compensation, travel expenses and recruiting expenses. General and administrative expenses also include facility-related costs, patent filing and prosecution costs, professional fees for legal, auditing and tax services, insurance costs, as well as payments made under our related party services agreement and milestone payments under our finder's services agreement with KPT Consulting, LLC, or KPT, or Finder's Services Agreement. We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company.

Table of Contents

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, contingent consideration 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. Except as described below, 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, 2017 included in our 2017 Annual Report on Form 10-K filed with the SEC on March 12, 2018.

Revenue

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

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

Inventory

Inventory includes the third-party cost of manufacturing and assembly of the finished product form of ESKATA, quality control and other overhead costs. Inventory is stated at the lower of cost or net realizable value. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. Our inventory is comprised solely of finished goods.

Contingent Consideration

We initially recorded the contingent consideration related to future potential payments based upon the achievement of certain development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. For example, if the timing of the development of an acquired drug candidate, or the size of potential commercial opportunities related to an acquired drug, differ from our

Table of Contents

assumptions, then the fair value of contingent consideration would be adjusted accordingly. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in our consolidated statement of operations.

Recently Issued Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification, or ASC, 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. We are evaluating the impact of ASU 2018-15 on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing disclosure requirements. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. We are evaluating the impact of ASU 2018-13 on our consolidated financial statements.

In June 2018, the FASB, issued ASU 2018-07, Compensation-Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with non-employees except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 is effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year, and early adoption is permitted. We are evaluating the impact of ASU 2018-07 on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. We adopted this standard as of January 1, 2018, the impact of which on our consolidated financial statements was not significant.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Under this ASU, entities should recognize revenue in an amount that reflects the consideration to which they expect to be entitled to in exchange for goods and services provided. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017. We adopted the provisions of this standard on January 1, 2018, using the modified retrospective transition method. We did not recognize any transition adjustments as a result of adopting ASU 2014-09 and, accordingly, comparative information has not been restated for the periods reported.

Table of Contents

Results of Operations

Comparison of Three Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
Revenues:			
ESKATA product sales, net	\$ 510	\$ —	\$ 510
Contract research	1,118	684	434
Total revenue, net	1,628	684	944
Cost of revenue	1,193	453	740
Gross profit	435	231	204
Operating expenses:			
Research and development	15,931	10,864	5,067
Sales and marketing	11,380	3,557	7,823
General and administrative	6,574	4,566	2,008
Total operating expenses	33,885	18,987	14,898
Loss from operations	(33,450)	(18,756)	(14,694)
Other income, net	710	564	146
Net loss	\$ (32,740)	\$ (18,192)	\$ (14,548)

Revenue

Revenue was \$1.6 million for the three months ended September 30, 2018, compared to \$0.7 million for the three months ended September 30, 2017. ESKATA product sales, net included \$0.5 million of gross revenue from sales of product to McKesson, our only customer, during the three months ended September 30, 2018, offset by \$39,000 of deductions for distribution and administrative fees. Contract research revenue of \$1.1 million and \$0.7 million for the three months ended September 30, 2018 and 2017, respectively, was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017.

Cost of Revenue

Cost of revenue was \$1.2 million for the three months ended September 30, 2018, and was comprised of \$0.2 million of costs related to ESKATA product sales, net and \$1.0 million of costs incurred to provide laboratory services to our clients through Confluence. Cost of revenue was \$0.5 million for the three months ended September 30, 2017, and

was comprised entirely of costs incurred to provide laboratory services to our clients through Confluence, which we acquired in August 2017.

Table of Contents

Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
ESKATA	\$ 742	\$ 2,307	\$ (1,565)
A-101 45% Topical Solution	2,697	1,444	1,253
JAK inhibitors	6,092	2,753	3,339
Personnel expenses	1,834	1,582	252
Other research and development expenses	3,133	1,446	1,687
Stock-based compensation	1,433	1,332	101
Total research and development expenses	\$ 15,931	\$ 10,864	\$ 5,067

The decrease in expenses associated with the development of ESKATA resulted primarily from the filing of our NDA in February 2017 following the completion of clinical trials. Expenses related to A-101 45% Topical Solution increased primarily due to the initiation of our Phase 3 clinical trials for the treatment of common warts during the third quarter of 2018. Development expenses for our JAK inhibitors increased due to continued growth in both preclinical and clinical trial expenses as we continue to conduct multiple Phase 2 clinical trials of ATI-501 and ATI-502. The increase in personnel expenses was primarily the result of increased headcount. The increase in stock-based compensation expense was primarily the result of new awards granted after September 30, 2017. Other research and development expenses primarily included expenses for medical affairs activities related to ESKATA and drug discovery. The increase in other research and development expenses was primarily driven by preclinical development of ATI-450, our MK-2 inhibitor.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Three Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
Direct marketing and professional fees	\$ 4,434	\$ 1,993	\$ 2,441

