

Aclaris Therapeutics, Inc.
Form 10-Q
May 08, 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 March 31, 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 Incorporation or Organization)	(I.R.S. Employer 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a 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

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

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on May 7, 2018 was 30,906,003.

Table of Contents

ACLARIS THERAPEUTICS, INC.

INDEX TO FORM 10-Q

	PAGE
<u>PART I.</u>	
<u>FINANCIAL</u>	
<u>INFORMATION</u>	
<u>Item 1. Financial</u>	2
<u>Statements</u>	
<u>Unaudited</u>	2
<u>Condensed</u>	
<u>Consolidated</u>	
<u>Balance Sheets as</u>	
<u>of March 31, 2018</u>	
<u>and December 31,</u>	
<u>2017</u>	
<u>Unaudited</u>	3
<u>Condensed</u>	
<u>Consolidated</u>	
<u>Statements of</u>	
<u>Operations and</u>	
<u>Comprehensive</u>	
<u>Loss for the three</u>	
<u>months ended</u>	
<u>March 31, 2018</u>	
<u>and 2017</u>	
<u>Unaudited</u>	4
<u>Condensed</u>	
<u>Consolidated</u>	
<u>Statement of</u>	
<u>Stockholders'</u>	
<u>Equity for the</u>	
<u>three months</u>	
<u>ended March 31,</u>	
<u>2018</u>	
<u>Unaudited</u>	5
<u>Condensed</u>	

Consolidated
Statements of
Cash Flows for the
three months
ended March 31,
2018 and 2017

Notes to 6
Unaudited
Condensed
Consolidated
Financial
Statements

Item 2. 20
Management's
Discussion and
Analysis of
Financial
Condition and
Results of
Operations

Item 3. 34
Quantitative and
Qualitative
Disclosures about
Market Risk

Item 4. Controls 34
and Procedures

PART II. OTHER
INFORMATION

Item 1. Legal 35
Proceedings

Item 1A. Risk 35
Factors

Item 2. 36
Unregistered Sales
of Equity
Securities and Use
of Proceeds

Item 6. Exhibits 37

Signatures 38

Table of Contents

Part I. FINANCIAL INFORMATION

Item 1. Financial Statements

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share data)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 54,881	\$ 20,202
Marketable securities	132,096	173,655
Accounts receivable, net	529	481
Prepaid expenses and other current assets	4,750	5,883
Total current assets	192,256	200,221
Marketable securities	—	14,997
Property and equipment, net	2,191	2,159
Intangible assets	7,330	7,349
Goodwill	18,504	18,504
Other assets	341	279
Total assets	\$ 220,622	\$ 243,509
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 8,155	\$ 7,822
Accrued expenses	5,668	4,940
Total current liabilities	13,823	12,762
Contingent consideration	5,244	4,378
Other liabilities	534	558
Deferred tax liability	549	549
Total liabilities	20,150	18,247
Stockholders' Equity:		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at March 31, 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 March 31, 2018 and December 31, 2017; 30,905,629 and 30,856,505 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively		
Additional paid in capital	390,464	384,943
Accumulated other comprehensive loss	(328)	(246)
Accumulated deficit	(189,664)	(159,435)
Total stockholders' equity	200,472	225,262
Total liabilities and stockholders' equity	\$ 220,622	\$ 243,509

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

2

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2018	2017
Revenue	\$ 1,118	\$ —
Cost of revenue	967	—
Gross profit	151	—
Operating expenses:		
Research and development	13,606	7,772
Sales and marketing	11,233	1,438
General and administrative	6,260	3,720
Total operating expenses	31,099	12,930
Loss from operations	(30,948)	(12,930)
Other income, net	719	371
Net loss	\$ (30,229)	\$ (12,559)
Net loss per share, basic and diluted	\$ (0.98)	\$ (0.48)
Weighted average common shares outstanding, basic and diluted	30,885,928	26,080,806
Other comprehensive loss:		
Unrealized loss on marketable securities, net of tax of \$0	\$ (65)	\$ (52)
Foreign currency translation adjustments	(17)	72
Total other comprehensive (loss) income	(82)	20
Comprehensive loss	\$ (30,311)	\$ (12,539)

