# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	I	FORM 10-Q
(Mark one)	QUARTERLY REPORT PURSUANT TO OF 1934	O SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
	For the quart	erly period ended March 31, 2018
	TRANSITION REPORT PURSUANT TO OF 1934	OR O SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
	For the transition per	od from to
	Commiss	ion File Number 001-37581
		Therapeutics, Inc. Registrant as Specified in Its Charter)
	Delaware (State or Other Jurisdiction of Incorporation or Organization) 640 Lee Road, Suite 200 Wayne, PA (Address of principal executive offices)	46-0571712 (I.R.S. Employer Identification No.) 19087 (Zip Code)
	Registrant's teleph	one number, including area code: (484) 324-7933
		N/A
	(Former name, former address	and former fiscal year, if changed since last report)
	months (or for such shorter period that the registrant	required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during was required to file such reports), and (2) has been subject to such filing requirements for
be submitted and		cally and posted on its corporate Web site, if any, every Interactive Data File required to 2.405 of this chapter) during the preceding 12 months (or for such shorter period that the
emerging growth		er, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an ler," "accelerated filer," "smaller reporting company" and "emerging growth company" in
	Large accelerated filer $\ \square$	Accelerated filer $\square$
	Non-accelerated filer □ (Do not check if a smaller reporting company	Smaller reporting company □
		Emerging growth company $\ oxtimes$
	owth company, indicate by check mark if the registra accounting standards provided pursuant to Section 1	ant has elected not to use the extended transition period for complying with any new or B(a) of the Exchange Act. □
Indicate by check	mark whether the registrant is a shell company (as o	efined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes □ No ⊠
The number of ou	tstanding shares of the registrant's common stock, p	ar value \$0.00001 per share, as of the close of business on May 7, 2018 was 30,906,003.

# ACLARIS THERAPEUTICS, INC.

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# Part I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

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

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

Assets		March 31, 2018	De	cember 31, 2017
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		_		_
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

# 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	<u></u>	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	3	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)	

# ACLARIS THERAPEUTICS, INC. CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (UNAUDITED)

# (In thousands, except share data)

	Common Stock			Additional	Other			Total	
	Par		_	Paid-in	Comprehensive	Accumulated	Sto	ckholders'	
	Shares	Valu	e	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	<u>—</u>	_		5,143	
Net loss	_	_	_		_	(30,229)		(30,229)	
Balance at March 31, 2018	30,905,629	\$ -		\$ 390,464	\$ (328)	\$ (189,664)	\$	200,472	

# 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	\$	_	

# 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

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

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 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

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.

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 Moi Marc	nths Ended h 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							
	Level 1	Level 2	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				

	December 31, 2017						
	Level 1	Level 2		2 Level 3			Total
Assets:							
Cash equivalents	\$ 19,339	\$	_	\$ -	_	\$	19,339
Marketable securities	_	18	8,652	-	_	1	88,652
Total Assets	\$ 19,339	\$ 18	8,652	\$ -		\$ 2	07,991
Liabilities:							
Acquisition-related contingent consideration	\$ _	\$	_	\$ 4,37	78	\$	4,378
Total liabilities	\$ 	\$		\$ 4,37	78	\$	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						
Marketable securities:	Amortized Cost	Gross ted Unrealized Gain					
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
			ecember				
	Amortized Cost	G: Unre	ecember ross ealized	G	017 ross ealized		Fair Value
Marketable securities:		G: Unre	ross ealized	G	ross ealized		
		G: Unre	ross ealized	G	ross ealized	\$	
Marketable securities:	Cost	G Unro G	ross ealized	G Unro	ross ealized oss	\$	Value
Marketable securities: Corporate debt securities	* 37,401	G Unro G	ross ealized	G Unro	ross ealized oss	\$	37,333
Marketable securities: Corporate debt securities Commercial paper	* 37,401 85,202	G Unro G	ross ealized	G Unro	ross ealized oss (68)	\$	37,333 85,202

#### 5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31, 2018		ember 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:

	N	1arch 31, 2018	Dec	ember 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.