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

Personnel expenses	3,447	682	2,765
Other sales and marketing expenses	2,739	402	2,337
Stock-based compensation	760	480	280
Total sales and marketing expenses	\$ 11,380	\$ 3,557	\$ 7,823

Direct marketing and professional fees, as well as other sales and marketing expenses, increased as a result of the commercial launch of ESKATA, which occurred in May 2018. Personnel and stock-based compensation expenses have increased due to increased headcount, including the hiring of our field sales force of 50 sales representatives in 2018. Other sales and marketing expenses included sales operations, travel costs, depreciation and other miscellaneous expenses. The increase in other sales and marketing expenses was primarily the result of costs related to our national launch meeting, employee training and samples fulfillment resulting from the commercial launch of ESKATA in May 2018.

Table of Contents

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
Personnel expenses	\$ 1,570	\$ 1,133	\$ 437
Professional and legal fees	1,600	1,083	517
Facility and support services	565	344	221
Other general and administrative expenses	519	275	244
Stock-based compensation	2,320	1,731	589
Total general and administrative expenses	\$ 6,574	\$ 4,566	\$ 2,008

Personnel and stock-based compensation expenses have increased due to increased headcount. Professional and legal fees included accounting, legal and investor relations costs associated with being a public company, as well as legal fees related to patents. The increase in professional and legal fees was related to legal and consulting expenses incurred as a result of the commercial launch of ESKATA in May 2018, as well as business development activities. Facility and support services included general office expenses and information technology costs, which have risen due to our increased headcount.

Other Income, Net

The \$0.1 million increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our financing transactions in 2017, as well as higher yields on those invested balances.

Comparison of Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended September 30,		
	2018	2017	Change
	(In thousands)		

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

Revenues:

ESKATA product sales, net	\$ 2,043	\$ —	\$ 2,043
Contract research	3,379	684	2,695
Other revenue	1,000	—	1,000
Total revenue, net	6,422	684	5,738
Cost of revenue	3,341	453	2,888
Gross profit	3,081	231	2,850
Operating expenses:			
Research and development	43,472	26,601	16,871
Sales and marketing	35,030	7,183	27,847
General and administrative	20,955	13,428	7,527
Total operating expenses	99,457	47,212	52,245
Loss from operations	(96,376)	(46,981)	(49,395)
Other income, net	2,189	1,392	797
Net loss	\$ (94,187)	\$ (45,589)	\$ (48,598)

Table of Contents

Revenue

Revenue was \$6.4 million for the nine months ended September 30, 2018, compared to \$0.7 million for the nine months ended September 30, 2017. ESKATA product sales, net included \$2.2 million of gross revenue from sales of product to McKesson, our only customer, during the nine months ended September 30, 2018, offset by \$0.2 million of deductions for distribution and administrative fees. Contract research revenue of \$3.4 million and \$0.7 million for the nine months ended September 30, 2018 and 2017, respectively, was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. Other revenue consisted of an up-front payment of \$1.0 million we received upon signing of the license agreement with Cipher in April 2018.

Cost of Revenue

Cost of revenue was \$3.3 million for the nine months ended September 30, 2018, and was comprised of \$0.3 million of costs related to ESKATA product sales, net and \$3.0 million of costs incurred to provide laboratory services to our clients through Confluence. Cost of revenue was \$0.5 million for the nine months ended September 30, 2017, and was comprised entirely of costs incurred to provide laboratory services to our clients through Confluence, which we acquired in August 2017.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Nine Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
ESKATA	\$ 1,990	\$ 4,716	\$ (2,726)
A-101 45% Topical Solution	4,223	2,314	1,909
JAK inhibitors	17,806	7,639	10,167
Personnel expenses	6,179	4,396	1,783
Change in contingent consideration	866	—	866
Other research and development expenses	7,492	3,683	3,809
Stock-based compensation	4,916	3,853	1,063
Total research and development expenses	\$ 43,472	\$ 26,601	\$ 16,871