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	Total
	Shares	Value	Paid in	Comprehensive	Accumulated	Stockholders'
			Capital	Loss	Deficit	Equity
Balance at December 31, 2017	30,856,505	\$ —	\$ 384,943	\$ (246)	\$ (159,435)	\$ 225,262
Exercise of stock options and vesting of RSUs	49,124	—	378	—	—	378
Unrealized loss on marketable securities	—	—	—	(65)	—	(65)
Foreign currency translation adjustment	—	—	—	(17)	—	(17)
Stock-based compensation expense	—	—	5,143	—	—	5,143
Net loss	—	—	—	—	(30,229)	(30,229)
Balance at March 31, 2018	30,905,629	\$ —	\$ 390,464	\$ (328)	\$ (189,664)	\$ 200,472

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

Table of Contents

ACLARIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (30,229)	\$ (12,559)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	222	50
Stock-based compensation expense	5,143	3,153
Change in fair value of contingent consideration	866	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,022	(2,597)
Accounts payable	316	831
Accrued expenses	788	(1,537)
Net cash used in operating activities	(21,872)	(12,659)
Cash flows from investing activities:		
Purchases of property and equipment	(298)	(195)
Purchases of marketable securities	(35,614)	(17,158)
Proceeds from sales and maturities of marketable securities	92,105	23,309
Net cash provided by investing activities	56,193	5,956
Cash flows from financing activities:		
Capital lease payments	(36)	—
Proceeds from the exercise of employee stock options	394	209
Net cash provided by financing activities	358	209
Net increase (decrease) in cash and cash equivalents	34,679	(6,494)
Cash and cash equivalents at beginning of period	20,202	30,171
Cash and cash equivalents at end of period	\$ 54,881	\$ 23,677
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	\$ 210	\$ 91
Offering costs included in accounts payable	\$ 20	\$ —

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. (see Note 12). 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 and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. 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 commercial product sales of ESKATA in May 2018.

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 March 31, 2018, the Company had cash, cash equivalents and marketable securities of \$186,977 and an accumulated deficit of \$189,664. 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, and commercialization of the Company’s products will require significant additional financing. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company’s failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, research and development

Table of Contents

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 March 31, 2018, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2018 and 2017, the condensed consolidated statement of stockholders' equity for the three months ended March 31, 2018, and the condensed consolidated statements of cash flows for the three months ended March 31, 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 March 31, 2018, the results of its operations and comprehensive loss for the three months ended March 31, 2018 and 2017 and its cash flows for the three months ended March 31, 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 months ended March 31, 2018 and 2017 are unaudited. The results for the three months ended March 31, 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 \$2.0 million 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 Topic 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services.

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

Table of Contents

entitled to under a contract with a customer is probable.

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 also receives revenue from grants under the Small Business Innovation Research program of the National Institutes of Health (“NIH”). The Company, through its Confluence subsidiary, currently has two active grants from NIH which are related to early-stage research. The Company recognizes revenue related to these grants as amounts become reimbursable under each grant, which is generally when research is performed and the related costs are incurred.

Intangible Assets

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

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

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which the Company performs during the fourth quarter, or when indicators of an impairment are present. The Company considers each of its operating segments, dermatology therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. The Company has attributed the full amount of the goodwill acquired with Confluence, or \$18,504, to the dermatology therapeutics segment. The annual impairment test performed by the Company is a qualitative assessment based upon current facts and circumstances related to operations of the dermatology therapeutics segment. If the qualitative assessment indicates an impairment may be present, the Company would perform the required quantitative analysis and an impairment charge would be recognized to the extent that the estimated fair value of the reporting unit is less than its carrying amount. However, any loss recognized would not exceed the total amount of goodwill allocated to that reporting unit.