#### 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

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 Month March	
	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 vield	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	E	Veighted Average Exercise Price	Weighted Average Remaining Contractual Term	ggregate Intrinsic Value
Outstanding as of December 31, 2017	3,328,757	\$	20.69	(in years) 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

<sup>(1)</sup> 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.

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:

		V	Weighted
			Average
		G	rant Date
	Number	F	air Value
	of Shares	P	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 Mo Mare	nths E ch 31,	nded
	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.

#### 9. Net Loss per Share

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

		onths Ended ch 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 Mon Marcl	
	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.

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,			
	2	2018	2	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.

#### 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.

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	Contract	Corporate	Total
Three Months Ended March 31, 2018	Therapeutics	Research	and Other	Company
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)

	Dei	rmatology	Co	ntract	Corporate	Total
Three Months Ended March 31, 2017	The	erapeutics	Res	search	and Other	Company
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.

#### 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.

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:

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

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.

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.

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.

#### **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

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.

#### **Results of Operations**

# Comparison of Three Months Ended March 31, 2018 and 2017

	Th	ree Months I				
		2018		2017		Change
	_		`.	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.

#### 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,					
		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.

#### General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Mo Mar					
	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.

#### **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		2018		2017	
		5)					
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)			

# **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

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

• 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

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

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.

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

None.

### Item 6. Exhibits

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

<sup>\*</sup> Filed herewith.

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

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

### **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)

#### COMMERCIAL SUPPLY MANUFACTURING SERVICES AGREEMENT

This Agreement (this "Agreement"), made this 24th day of January 2018 ("Effective Date") by James Alexander Corporation, a New Jersey corporation having its principal offices at 845 Route 94, Blairstown, New Jersey 07825 ("James Alexander"), and Aclaris Therapeutics, Inc., a Delaware corporation, having its principal offices at 101 Lindenwood Drive, Suite 400, Malvern, Pennsylvania 19355 ("Aclaris"). For purposes of this Agreement, James Alexander and Aclaris may be referred to in this Agreement jointly as the "Parties" or individually as a "Party".

#### **BACKGROUND**

- A. James Alexander specializes in drug product manufacturing for the pharmaceutical industry and has certain technical and commercial information and know-how relating to, drug product manufacturing for pharmaceutical products.
- B. Aclaris is a corporation that develops and markets pharmaceutical products.
- C. Aclaris desires to engage James Alexander to manufacture crushable glass ampoules to be used with Aclaris' proprietary hydrogen peroxide drug product for commercial sale in the Territory (as defined below).

#### **TERMS**

In consideration of the mutual promises made by the parties hereto and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, intending to be legally bound, the parties hereto agree as follows:

#### 1. **DEFINITIONS**

The following terms as used in this Agreement shall have the meanings set forth in this Article unless the context clearly indicates to the contrary:

(a) "Affiliate(s)" means, in relation to any Person, any Person that controls, is controlled by or is under common control with that Person. For purposes of this definition, "control" means (i) beneficial and/or legal ownership of at least fifty percent (50%) or more of the outstanding voting securities of a company or other business organization with voting securities (or such percentage as required under any particular jurisdiction to confer controlling powers through ownership of voting securities broadly equivalent to the controlling powers attendant on ownership of at least fifty percent (50%) or more of outstanding securities in a United States corporation, (ii) a fifty percent

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(50%) or greater interest in the net assets or profits of a partnership or other business organization without voting securities, or (iii) the ability, whether directly or indirectly, to direct the affairs, management or policies of any such Person.