The decrease in costs associated with the development of ESKATA resulted primarily from the filing of our NDA in February 2017 following the completion of clinical trials. Expenses related to A-101 45% Topical Solution increased primarily due to the initiation of our Phase 3 clinical trials for the treatment of common warts during the third quarter of 2018. Development expenses for our JAK inhibitors increased due to continued growth in both preclinical and clinical trial expenses as we continue to conduct multiple Phase 2 clinical trials of ATI-501 and ATI-502. The increase in personnel expenses was primarily the result of increased headcount. The increase in stock-based compensation expense was primarily the result of new awards granted after September 30, 2017. The change in contingent consideration was the result of updates to our assumptions related to drug discovery research on our soft-JAK inhibitors, which progressed more quickly than originally planned. Other research and development expenses primarily included expenses for medical affairs activities related to ESKATA, and expenses related to drug discovery performed by Confluence, which we acquired in August 2017; we did not incur similar drug discovery expenses prior to such acquisition. The increase in other research and development expenses was also driven by preclinical development of ATI-450, our MK-2 inhibitor.

Table of Contents

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Nine Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
Direct marketing and professional fees	\$ 13,494	\$ 3,806	\$ 9,688
Personnel expenses	11,105	1,507	9,598
Other sales and marketing expenses	7,744	610	7,134
Stock-based compensation	2,687	1,260	1,427
Total sales and marketing expenses	\$ 35,030	\$ 7,183	\$ 27,847

Direct marketing and professional fees, as well as other sales and marketing expenses, increased as a result of the commercial launch of ESKATA, which occurred in May 2018. Personnel and stock-based compensation expenses have increased due to increased headcount, including the hiring of our field sales force of 50 sales representatives during the nine months ended September 30, 2018. Other sales and marketing expenses included sales operations, travel costs, depreciation and other miscellaneous expenses. The increase in other sales and marketing expenses was primarily the result of costs related to our national launch meeting, employee training and samples fulfillment resulting from the commercial launch of ESKATA in May 2018.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Nine Months Ended September 30,		
	2018	2017	Change
	(In thousands)		
Personnel expenses	\$ 5,124	\$ 2,984	\$ 2,140
Professional and legal fees	4,285	2,893	1,392
Facility and support services	1,774	949	825
Milestone payment	1,500	1,000	500
Other general and administrative expenses	1,336	715	621
Stock-based compensation	6,936	4,887	2,049
Total general and administrative expenses	\$ 20,955	\$ 13,428	\$ 7,527

Personnel and stock-based compensation expenses have increased due to increased headcount. Professional and legal fees included accounting, legal and investor relations costs associated with being a public company, as well as legal fees related to patents. The increase in professional and legal fees was related to legal and consulting expenses incurred as a result of the commercial launch of ESKATA in May 2018, as well as business development activities. The milestone payment of \$1.5 million in the nine months ended September 30, 2018 was made upon the achievement of specified commercial milestones under the terms of the Finder's Services Agreement with KPT. The milestone payment of \$1.0 million in the nine months ended September 30, 2017 was made upon the achievement of specified regulatory milestones pursuant to the Finder's Services Agreement with KPT. Facility and support services included general office expenses and information technology costs which have risen due to our increased headcount.

Other Income, Net

The \$0.8 million increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our financing transactions in 2017, as well as higher yields on those invested balances.

Table of Contents

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Prior to our acquisition of Confluence in August 2017, we did not generate any revenue. We have financed our operations since inception primarily through sales of our equity securities in public offerings and a private placement transaction. As described below, in October 2018 we entered into a loan facility with an institutional lender.

As of September 30, 2018, we had cash, cash equivalents and marketable securities of \$134.3 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards liquidity and capital preservation.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our recent debt financing obligation, sublease obligations, capital lease obligations and contingent obligations under acquisition and intellectual property licensing agreements, which are summarized below under “Contractual Obligations and Commitments.”

At-The-Market Facility

In November 2016, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which Cowen acted as our agent in connection with sales of our common stock from time to time under an “at-the-market” equity facility. In April 2017, we sold 635,000 shares of our common stock at a weighted average price per share of \$31.50, for aggregate gross proceeds of approximately \$20.0 million. We paid underwriting discounts and commissions of \$0.6 million, and we also incurred expenses of \$0.1 million in connection with this sale. In October 2018, we terminated the at-the-market sales agreement with Cowen without having sold any additional shares of common stock.

August 2017 Public Offering

In August 2017, we closed a follow-on public offering in which we sold 3,747,602 shares of common stock at a price to the public of \$23.02 per share, for aggregate gross proceeds of \$86.3 million. We paid underwriting discounts and commissions of \$5.2 million, and we also incurred expenses of \$0.2 million in connection with the offering. As a result, the net offering proceeds received by us were \$80.9 million.