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

Table of Contents

the payment of the contingent consideration and the passage of time. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in the Company's consolidated statement of operations.

Segment Data

The Company operates in two segments, dermatology therapeutics and contract research, for the purposes of assessing performance and making operating decisions. The Company's dermatology therapeutics segment, which did not generate any revenue through March 31, 2018, is focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. The Company's contract research segment is focused on providing laboratory services under contract research arrangements to pharmaceutical and biotech companies looking to supplement their research and development efforts with difficult-to-execute specialty skills and programs.

Recently Issued Accounting Pronouncements

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

Table of Contents

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 expects to finalize its allocation of the purchase price upon the finalization of valuations for the identified intangible assets, final resolution of the post-closing working capital adjustment and certain tax accounts that are based on the best estimates of management. The completion and filing of federal and state tax returns for the acquired entity may result in adjustments to the carrying value of assets and liabilities.

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	
	March 31,	
	2018	2017
Revenue	\$ 1,118	\$ 1,236
Gross profit	151	563
Total operating expenses	31,099	13,607
Net loss	(30,229)	(12,673)

The supplemental unaudited pro forma financial results for the three months ended March 31, 2017 include adjustments to exclude \$301 of revenue billed to the Company by Confluence. The supplemental unaudited pro forma financial results for the three months ended March 31, 2017 also includes an adjustment for amortization expense related to the other intangible assets acquired.

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:

	March 31, 2018			Total
	Level 1	Level 2	Level 3	
Assets:				
Cash equivalents	\$ 36,035	\$ 17,471	\$ —	\$ 53,506
Marketable securities	—	132,096	—	132,096
Total Assets	\$ 36,035	\$ 149,567	\$ —	\$ 185,602
Liabilities:				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 5,244	\$ 5,244
Total liabilities	\$ —	\$ —	\$ 5,244	\$ 5,244

Table of Contents

	December 31, 2017			Total
	Level 1	Level 2	Level 3	
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 March 31, 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 and asset-backed securities, which were valued based upon Level 2 inputs. In determining the fair value of its Level 2 investments the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. On a quarterly basis, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of those quoted prices. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to the quoted prices obtained from the third-party pricing service. During the three months ended March 31, 2018 and the year ended December 31, 2017, there were no transfers between Level 1, Level 2 and Level 3.

As of March 31, 2018 and December 31, 2017, the fair value of the Company's available for sale marketable securities by type of security was as follows:

	March 31, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 36,733	\$ —	\$ (115)	\$ 36,618
Commercial paper	48,610	—	(3)	48,607
Asset-backed securities	21,003	—	(35)	20,968
U.S. government agency debt securities	25,985	—	(82)	25,903
Total marketable securities	\$ 132,331	\$ —	\$ (235)	\$ 132,096

	December 31, 2017			
	Amortized	Gross	Gross	Fair
	Cost	Unrealized	Unrealized	Value
		Gain	Loss	
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

Table of Contents

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31, 2018	December 31, 2017
Computer equipment	\$ 817	\$ 650
Manufacturing equipment	562	511
Lab equipment	721	721
Furniture and fixtures	524	327
Leasehold improvements	250	430
Property and equipment, gross	2,874	2,639
Accumulated depreciation	(683)	(480)
Property and equipment, net	\$ 2,191	\$ 2,159

Depreciation expense was \$203 and \$50 for the three months ended March 31, 2018 and 2017, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2018	December 31, 2017
Employee compensation expenses	\$ 2,999	\$ 3,010
Research and development expenses	1,362	627
Sales and marketing expenses	521	39
Payable to NST	—	590
Vixen contract payable	100	100
Capital leases, current portion	142	142
Other	544	432
Total accrued expenses	\$ 5,668	\$ 4,940

7. Stockholders' Equity

Preferred Stock

As of March 31, 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 March 31, 2018 or December 31, 2017.