- (b) "Agency" shall mean any United States of America or state governmental regulatory authority involved in regulating any aspect of the development, market approval, Manufacturing, sale, distribution or use of pharmaceutical products. Specific requirements for laws, regulations and standards of non-U.S. governmental regulatory bodies may be added by mutual written agreement of the parties on a country-by-country basis, and when so agreed, shall be encompassed by the term "Agency."
- (c) "Applicable Laws and Regulations" shall mean all applicable ordinances, rules, regulations, laws, guidelines, current good manufacturing practices, guidances, statutes, requirements and court orders of any kind whatsoever, as amended from time to time, including the bodies of law and regulations governing the manufacture of pharmaceutical products in the United States of America. Specific requirements for laws, regulations and standards of non-U.S. governmental regulatory bodies may be added by mutual written agreement of the parties on a country-by-country basis, and when so agreed, shall be encompassed by the term "Applicable Laws and Regulations."
- (d) "Aclaris Parties" shall have the meaning given to it in Section 14 (b) herein.
- (e) **"Applicator"** shall mean a crushable glass ampoule manufactured and supplied by James Alexander for Aclaris pursuant to this Agreement.
- (f) **"Business Day"** shall mean any day other than a Saturday, Sunday or a national holiday in the United States.
- (g) "Calendar Quarter" shall mean a three-month period commencing on January 1, April 1, July 1 or October 1, as applicable.
- (h) **"Calendar Year"** shall mean a period of time commencing on January 1 and ending on the following December 31.
- (i) **"cGMP"** shall mean all applicable laws, regulations and standards of the United States of America relating to the Manufacture of the Drug Product including but not limited to, the FDA current Good Manufacturing Practices, as set forth in Title 21 of the United States Code of Federal Regulations as such regulations and guidelines may be revised from time to time, and any other applicable laws, guidelines and regulations.
- (j) **"Competitive Product"** shall mean any applicator which (x) contains [\*\*\*] concentration of hydrogen peroxide and (y) is used for dermatological conditions, diseases and/or disorders.
- (k) "Delivery Date" shall mean the date set forth in the relevant purchase order on which James Alexander must deliver the Drug Product to Aclaris or the authorized agent of Aclaris.

- (l) **"Drug Product"** shall mean Aclaris' proprietary hydrogen peroxide drug product contained within the Applicator in a finished dosage form.
- (m) "Facility" shall mean James Alexander's facilities located at 845 Route 94, Blairstown, New Jersey 07825 and all other facilities used in the Manufacture of the Drug Product; provided that such other facilities have been approved by Aclaris, in writing, for the Manufacture of the Drug Product.
- (n) **"FDA"** shall mean the United States Food and Drug Administration or any successor agency having substantially the same function.
- (o) "First Commercial Sale" shall mean the date, with respect to a country in the Territory, the first commercial sale to a Third Party for monetary value of the Drug Product in such country for use or consumption by the end user of such product in such country after all approvals of Regulatory Authorities that are required for the commercialization of such product in such country have been obtained in such country. For the avoidance of doubt, sales prior to receipt of all approvals of Regulatory Authorities necessary to commence commercial sales of the Drug Product in a particular country, such as so-called "treatment IND sales", "named patient sales", "compassionate use sales", clinical trial supplies, and samples, in each case, where Aclaris and/or its Affiliate receives no cash compensation for such sales, shall not be construed as a First Commercial Sale.
- (p) "Force Majeure" shall mean any of the following events or conditions, provided that such event or condition is not reasonably within the control of either Party: acts of state or governmental action, including the acts of the United States Food and Drug Administration, orders, legislation, regulations, restrictions, priorities or rationing, riots, disturbance, war (declared or undeclared), national or regional emergency, injunctions, labor trouble, acts of terrorism, strikes, lockouts, slowdowns, prolonged shortage of energy supplies, interruption of transportation, embargo (inability to procure or shortage of supply materials, equipment or production facilities), delay of subcontractors or vendors, fire, earthquake, flood, hurricane, typhoon, and/or explosion,
- (q) **"Intellectual Property**" shall have the meaning given to it in Section 10(a)(iii) herein.
- (r) "James Alexander Parties" shall have the meaning given to it in Section 14 (a) herein.
- (s) "[\*\*\*]" shall have the meaning given to it in Section 14 (a) herein.
- (t) "[\*\*\*]" shall have the meaning given to it in Section 14 (a) herein.
- (u) "Losses" shall have the meaning given to it in Section 14 (a) herein.
- (v) **"Manufacture"** shall mean filling and sealing and all other operations and services of James Alexander necessary for the manufacture of commercial supplies of the Drug Product in

Execution Copy accordance with the Specifications including without limitation the design, use and assembly of the dispenser/applicator and/or packages for the commercial supplies of the Drug Product. Such Drug

Product shall be used by Aclaris for commercial sale of the Drug Product in the Territory.