October 2018 Public Offering

In October 2018, we closed a follow-on public offering in which we sold 9,941,750 shares of common stock at a price to the public of \$10.75 per share, for aggregate gross proceeds of \$106.9 million. We paid underwriting discounts and commissions of \$6.4 million to the underwriters in connection with the offering.

Loan and Security Agreement with Oxford

On October 15, 2018, we entered into the Loan and Security Agreement with Oxford. The Loan and Security Agreement provides for up to \$65.0 million in term loans. Of the \$65.0 million, we borrowed \$30.0 million on October 31, 2018. The remaining \$35.0 million will become available for draw beginning on the closing date of the RHOFAD acquisition and ending on the earlier of March 31, 2019 or an event of default. Should we not draw all or a portion of the \$35.0 million during the applicable draw timeframe, or if we prepay the entirety of the amount drawn during the applicable draw timeframe, we will be required to pay Oxford a non-utilization fee equal to 1.0% of the undrawn portion.

The Loan and Security Agreement provides for interest only payments through the payment date immediately prior to November 1, 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 1, 2021 and continuing through the maturity date of October 1, 2023. All unpaid principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual

Table of Contents

interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue plus 6.25%. The Loan and Security Agreement also provides for a final payment equal to 5.75% of the original principal amount of the term loans drawn, which final payment is due on October 1, 2023 or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

We have the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of (i) 3% of the original principal amount of the aggregate term loans drawn for any prepayment prior to the first anniversary of the applicable funding date, (ii) 2% of the original principal amount of the aggregate term loans drawn for any prepayment between the first and second anniversaries of the applicable funding date or (iii) 1% of the original principal amount of the aggregate term loans drawn for any prepayment after the second anniversary of the applicable funding date but before October 1, 2023. We also have the option to prepay the term loans in part, once in a three-month period, of an amount of \$2.0 million or greater, subject to the same prepayment fees and other specified limitations.

Our obligations under the Loan and Security Agreement are secured by substantially all of our assets, except that the collateral does not include our intellectual property. However, we have agreed not to encumber any of our intellectual property. The Loan and Security Agreement contains customary representations, warranties and covenants, including covenants that limit our ability, subject to specified exceptions, to convey, sell, lease, transfer, assign or otherwise dispose of assets; engage in any business other than the businesses currently engaged in; liquidate or dissolve; undergo specified change of control events; create, incur, assume or be liable for indebtedness; create, incur, allow or suffer any liens on property; pay dividends and make other restricted payments; make investments; or enter into any material transactions with affiliates. The Loan and Security Agreement also contains specified financial covenants related to minimum consolidated future revenues.

The Loan and Security Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill our obligations under the Loan and Security Agreement, the occurrence of a material adverse change, specified defaults or our failure to keep our common stock listed on the Nasdaq Stock Market. In the event of default, Oxford would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan and Security Agreement.

Cash Flows

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

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

	Nine Months Ended September 30,	
	2018	2017
	(In thousands)	
Net cash used in operating activities	\$ (73,563)	\$ (36,453)
Net cash provided by (used in) investing activities	79,873	(34,127)
Net cash provided by financing activities	78	100,464
Net increase in cash and cash equivalents	\$ 6,388	\$ 29,884

Operating Activities

During the nine months ended September 30, 2018, operating activities used \$73.6 million of cash primarily resulting from our net loss of \$94.2 million, partially offset by changes in our operating assets and liabilities of \$3.7 million, and non-cash adjustments of \$16.9 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2018 consisted of an \$8.8 million increase in accounts payable and accrued expenses, which was partially offset by a \$3.5 million increase in prepaid expenses and other current assets, a \$0.6 million

Table of Contents

increase in accounts receivable and a \$1.0 million increase in inventory. The increase in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of September 30, 2018, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of September 30, 2018 primarily included sales and marketing expenses related to the commercial launch of ESKATA in May 2018, as well as expenses related to our Phase 3 clinical trials for A-101 45% Topical Solution, and our Phase 2 clinical trials for ATI-501 and ATI-502. The increase in prepaid expenses and other current assets was primarily due to sales and marketing expenses related to our direct-to-consumer advertising campaign for ESKATA which began in October 2018, partially offset by a \$2.0 million Prescription Drug User Fee Act, or PDUFA, fee paid to the FDA in conjunction with the filing of the NDA for ESKATA, for which we received a refund during the nine months ended September 30, 2018. The increases in accounts receivable and inventory were the result of the commercial launch of ESKATA. Non-cash expenses of \$16.9 million were primarily composed of stock-based compensation expense.