Common Stock

As of March 31, 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. No dividends have been declared through March 31, 2018.

Table of Contents

At-The-Market Equity Offering

In November 2016, the Company entered into an at-the-market sales agreement with Cowen and Company, LLC to sell the Company's securities under a shelf registration statement filed in November 2016. During the three months ended March 31, 2018, the Company did not issue any shares of common stock under the at-the-market sales agreement. As of March 31, 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 Offering 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 (the "Public Offering"), 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 in connection with the Public Offering. In addition, the Company incurred expenses of \$176 in connection with the Public Offering. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and offering expenses, were \$80,918.

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 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 March 31, 2018, 150,624 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

Table of Contents

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 March 31, 2018, 1,599,031 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 957,013 and 984,720 were outstanding as of March 31, 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.

Stock Option Valuation

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

	Three Months Ended			
	March 31,			
	2018		2017	
Risk-free interest rate	2.61	%	2.10	%
Expected term (in years)	6.3		6.0	
Expected volatility	95.60	%	95.20	%
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 March 31, 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	1,090,000	22.17		
Exercised	(46,700)	8.43		
Forfeited and cancelled	(25,147)	28.40		
Outstanding as of March 31, 2018	4,346,910	\$ 21.15	8.60	\$ 10,779
Options vested and expected to vest as of March 31, 2018	4,346,910	\$ 21.15	8.60	\$ 10,779
Options exercisable as of March 31, 2018	1,265,616 (1)	\$ 15.33	7.55	\$ 8,066

(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 March 31, 2018.

Table of Contents

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2018 was \$17.43 per share.

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

Restricted Stock Units

The following table summarizes RSU activity from January 1, 2018 through March 31, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2017	283,553	\$ 27.02
Granted	317,360	22.14
Vested	(3,150)	20.39
Forfeited and cancelled	(2,500)	23.62
Outstanding as of March 31, 2018	595,263	\$ 24.46

Stock Based Compensation

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

	Three Months Ended March 31,	
	2018	2017
Cost of revenue	\$ 176	\$ —
Research and development	1,727	1,217
Sales and marketing	907	380
General and administrative	2,333	1,556
Total stock-based compensation expense	\$ 5,143	\$ 3,153

As of March 31, 2018, the Company had unrecognized stock based compensation expense for stock options and RSUs of \$50,862 and \$11,752, respectively, which is expected to be recognized over weighted average periods of 3.12 years and 3.41 years, respectively.

Table of Contents

9. Net Loss per Share

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

	Three Months Ended	
	March 31, 2018	2017
Numerator:		
Net loss	\$ (30,229)	\$ (12,559)
Denominator:		
Weighted average shares of common stock outstanding	30,885,928	26,080,806
Net loss per share, basic and diluted	\$ (0.98)	\$ (0.48)

The Company's potentially dilutive securities, which included stock options and RSUs, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential shares of common stock excluded from the calculation of diluted net loss per share for the three months ended March 31, 2018 and 2017. All share amounts presented in the table below represent the total number outstanding as of March 31, 2018 and 2017.

	Three Months Ended	
	March 31, 2018	2017
Options to purchase common stock	4,346,910	2,656,941
Restricted stock unit awards	595,263	214,343
Total potential shares of common stock	4,942,173	2,871,284

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 \$276 and \$84 for the three months ended March 31, 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.

Table of Contents

As of March 31, 2018, future minimum lease payments under these agreements were as follows:

Year Ending December 31,	
2018	\$ 568
2019	627
2020	589
2021	605
2022	622
Thereafter	532
Total	\$ 3,543

Capital Leases for 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.