- (w) **"Non-Competitive Product"** shall mean any applicator that (i) contains any ingredient, provided the ingredient is not a peroxide or is less than [\*\*\*], (ii) is used for conditions, diseases or disorders other than dermatological conditions, diseases and/or disorders, and (iii) that infringes a patent within the Aclaris Intellectual Property.
- (x) "Non-Conforming Drug Product" shall have the meaning given to it in Section 8(c) herein.
- (y) "Person" shall mean shall mean any corporation, firm, partnership or other entity.
- (z) **"Proprietary Information"** shall have the meaning given it in Section 11 (a) herein.
- (aa) "Regulatory Authority" means (a) the United States Food and Drug Administration; (b) for any member state of the European Union, the European Medicines Agency; (c) any successor organization of any such entities; and (d) any other government regulatory authority with regulatory oversight of the Manufacture, supply, use or sale of Drug Product in or for the Territory, as such other authorities are mutually agreed upon by the Parties in writing.
- (bb) **"Specification"** shall mean the quality standards, including temperature monitoring and analytical procedures and acceptance criteria that are established to confirm the quality of the Drug Product which are contained or referenced in the master lot record as set forth in Appendix 1 for the Drug Product or as otherwise mutually agreed to in writing by the Parties. The Parties acknowledge that the Specifications may be revised, from time to time, during the Term of this Agreement by mutual written agreement of James Alexander and Aclaris.
- (cc) **"Term"** shall have the meaning given to it in Section 12 (a) herein.
- (dd) "**Territory**" shall mean worldwide.
- (ee) "**Third Party**" shall mean any person or entity other than a Party to this Agreement or such Party's Affiliate.
- (ff) "Third Party Rights" shall have the meaning given to it in Section 10 (a) (iv) herein.

# 2. ENGAGEMENT OF JAMES ALEXANDER

Subject to Section 5 (h), James Alexander agrees to exclusively Manufacture the Drug Product for Aclaris and Aclaris agrees to purchase and pay for the Manufacture of the Drug Product on the terms and conditions set forth in this Agreement. James Alexander shall be responsible solely for the Manufacturing of such Drug Product. Further, during the Term of the Agreement, James Alexander agrees not to Manufacture any Competitive Product which directly or indirectly

Execution Copy competes with the Drug Product in the Territory. For the avoidance of doubt, during the Term of this Agreement, James Alexander may continue to Manufacture Non-Competitive Products for Third Parties in the Territory.

#### 3. **PAYMENT AND SHIPPING**

- (a) <u>Shipping</u>. All Drug Product will be shipped FOB Facility (Incoterms 2011) and risk of loss of the Drug Product shall be borne by Aclaris upon delivery by James Alexander to a common carrier. James Alexander will arrange shipments of all Drug Product from its Facility to a third party or to Aclaris, as directed by Aclaris and at Aclaris' expense.
- (b) <u>Payment</u>. James Alexander shall invoice Aclaris concurrently with any shipment of the Drug Product and Aclaris shall make full payment to James Alexander at the address specified on the invoice, no later than thirty (30) calendar days from the date of receipt of the invoice. If Aclaris has not made payment in full by the expiration of such thirty (30) day period, James Alexander shall be entitled to interest on such unpaid amount equal to [\*\*\*] per month for any unpaid amounts.
- (c) <u>Failure to Take Delivery</u>. If Aclaris or its authorized agent fails to take delivery on any scheduled Delivery Date, then Aclaris shall be billed at that time for all unshipped Drug Product and on the first of each month thereafter for reasonable administration and storage costs for all such unshipped Drug Product.
- (d) <u>Title and Risk of Loss</u>. Title and risk of loss to the Drug Product and any Manufacturing materials supplied by Aclaris to James Alexander and used in connection with the Manufacturing services provided by James Alexander pursuant to this Agreement shall remain with Aclaris while such items are in the possession of James Alexander and for the duration of the provision of such services by James Alexander to Aclaris. Aclaris shall be solely responsible for insuring such Drug Product and other Manufacturing materials. Title and risk of loss with respect to any Manufacturing materials supplied by James Alexander and used in connection with the Manufacturing services provided by James Alexander will remain with James Alexander until James Alexander delivers, in accordance with Aclaris' instructions, the Drug Product to a common carrier for shipment to Aclaris.