During the nine months ended September 30, 2017, operating activities used \$36.5 million of cash, primarily resulting from our net loss of \$45.6 million and changes in our operating assets and liabilities of \$1.2 million, partially offset by non-cash adjustments of \$10.4 million. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2017 consisted of a \$4.3 million increase in prepaid expenses and other current assets partially offset by a \$3.1 million increase in accounts payable and accrued expenses. The increase in prepaid expenses and other current assets was primarily due to a \$2.0 million PDUFA fee paid to the FDA in conjunction with the filing of the NDA for ESKATA, as well as deposits made for clinical supplies and development activities which were incurred during the fourth quarter of 2017. The increase in accounts payable and accrued expenses was primarily due to expenses incurred, but not yet paid, in connection with our Phase 2 clinical trials for A-101 45% Topical Solution, ATI-501 and ATI-502, as well as the timing of vendor invoicing and payments. Non-cash expenses of \$10.4 million were primarily composed of stock-based compensation expense.

Investing Activities

During the nine months ended September 30, 2018, investing activities provided \$79.9 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$193.4 million, partially offset by purchases of marketable securities of \$112.3 million, and purchases of equipment of \$1.2 million.

During the nine months ended September 30, 2017, investing activities used \$34.1 million of cash, consisting of purchases of marketable securities of \$120.5 million, \$9.6 million for the acquisition of Confluence and purchases of equipment of \$0.7 million, partially offset by proceeds from sales and maturities of marketable securities of \$96.7 million.

Financing Activities

During the nine months ended September 30, 2018, financing activities provided \$0.1 million of cash and included \$0.6 million from the exercise of employee stock options, partially offset by \$0.5 million of capital lease payments.

During the nine months ended September 30, 2017, financing activities provided \$100.5 million of cash and included \$19.3 million of net proceeds from the sale of common stock in April 2017 under our at-the-market equity facility with Cowen, and \$80.9 million of net proceeds from our August 2017 public offering, as well as \$0.2 million of cash received from the exercise of employee stock options.

Funding Requirements

We plan to focus in the near term on the commercialization of ESKATA for the treatment of raised SKs, and RHOFADÉ for the treatment of persistent facial erythema associated with rosacea in adults, if we close our acquisition of that product, as well as the clinical development of our drug candidates. We anticipate we will incur net losses for the next several years as we continue to commercialize ESKATA and RHOFADÉ, continue the clinical development of A-

Table of Contents

101 45% Topical Solution for the treatment of common warts and continue research and development of ATI-501 and ATI-502 for the treatment of AA, and potentially for other dermatological conditions, as well as the identification, research and development of other compounds. We plan to continue to invest in discovery efforts to explore additional drug candidates, 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 candidates currently in 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, sales, marketing and direct-to-consumer advertising costs, legal and other regulatory expenses, and administrative and overhead costs. In addition, pursuant to the APA, and upon the terms and subject to the conditions thereof, we are required to pay Allergan total cash consideration of \$65.0 million, including \$58.5 million to be paid at the closing and \$6.5 million to be placed in escrow, plus the book value of Allergan's inventory of RHOFADÉ commercial product and samples, which we estimate to be approximately \$1 million. Our future funding requirements will be heavily determined by the resources needed to support the commercialization of ESKATA and, if we complete the acquisition, the commercialization of RHOFADÉ, and the development 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 LLC, 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 our existing cash, cash equivalents and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of our unaudited condensed consolidated financial statements that appear in Item 1 of this Quarterly Report on Form 10-Q based on our current operating assumptions including the commercialization of ESKATA, the closing of our acquisition of RHOFADÉ, the commercialization of RHOFADÉ, conducting Phase 3 clinical trials for A-101 45% Topical Solution for the treatment of common warts, the continued development of ATI-501 and ATI-502 as potential treatments for AA and other indications, and the development of ATI-450 as a potential treatment for psoriasis and other dermatologic conditions. 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 45% Topical Solution for the treatment of common warts, if approved, to complete the clinical development of ATI-501 and ATI-502, to develop our preclinical compounds, to support our discovery efforts, and to pursue in-licenses or acquisitions of other drug candidates. We also expect to incur significant expenses related to the commercialization of ESKATA and, if we close the acquisition, RHOFADÉ, including product manufacturing, sales, marketing, direct-to-consumer advertising and distribution costs. 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 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;

Table of Contents

- the scope, progress, results and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our drug candidates;
- the cost of manufacturing commercial quantities of ESKATA, RHOFADÉ and any drug candidates 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 occupy space for our headquarters in Wayne, Pennsylvania under a sublease agreement that has a term through October 2023. We lease office space in Malvern, Pennsylvania under an operating lease agreement that has a term through November 2019. We occupy office and laboratory space in St. Louis, Missouri under an operating lease agreement which has a term through December 2018.