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 agreed to pay \$590 to NST Consulting, LLC, which amount represents accelerated rent payments. Total payments made under the sublease during the three months ended March 31, 2018 and 2017 were \$570 and \$75, 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 months ended March 31, 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 March 31,	
	2018	2017
Services provided by NST Consulting, LLC	\$ —	\$ 56
Services provided to NST Consulting, LLC	—	(11)
General and administrative expense, net	\$ —	\$ 45
Net payments made to NST Consulting, LLC	\$ —	\$ 135

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

Table of Contents

12. Agreements Related to Intellectual Property

Assignment Agreement and Finder's Services Agreement

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

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

13. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the three months ended March 31, 2018 and 2017 due to the Company's conclusion that a valuation allowance was required for those periods.

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 and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. 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 will be 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. 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.

Table of Contents

The Company's results of operations by segment for the three months ended March 31, 2018 and 2017 are summarized in the tables below:

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Three Months Ended March 31, 2018				
Revenue	\$ —	\$ 2,502	\$ (1,384)	\$ 1,118
Cost of revenue	—	2,120	(1,153)	967
Research and development	13,606	—	—	13,606
Sales and marketing	11,221	12	—	11,233
General and administrative	—	472	5,788	6,260
Loss from operations	\$ (24,827)	\$ (102)	\$ (6,019)	\$ (30,948)

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Three Months Ended March 31, 2017				
Revenue	\$ —	\$ —	\$ —	\$ —
Cost of revenue	—	—	—	—
Research and development	7,772	—	—	7,772
Sales and marketing	1,438	—	—	1,438
General and administrative	93	—	3,627	3,720
Loss from operations	\$ (9,303)	\$ —	\$ (3,627)	\$ (12,930)

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 \$142 and \$175 of net assets, composed principally of cash, as of March 31, 2018 and December 31, 2017, respectively.

Intersegment Revenue

Revenue for the contract research segment includes \$1,384 for services performed on behalf of the dermatology therapeutics segment for the three months ended March 31, 2018. The Company did not generate any revenue in the three months ended March 31, 2017. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

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 and differentiated 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 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 product launch in the United States. We have also hired a targeted 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 raised SKs to Cipher Pharmaceuticals Inc., or Cipher. Under the terms of the license agreement, we will receive an upfront payment of \$1.0 million, 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 plan to propose a twice-weekly dosing regimen to the FDA for our planned Phase 3 clinical trials of A-101 45% Topical Solution for the treatment of common warts, which we expect to initiate in the second half of 2018. We expect to report data from these Phase 3 clinical trials in the second half of 2019 and, if those results are positive, to submit an NDA to the FDA thereafter.

We are developing our JAK inhibitor drug candidate ATI-501, which we in-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. We are evaluating the results of these clinical trials to finalize the design of our planned Phase 2 dose-response clinical trial of ATI-501 which we expect to initiate in the first half of 2018.

We are developing ATI-502, which we also in-licensed from Rigel, as a topical treatment for AA, vitiligo and AGA. We submitted an IND to the FDA for ATI-502 for the treatment of AA in July 2017. We are also developing another series of JAK inhibitors for the treatment of AGA. 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:

Study	Indication	Objective	Patients	P Preliminary Expected Results	
				Initiation	Expected
ATI-501					
AUAT-201	AT/AU	Dose-ranging	120-160	1H 2018	Mid 2019
ATI-502					

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

AA-201	AA	Dose-ranging	120	Initiated	2H 2018
AA-202	AA	PK/PD	12	Initiated	1H 2018
AUATB-201	AA (Eyebrow)	Open-label study	24	Initiated	Mid 2018
VITI-201	Vitiligo	Open-label study	24	Initiated	1H 2019
AGA-201	AGA	Open-label study	24	1H 2018	1H 2019

Table of Contents

In August 2017, we acquired Aclaris Life Sciences Inc. (formerly known as Confluence Life Sciences, Inc.), or Confluence. The acquisition of Confluence 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. Through the acquisition of Confluence, we also acquired several preclinical drug candidates, 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 and ITK inhibitors in the second half of 2019. We plan to develop ATI-450 for the treatment of psoriasis, psoriatic arthritis, rheumatoid arthritis, cryopyrin-associated periodic syndrome, pyoderma gangrenosum and inflammatory bowel disease. We plan to develop our ITK inhibitors for the treatment of atopic dermatitis and psoriasis.