#### 4. PRICE

The price for the Manufacturing of the Drug Product shall be as set forth in Appendix 2. James Alexander shall bear and pay all federal, state and local taxes based upon or measured by its net income, and all franchise taxes based upon its corporation existence, or its general corporate right to transact business. Any other tax, however denominated and measured, imposed upon the Drug Product or Manufacturing services or upon their installation, storage, inventory, sales, transportation, delivery, use or consumption shall be paid directly by Aclaris, or if prepaid by James Alexander, shall be invoiced to Aclaris, at cost, as a separate item and paid by Aclaris to James Alexander.

#### 5. **FORECAST, PURCHASE AND SUPPLY**

- (a) <u>Purchase and Supply</u>. During the Term of this Agreement and subject to paragraph (d) of this Article 5, Aclaris shall purchase and James Alexander shall Manufacture and supply such quantities of the Drug Product as may be set forth on purchase orders submitted by Aclaris under this Agreement. Aclaris shall, at its expense, provide James Alexander with sufficient bulk quantities of any Manufacturing materials to be provided by Aclaris pursuant to the applicable purchase order at least sixty (60) days prior to the confirmed Delivery Date, in order that James Alexander may perform the Manufacturing services in a timely manner. James Alexander shall maintain sufficient inventories of Manufacturing components and other Manufacturing material it is required to supply to Manufacture quarterly firm orders volumes, taking into account the lead times for such Manufacturing materials.
- (b) <u>Forecasts</u>. On or before the 15<sup>th</sup> day of each month following the Effective Date, during the Term of this Agreement, Aclaris will provide James Alexander with a written twelve (12) month rolling forecast of the quantity of the Drug Product that Aclaris expects to require from James Alexander. The forecast shall be non-binding upon Aclaris, provided James Alexander may reasonably rely on the first six (6) months of any forecast for purchasing Manufacturing materials necessary for use in the Manufacture of the Drug Product.
- (c) <u>Orders.</u> No later than ninety (90) calendar days prior to the start of each Calendar Quarter, Aclaris will provide James Alexander with a quarterly purchase order setting forth (i) the quantity of the Drug Product ordered for delivery during the next Calendar Quarter, (ii) the Delivery Date(s) for such Drug Product, (iii) the quantity of Drug Product to be delivered on the Delivery Date(s) and supportive documentation, and (iv) the lot numbers to be applied to such Drug Product.
- (d) <u>Acceptance of Orders</u>. Provided the purchase orders are consistent with the forecast and other terms and conditions of this Agreement, within ten (10) calendar days of receipt of a purchase order, James Alexander shall either (i) notify Aclaris in writing of its acceptance of such purchase order as a binding order or (ii) propose alternate Delivery Dates for such Drug Product, in which event the Parties shall promptly reach mutual agreement on acceptable Delivery Dates.
- (e) <u>Order Greater than Forecast</u>. James Alexander shall have no obligation to accept purchase orders for Drug Product for quantities exceeding the forecast. However, James Alexander shall use commercially reasonable efforts to supply the quantity of Drug Product ordered, regardless of the quantity forecast by Aclaris, subject to availability of Manufacturing material and the capacity limitations of James Alexander's Manufacturing equipment and the Facility.
- (f) Amendment of Purchase Orders. James Alexander will use commercially reasonable efforts to accommodate a request to amend a purchase order to increase or decrease the quantity of Drug Product to be delivered; provided that in no event shall James Alexander be required to incur any costs or suffer any losses in connection with such amendment or its efforts to accommodate such change. Any such costs or losses incurred by James Alexander shall be paid for by Aclaris. If the lead time necessary to acquire Manufacturing components or other material is greater than ninety (90) calendar days, with Aclaris' prior written consent, James Alexander may submit orders for such components or other material based on Aclaris' quantity forecast in a timely manner and Aclaris shall be liable for such costs incurred by James Alexander in the event that Aclaris fails to