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

We lease a fleet of automobiles for our sales force and other field-based employees under the terms of a master lease agreement. The lease term for each automobile begins on the date we take delivery and continues for a period of four years.

Under various agreements, we will be required to make milestone payments and pay royalties and other amounts to third parties.

Under the assignment agreement with the Estate of Mickey Miller pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of ESKATA 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 remaining payment of \$3.0 million upon the achievement of a specified commercial milestone. In addition, we have agreed to pay royalties on sales of ESKATA 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 stock purchase agreement with the selling stockholders of Vixen, we are obligated to make aggregate payments of up to \$18.0 million upon the achievement of specified pre-commercialization milestones for three products covered by the 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 products covered by the Vixen patent rights.

Table of Contents

We are also obligated to make a payment of \$0.1 million on March 24th of each year, through March 24, 2022, which amounts are creditable against any specified future payments that may be paid under the stock purchase agreement. With respect to any covered products that we commercialize, we are obligated to pay a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. If we sublicense any of the patent rights and know-how acquired pursuant to the stock purchase agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

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

Under a merger agreement with Confluence we are obligated to make aggregate payments of up to \$80.0 million upon the achievement of specified development, regulatory and commercialization milestones. With respect to any covered products we commercialize, we are obligated to pay a low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. If we sublicense any of the patent rights and know-how acquired pursuant to the merger agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

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.

In October 2018, we borrowed \$30.0 million under the Loan and Security Agreement with Oxford. We will be able to borrow up to an additional \$35.0 million beginning on the closing date of the acquisition of RHOFAD and ending on the earlier of March 31, 2019 or an event of default. Any amounts borrowed under the Loan and Security Agreement will be subject to interest only through October 2021, after which we will be required to make principal and interest payments through the maturity date of October 2023.

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, 2018, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and our Chief

Financial Officer have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level.

(b) Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting during our fiscal quarter ended September 30, 2018 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 new risk factors set forth immediately 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, 2017, filed with the SEC on March 12, 2018.

Risks Related to Our Acquisition of RHOFADÉ and Loan and Security Agreement with Oxford

We may not close the acquisition or realize the anticipated benefits from our acquisition of RHOFADÉ.

We may not close the acquisition of RHOFADÉ. The completion of the acquisition is subject to the satisfaction or waiver of a number of closing conditions in the APA, including the receipt of regulatory approval, the absence of certain governmental restraints and the absence of a material adverse effect on us or the RHOFADÉ business. Even if we do close the acquisition, the success of our acquisition of RHOFADÉ will depend, in large part, on our ability to realize operating synergies from combining RHOFADÉ with our portfolio of drug candidates and ESKATA.

The failure to successfully integrate and manage the challenges presented by the integration process may result in our failure to achieve some or all of the anticipated benefits of the acquisition. Potential difficulties that may be encountered include the following:

- complexities associated with managing an additional commercial-stage drug;

- training our sales force to market both ESKATA and RHOFADÉ;
- current and prospective employees may experience uncertainty regarding their future roles with our company, which might adversely affect our ability to retain, recruit and motivate key personnel;
- our due diligence processes in connection with the acquisition may fail to identify significant problems, risks, liabilities or other shortcomings or challenges associated with the RHOFADÉ assets, including problems, risks, liabilities or other shortcomings or challenges with respect to intellectual property, product quality and safety and other known and unknown liabilities; and
- performance shortfalls as a result of the diversion of management's attention caused by completing the acquisition and integrating RHOFADÉ.

If any of these events were to occur, our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition could be adversely affected, or could reduce our future earnings or otherwise adversely affect our business and financial results and, as a result, adversely affect the market price of our common stock.

Table of Contents

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

We have entered into a Loan and Security Agreement with Oxford, pursuant to which we borrowed \$30.0 million on October 31, 2018, and can draw an additional \$35.0 million beginning on the closing date of our acquisition of RHOFAD until March 31, 2019. Our obligations under the Loan and Security Agreement are secured by substantially all of our assets except for our intellectual property, and we may not encumber our intellectual property without Oxford's prior written consent. The Loan and Security Agreement contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and other specified business transactions. The Loan and Security Agreement also contains specified financial covenants related to us achieving specified minimum consolidated revenues in future periods. Our obligations under the Loan and Security Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the covenants and conditions of the Loan and Security Agreement, including our failure to achieve the minimum revenue covenants, could result in an event of default, which could result in an acceleration of amounts due under the Loan and Security Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and Oxford could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business.