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 financed our operations with sales of our convertible preferred stock, as well as net proceeds from our initial public offering, or IPO, in October 2015, a private placement of our common stock in June 2016, public offerings of our common stock in November 2016 and August 2017, and an at-the-market facility with Cowen and Company LLC, or Cowen, that we entered into in November 2016.

Since our inception, we have incurred significant operating losses. Our net loss was \$30.2 million for the three months ended March 31, 2018 and \$68.5 million for the year ended December 31, 2017. As of March 31, 2018, we had an accumulated deficit of \$189.7 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 begin to commercialize ESKATA. In addition, ESKATA and our drug candidates, if approved, may not achieve commercial success. Though we have commercially launched ESKATA, we do not expect to generate substantial revenue from sales of ESKATA in the near term, if at all. 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.

Components of Our Results of Operations

Revenue

We account for revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers. Under 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.

Table of Contents

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 it is 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.

We 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 also receive revenue from grants under the Small Business Innovation Research program of the National Institutes of Health, or NIH. Through our Confluence subsidiary, we currently have two active grants from NIH which are related to early-stage research. We recognize revenue related to these grants as amounts become reimbursable under each grant, which is generally when research is performed and the related costs are incurred.

Cost of Revenue

Cost of revenue consists of costs incurred in connection with the provision of laboratory services to our clients through Confluence. Cost of revenue primarily includes:

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

Research and Development Expenses

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

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

Table of Contents

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. 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 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 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 expect to launch in the fourth quarter of 2018.

Additionally, we anticipate significant increases in our sales and marketing expenses as a result of the launch of commercial product sales of ESKATA in May 2018.

Table of Contents

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. 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. 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.

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. 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.

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which we perform during the fourth quarter, or when indicators of an impairment are present. We consider each of our operating segments, dermatology therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. We have attributed the full amount of the goodwill acquired with Confluence, or \$18,504, to the dermatology therapeutics segment. The annual impairment test performed by us is a qualitative assessment based upon current facts and circumstances related to operations of the dermatology therapeutics segment. If the qualitative assessment indicates an impairment may be present, we would perform the required quantitative analysis and an impairment charge would be recognized to the extent that the estimated fair value of the reporting unit is less than its carrying amount. However, any loss recognized would not exceed the total amount of goodwill allocated to that reporting unit.

Intangible Assets

Intangible assets include both finite lived and indefinite lived assets. Finite lived intangible assets are amortized over their estimated useful life based on the pattern over which the intangible assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the straight-line method of amortization is used. Indefinite lived intangible assets are not amortized. In-process research and development assets acquired in a business combination are considered

Table of Contents

indefinite lived until the completion or abandonment of the associated research and development efforts. We test intangible assets for impairment at least annually, or if indicators of impairment are present. We recognize impairment losses when and to the extent that the estimated fair value of an intangible asset is less than its carrying value.

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 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 January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. We 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 March 31, 2018 and 2017

	Three Months Ended March 31,		
	2018	2017	Change
	(In thousands)		
Revenue	\$ 1,118	\$ —	\$ 1,118
Cost of revenue	967	—	967
Gross profit	151	—	151
Operating expenses:			
Research and development	13,606	7,772	5,834
Sales and marketing	11,233	1,438	9,795
General and administrative	6,260	3,720	2,540
Total operating expenses	31,099	12,930	18,169
Loss from operations	(30,948)	(12,930)	(18,018)
Other income, net	719	371	348
Net loss	\$ (30,229)	\$ (12,559)	\$ (17,670)

Revenue

Revenue was \$ 1.1 million for the three months ended March 31, 2018, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. We did not generate any revenue in the three months ended March 31, 2017.