Execution Copy purchase sufficient quantities of the Drug Product, due to amending a purchase order or otherwise, as provided in the forecast on which James Alexander relied.

- (g) <u>Cancellations</u>. Aclaris may cancel any purchase order by providing James Alexander written notice at least ninety (90) calendar days prior to the Delivery Date. In the event that Aclaris cancels any order for Drug Product, Aclaris shall reimburse James Alexander for indirect and direct costs reasonably incurred by James Alexander in connection with performance of such purchase order up to the time of receipt of such notice, including but not limited to the cost of any Manufacturing components or other material purchased or committed to be purchased by James Alexander with respect to such cancelled order which are noncancellable, nonreturnable and cannot reasonably be used by James Alexander for another Third Party customer of James Alexander within the ninety (90) day period following Aclaris' cancellation. Upon payment to James Alexander of the costs of cancellation, James Alexander shall upon request by Aclaris, deliver to Aclaris, at Aclaris' expense, any unused Manufacturing components paid for by Aclaris.
- (h) <u>Minimum Purchase Commitments</u>. During each Calendar Year during the Term of this Agreement, Aclaris agrees to purchase from James Alexander and James Alexander agrees to sell to Aclaris a quantity of Drug Product constituting no less than the annual minimum number of units of Drug Product as provided in Appendix 3 of this Agreement ("Minimum Purchase Commitment"). If it becomes evident, during any given Calendar Year during the Term of this Agreement, that Aclaris will not be able to purchase the Minimum Purchase Commitment, Aclaris shall promptly notify James Alexander, in writing, and both parties shall meet in person or by phone to discuss in good faith an acceptable resolution, including but not limited to, a modification to the Minimum Purchase Commitment. Notwithstanding the foregoing, if Aclaris does not purchase the Minimum Purchase Commitment from James Alexander during any given Calendar Year during the Term of this Agreement, James Alexander, upon sixty (60) Business Days prior written notice to Aclaris, may, at James Alexander's discretion, notify Aclaris that James Alexander's obligation to exclusively Manufacture the Drug Product for Aclaris pursuant to section 2 of this Agreement shall be converted, immediately, to a nonexclusive obligation to Manufacture the Drug Product for Aclaris in accordance with the terms of this Agreement.
- (i) <u>Terms of Agreement Govern.</u> No modification or amendment to this Agreement shall be effected by or result from the receipt, acceptance, signing or acknowledgment of any Party's purchase orders, order acknowledgements, invoices, shipping documents or other business forms containing terms or conditions in addition to or different from the terms and conditions set forth in this Agreement, and the terms of this Agreement shall supersede any provision in any purchase order or other document that is in addition to or inconsistent with the terms of this Agreement.

## 6. <u>COMPLIANCE WITH AGENCY REGULATIONS</u>

(a) <u>Covenant</u>. The Parties agree to comply with all Applicable Laws and Regulations of any Agency, including but not limited to cGMPs. James Alexander shall be solely responsible for all the necessary permissions and licenses for Manufacturing of the Drug Product; <u>provided</u>, <u>however</u>, that Aclaris shall have sole responsibility for obtaining any permits or licenses from any Agency necessary or required for the labeling, use, marketing, sale or entering into commerce of the Drug Product in the Territory.