Risks Related to our Business and Intellectual Property

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical, biotechnology and

specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions.

With respect to ESKATA for the treatment of raised SKs, we are aware of two biopharmaceutical companies developing drug candidates which target SK, and another company that currently markets a line of cosmetic products targeting skin conditions, including SK. We are also aware of early research being conducted with Akt inhibitors as a potential treatment for SK.

With respect to RHOFADE for the treatment of persistent facial redness due to rosacea, we are aware of one other drug that shares this indication. MIRVASO (brimonidine) topical gel, 0.33%, which was approved in 2013, is currently marketed by Galderma Laboratories, L.P.

Table of Contents

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of four companies developing drug candidates for the treatment of common warts. In addition, other drugs have been used off-label as treatments for common warts. We could also encounter competition from over-the-counter treatments for common warts.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ESKATA or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for our drug, which could result in our competitors establishing a strong market position before we are able to enter the market.

With respect to ATI-501 and ATI-502 for the treatment of AA, we anticipate competing with sensitizing agents such as diphencyprone, and topical, intralesional and systemic corticosteroids, which have been found to occasionally reduce symptoms of AA. Other treatments utilized for patchy AA include anthralin and minoxidil solution. We may also compete with companies developing chemical agents to be used in topical immunotherapies, as well as companies developing biologics, immunosuppressive agents, laser therapy, phototherapy, other JAK inhibitors and prostaglandin analogues to treat AA.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical development, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

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 U.S. 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

Table of Contents

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 U.S. patent law. These include provisions that affect the way patent applications are 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 patents and patent applications that we exclusively licensed 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 competitors 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 high-concentration hydrogen peroxide of at least 23%, including ESKATA and A-101 45% Topical Solution, are scheduled to expire in 2022, and our issued U.S. formulation patent with claims directed to high-concentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution, and methods of use is scheduled to expire in 2035. The issued U.S. patents that we have agreed to exclusively license from Allergan relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which cover the approved use of RHOFADÉ, expire between January 2024 and May 2028. The issued U.S. patent that covers cream formulations of oxymetazoline, including RHOFADÉ, expires in December 2031. The issued U.S. patents relating to methods of treating facial erythema associated with rosacea by topically administering once or twice daily 1% or 1.5% oxymetazoline expire in June 2035. The patents and applications that we have agreed to exclusively sublicense from Allergan that may relate to RHOFADÉ expire between May 2024 and May 2025. Certain issued U.S. patents relating to our JAK inhibitors, ATI-501 and ATI-502, are scheduled

Table of Contents

to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S. and Japanese patents that we exclusively licensed from Columbia University with claims directed to the use of third party JAK inhibitors for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, expire in 2031. We currently do not have any patents issued directed to our "soft" JAK inhibitors, but any claims that may issue would expire in 2038. Our issued U.S. patent covering our lead inhibitors of the MK-2 signaling pathway inhibitor, expires in 2034 and other issued patents covering different MK-2 signaling pathway inhibitors expire in 2031 and 2032. Our issued patents covering our novel inhibitors of ITK expire between 2035 and 2038. 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. Further, our issued patents could be found invalid or unenforceable if challenged in court.

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. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar administrative proceedings outside the United States, in parallel with litigation or, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would harm our business.

In such a proceeding, a court or administrative board 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 that our patents do not cover the technology. An adverse result in any such 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 and warts. 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.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Table of Contents

We are aware that a third party generic pharmaceutical company completed a Phase 3 clinical trial in March 2018 evaluating the reduction in erythema in adults with moderate to severe facial erythema associated with rosacea with a 1% oxymetazoline topical cream in comparison to an oxymetazoline reference listed drug. While conducting such a clinical trial may not be an act of patent infringement in the United States, such a clinical trial could serve as the basis for the third party to file an Abbreviated New Drug Application, or ANDA, or 505(b)(2) application for a generic of RHOFADÉ that relies in whole or in part on studies conducted by Allergan, which could trigger a potential patent infringement lawsuit. If we were to bring a patent infringement lawsuit against such a third party for infringing any of the U.S. patents relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline that we have agreed to exclusively license from Allergan, we may be required to join Allergan as a party to such a lawsuit. In addition, if we were to bring a patent infringement lawsuit against a third party for infringing certain patents that we have agreed to sublicense from Allergan relating to the use of oxymetazoline for treating rosacea or purpura by topical application, we may also be required to join Allergan and another third party as parties to such a lawsuit.