Cost of Revenue

Cost of revenue was \$ 1.0 million for the three months ended March 31, 2018, and was comprised entirely of costs incurred to provide laboratory services to our clients through Confluence, which we acquired in August 2017. We did not incur any cost of revenue in the three months ended March 31, 2017.

Table of Contents

Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended		
	March 31,		
	2018	2017	Change
	(In thousands)		
ESKATA	\$ 693	\$ 1,167	\$ (474)
A-101 45% Topical Solution	1,011	196	815
JAK inhibitors	5,281	2,555	2,726
Personnel expenses	2,710	2,587	123
Stock-based compensation	1,727	1,217	510
Change in contingent consideration	866	—	866
Other research and development expenses	1,318	50	1,268
Total research and development expenses	\$ 13,606	\$ 7,772	\$ 5,834

A-101 45% Topical Solution increased primarily due to our Phase 2 clinical trials for the treatment of common warts which we initiated in June 2017. JAK inhibitors increased due to continued growth in preclinical and clinical trial development expenses related to the technology. 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. The increase in stock-based compensation expense is primarily the result of new awards granted after March 31, 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 primarily included expenses related to medical affairs activities, and expenses related to drug discovery performed by Confluence, which we acquired in August 2017; therefore, we did not incur similar expenses in the three months ended March 31, 2017.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

Three Months Ended
March 31,

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

	2018	2017	Change
	(In thousands)		
Direct marketing and professional fees	\$ 4,359	\$ 629	\$ 3,730
Personnel expenses	3,872	359	3,513
Stock-based compensation	907	380	527
Other sales and marketing expenses	2,095	70	2,025
Total sales and marketing expenses	\$ 11,233	\$ 1,438	\$ 9,795

Direct marketing and professional fees, as well as other sales and marketing expenses, increased as we prepared for the launch of commercial product sales 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 three months ended March 31, 2018.

Table of Contents

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended March 31,		
	2018	2017	Change
	(In thousands)		
Personnel expenses	\$ 1,798	\$ 948	\$ 850
Professional and legal fees	1,120	704	416
Facility and support services	637	292	345
Share-based compensation	2,333	1,556	777
Other general and administrative expenses	372	220	152
Total general and administrative expenses	\$ 6,260	\$ 3,720	\$ 2,540

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. Professional and legal fees increased as we prepared for the commercial product launch of ESKATA, which occurred in May 2018. Facility and support services included general office expenses and information technology costs which have risen due to our increased headcount.

Other Income, Net

The \$0.3 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.

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 through sales of our convertible preferred stock, as well as net proceeds from our IPO in October 2015, our private placement in June 2016, our public offerings in November 2016 and August 2017 and our at-the-market facility with Cowen.

As of March 31, 2018, we had cash, cash equivalents and marketable securities of \$187.0 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 sublease 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 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. The shares were sold through Cowen pursuant to a sales agreement with them dated November 2, 2016. Following these sales, we may offer and sell additional shares of our common stock having an aggregate offering price of up to approximately \$55.0 million from time to time through Cowen pursuant to the sales agreement.

August 2017 Public Offering

In August 2017, we closed our 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, after deducting underwriting discounts, commissions and offering expenses, were \$80.9 million.

Cash Flows

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

	Three Months Ended	
	March 31,	
	2018	2017
	(In thousands)	
Net cash used in operating activities	\$ (21,872)	\$ (12,659)
Net cash provided by investing activities	56,193	5,956
Net cash provided by financing activities	358	209
Net increase (decrease) in cash and cash equivalents	\$ 34,679	\$ (6,494)

Table of Contents

Operating Activities

During the three months ended March 31, 2018, operating activities used \$21.9 million of cash primarily resulting from our net loss of \$30.2 million, partially offset by changes in our operating assets and liabilities of \$2.1 million, and non-cash adjustments of \$6.2 million. Net cash provided by changes in our operating assets and liabilities during the three months ended March 31, 2018 consisted of a \$1.0 million decrease in prepaid expenses and other current assets and a \$1.1 million increase in accounts payable and accrued expenses. The decrease 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, for which we received a refund during the three months ended March 31, 2018, partially offset by deposits made for clinical supplies and development activities that are expected to be incurred during the second quarter of 2018. 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 \$6.2 million were primarily composed of stock-based compensation expense.