- (b) Aclaris Representation. Aclaris represents, warrants and covenants that all Drug Product and other Manufacturing materials supplied by Aclaris under this Agreement shall, at the time of delivery to James Alexander comply with all Applicable Laws and Regulations and Agency requirements in effect on the day of such delivery. Without limiting the foregoing, Aclaris guarantees that no Drug Product or Manufacturing materials supplied by Aclaris under this Agreement shall, at the time of delivery, be (a) adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act, or any similar law in the Territory, or (b) an article which may not, under the provisions of the U.S. Federal Food, Drug and Cosmetic Act, or any similar law in the Territory, be introduced into interstate commerce in the Territory.
- (c) <u>James Alexander Representation</u>. James Alexander represents, warrants and covenants that all Manufacturing materials supplied by James Alexander under this Agreement shall, at the time of delivery to Aclaris, comply with all Applicable Laws and Regulations and Agency requirements in effect on the day of such delivery. Without limiting the foregoing, James Alexander guarantees that no Manufacturing materials supplied by James Alexander under this Agreement shall, at the time of delivery, be (a) adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act, or any similar law of any U.S. state or Agency, or (b) an article which may not, under the provisions of the U.S. Federal Food, Drug and Cosmetic Act, or any similar law of any U.S. state or Agency, be introduced into interstate commerce.

## 7. **FACILITY**

- (a) <u>Manufacturing</u>. James Alexander hereby agrees to perform the Manufacturing of the Drug Product(s) at its Facilities and shall not Manufacture or store the Drug Product(s) at any other location without the prior written consent of Aclaris.
- (b) <u>Compliance with Laws</u>. James Alexander will comply with all Applicable Laws and Regulations relating to the Manufacturing services to be provided by James Alexander under this Agreement, including but not limited to cGMPs.

## 8. **QUALITY OF MANUFACTURING AND WARRANTIES**

(a) <u>Limited Warranty</u>. James Alexander warrants that at the time of delivery to Aclaris, the Manufacturing services provided hereunder shall be conducted in accordance with cGMPs and consistent with and conform to the Specifications. James Alexander also warrants that neither it nor its representatives or employees involved with the Manufacturing services have been debarred pursuant to the Federal Food, Drug and Cosmetic Act including but not limited to debarment pursuant to section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 335a, or is the subject of a conviction described in such section. James Alexander agrees to inform Aclaris in writing immediately if James Alexander or any person performing services on its behalf under this Agreement is debarred or is the subject of a conviction described in section 306, or if any action, suit, claim, investigation, or proceeding is pending relating to the debarment or conviction of James Alexander or any person performing such services.

- (b) <u>Testing of Drug Product</u>. Aclaris is responsible for testing the Drug Product to assure that they are in conformity with the Specifications. Aclaris, upon receipt of the Drug Product from James Alexander, shall have thirty (30) calendar days to inspect such Drug Product. Any Drug Product that are not rejected within such thirty (30) day period shall be deemed to have been accepted by Aclaris.
- Non-Conforming Drug Product. In the event Aclaris and/or its agent(s) believes that the Drug Product are defective or do not conform to the Specifications set forth herein ("Non-Conforming Drug Product"), Aclaris shall send to James Alexander via overnight delivery service or certified mail, return receipt requested, within five (5) Business Days of discovery of the defect, a notice of rejection along with samples of the rejected Drug Product. If James Alexander agrees that the Drug Product are Non-Conforming Drug Product, James Alexander, at Aclaris' option, will either Manufacture new Drug Product, at James Alexander's expense, and ship them to Aclaris within a commercially reasonable timeframe subject to James Alexander's capacity, or shall issue a full refund for that particular lot to Aclaris within thirty (30) calendar days from the date of Aclaris' request for same. If James Alexander does not agree with Aclaris' determination that the Drug Product fail to meet the Specifications, then after reasonable efforts to resolve the disagreement, either Party may pursue available remedies under this Agreement; provided, however, James Alexander must inform Aclaris within ten (10) Business Days if James Alexander determines that the Drug Product rejected by Aclaris met the Specifications. Exclusive Remedy. EXCEPT IN THE EVENT OF JAMES ALEXANDER'S GROSS NÉGLIGENCE, INTENTIONAL MISCONDUCT OR NEGLIGENT OMISSION AND EXCEPT AS PROVIDED IN SECTION 14, THE OBLIGATION OF JAMES ALEXANDER TO MANUFACTURE AND REPLACE NON-CONFORMING DRUG PRODUCT, AT JAMES ALEXANDER'S EXPENSE SHALL BE ACLARIS' SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR NON-CONFORMING DRUG PRODUCT, IN LIEU OF ANY OTHER REMEDY OR ANY WARRANTY, EXPRESS OR IMPLIED.