With respect to ATI-501 and ATI-502, if we do not elect to exercise our first right to do so, Rigel may enforce the licensed patents relating to ATI-501 and ATI-502 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-501 and ATI-502 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.

The RHOFADÉ patents that we have agreed to exclusively license from Allergan are subject to a cross-license agreement with a third party, which will place obligations and limitations on our ability to prosecute, maintain and enforce such patents solely as they relate to an alpha adrenoreceptor agonist that is not oxymetazoline.

We have agreed to exclusively license from Allergan a family of U.S. patents and applications relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028. This patent family covers the approved use of RHOFADÉ. This patent family is also subject to an exclusive license granted by Allergan to a third party, which will place obligations and limitations on our ability to prosecute, maintain and enforce such patents solely as they relate to an alpha adrenoreceptor agonist that is not oxymetazoline.

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 ESKATA for the treatment of raised SKs is currently covered by patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. The use of A-101 45% Topical Solution for the treatment of warts is currently covered by issued patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. A U.S. patent is issued, and patent applications are pending in the United States, the European Union and other foreign countries directed to high-concentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution and methods of use. With respect to RHOFADÉ, the family of patents and applications relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028, is not filed outside of the United States. Accordingly, the patent protection for RHOFADÉ outside of the United States is based upon a family of patents and applications in the United States, the European Union and other major foreign markets that cover certain cream formulations of oxymetazoline, including RHOFADÉ, which expires in December 2031 and a family of patents and applications in the United States, the European Union and other major foreign markets relating to methods of treating facial erythema associated with rosacea by topically administering once or twice

Table of Contents

daily 1% or 1.5% oxymetazoline, which expires in June 2035. RHOFADÉ may also be covered by certain patents and applications in the United States, the European Union and other major foreign markets that expire between May 2024 and May 2025, which we have agreed to exclusively sublicense from Allergan.

Our JAK inhibitors, ATI-501 and ATI-502, are currently covered in patents and applications in the United States, the European Union, and other major foreign markets. Additionally, U.S. and Japanese patents have issued in the patent portfolio licensed from Columbia University, which are directed to the use of certain third party JAK inhibitors for the treatment of hair loss disorders and applications are pending in the United States, the European Union, 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.

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.

The validity, scope and enforceability of any of our patents that cover ESKATA, RHOFADÉ, A-101 45% Topical Solution or any of our other drug candidates can be challenged by competitors.

The likelihood that a third party will challenge our patents covering ESKATA or RHOFADÉ is increased now that these products have received marketing approval from the FDA. The challenge may come in the form of a patent office proceeding, such as an inter partes review, challenging the validity of the patents or a district court proceeding, such as a paragraph IV litigation arising out of the filing of an ANDA.

If a third party files an ANDA or 505(b)(2) application for a generic of ESKATA or RHOFADÉ, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor

Table of Contents

of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with ESKATA or RHOFADÉ. We are aware that a third party generic pharmaceutical company completed a Phase 3 clinical trial in March 2018 evaluating the reduction in erythema in adults with moderate to severe facial erythema associated with rosacea with a 1% oxymetazoline topical cream in comparison to an oxymetazoline reference listed drug. Such a clinical trial could serve as the basis for filing an ANDA or 505(b)(2) application for a generic of RHOFADÉ that relies in whole or in part on studies conducted by Allergan, triggering the potential for a paragraph IV certification and subsequent patent infringement lawsuit. Any such lawsuit could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement and the approval of a generic version of RHOFADÉ sooner than anticipated.

If A-101 45% Topical Solution, our JAK inhibitors, or any of our other drug candidates advance through development or is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio covering these drug candidates. Any such challenge could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement.

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

None.

Table of Contents

Item 6. Exhibits

Exhibit No.	Document
3.1	<u>Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).</u>
3.2	<u>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 SEC on October 13, 2015).</u>
31.1*	<u>Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.</u>
31.2*	<u>Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.</u>
32.1**	<u>Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.</u>
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.

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 6, 2018 By: /s/ Neal Walker
Neal Walker
President and Chief Executive Officer
(On behalf of the Registrant)

Date: November 6, 2018 By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(Principal Financial Officer)