During the three months ended March 31, 2017, operating activities used \$12.7 million of cash primarily resulting from our net loss of \$12.6 million and cash used by changes in our operating assets and liabilities of \$3.3 million, partially offset by non-cash adjustments of \$3.2 million. Net cash used by changes in our operating assets and liabilities during the three months ended March 31, 2017 consisted of a \$2.6 million increase in prepaid expenses and other current assets and a \$0.7 million decrease 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. The decrease in accounts payable and accrued expenses was primarily due to bonuses which were earned in 2016 and paid during the three months ended March 31, 2017, partially offset by the timing of vendor invoicing and payments. Non-cash expenses of \$3.2 million were primarily composed of share-based compensation expense.

Investing Activities

During the three months ended March 31, 2018, investing activities provided \$56.2 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$92.1 million, partially offset by purchases of marketable securities of \$35.6 million, and purchases of equipment of \$0.3 million.

During the three months ended March 31, 2017, investing activities provided \$6.0 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$23.3 million, partially offset by purchases of marketable securities of \$17.2 million and purchases of equipment of \$0.2 million.

Financing Activities

During the three months ended March 31, 2018, financing activities provided \$0.4 million of cash primarily from the exercise of employee stock options.

During the three months ended March 31, 2017, financing activities provided \$0.2 million of cash 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 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, continue the clinical development of A-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

Table of Contents

programs if, among other things, our clinical trials are not successful or if the FDA does not approve or 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. Our future funding requirements will be heavily determined by the resources needed to support the commercialization of ESKATA 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, 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, completion of our Phase 2 clinical trials and initiation of Phase 3 clinical trials for A-101 45% Topical Solution for the treatment of common warts and the continued development of ATI-501 and ATI-502 as potential treatments for AA and other indications. 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 complete the clinical development and, if approved, commercialize A-101 45% Topical Solution for the treatment of common warts, to complete the clinical development of ATI-501 and ATI-502, and to pursue in-licenses or acquisitions of other drug candidates. We also expect to incur significant expenses related to the commercialization of ESKATA, 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;
- 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 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

Table of Contents

- 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.

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

Under the assignment agreement 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 aggregate payments of up to \$4.5 million upon the achievement of specified commercial milestones. In addition, we have agreed to pay royalties on sales of 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. 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

Table of Contents

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.

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.

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

Table of Contents

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 March 31, 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.

Management's assessment of disclosure controls and procedures excluded consideration of Confluence's internal control over financial reporting, which was acquired during the third quarter of 2017. This exclusion is consistent with guidance provided by the staff of the SEC that an assessment of a recently acquired business may be omitted from management's report on internal control over financial reporting for up to one year from the date of acquisition, subject to specified conditions. Confluence's total assets were \$1.5 million as of March 31, 2018 and Confluence's total revenues were \$1.1 million during the three months ended March 31, 2018.

(b) Changes in Internal Controls Over Financial Reporting

There have not been any changes in our internal controls over financial reporting during our fiscal quarter ended March 31, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As a result of our acquisition of Confluence, we are in the process of designing and implementing controls over intangible assets.

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. 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.

Table of Contents

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

None.

36

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>
10.1*+	<u>Commercial Supply Manufacturing Services Agreement, by and between the Registrant and James Alexander Corporation, dated as of January 24, 2018.</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.

- + Confidential treatment has been requested with respect to portions of this exhibit, indicated by asterisks, which has been filed separately with the SEC.

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: May 8, 2018 By: /s/ Neal Walker
Neal Walker
President and Chief Executive Officer
(On behalf of the Registrant)

Date: May 8, 2018 By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(Principal Financial Officer)