# 9. **REPRESENTATIONS AND WARRANTIES**

- (a) <u>Existence and Power</u>. Each Party hereby represents and warrants to the other Party that such Party (i) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (ii) has the corporate power and authority to own and operate its property and assets, and to carry on its business as it is now being conducted, and (iii) is in compliance with all requirements of Applicable Laws and Regulations, except for any noncompliance that would not materially adversely affect such Party's ability to perform its obligations under this Agreement.
- (b) <u>Authorization and Enforcement of Obligations</u>. Each Party hereby represents and warrants to the other Party that such Party (i) has the corporate power and authority to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

- (c) <u>No Consents</u>. Each Party hereby represents and warrants to the other Party that any necessary consents, approvals and authorizations of all Agencies and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.
- (d) <u>No Conflict</u>. Each Party hereby represents and warrants to the other Party that the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws and Regulations applicable to such Party and (ii) do not materially conflict with, or constitute a material default or require any consent under, any material contractual obligation of such Party.
- (e) <u>Disclaimer</u>. OTHER THAN AS EXPRESSLY PROVIDED FOR IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY OF NON-INFRINGEMENT OF THIRD PARTY RIGHTS. THIS IS FOR ANY MATTER ARISING OUT OF OR RELATING TO THIS AGREEMENT, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

#### 10. <u>INTELLECTUAL PROPERTY; TRADEMARKS AND OWNERSHIP; SUBLICENSE</u>

- (a) <u>Intellectual Property</u>. Aclaris represents and warrants that:
- (i) Aclaris' Specifications for the Drug Product are its or its Affiliates' property, except to the extent the Specifications contain the Proprietary Information of James Alexander;
  - (ii) Aclaris may lawfully disclose the Specifications of the Drug Product to James Alexander;
- (iii) The Drug Product and all Aclaris Intellectual Property licensed to James Alexander by Aclaris in connection with the provision of Manufacturing services or the supply of the Drug Product according to the Drug Product Specifications (i) is Aclaris' or its Affiliate's unencumbered property or (ii) may be lawfully used by James Alexander during the Term as directed by Aclaris. "Aclaris Intellectual Property" shall mean U.S. Patent No. 9,675,639 and any patent applications claiming priority thereto and foreign equivalents thereof, and any copyright, industrial designs, and know-how related to thereto that is owned or controlled by or licensed to Aclaris or any of Aclaris' Affiliates; and
- (iv) to Aclaris' knowledge, there are no actions or other legal proceedings, the subject of which is the infringement of the Intellectual Property of any Third Party ("Third Party Rights") related to the Drug Product or any of the Drug Product Specifications provided by Aclaris to James Alexander. To Aclaris' knowledge, it is not aware of any Third Party Rights that would be infringed by the Manufacture, use and sale of the Drug Product and use of the Drug Product Specifications in the Manufacture of the Drug Product under this Agreement.

- (b) to James Alexander's knowledge, James Alexander represents and warrants that there are no actions or other legal proceedings, the subject of which is the infringement of the Intellectual Property of any Third Party ("Third Party Rights") related to the Drug Product or any of the Manufacturing services provided by James Alexander under this Agreement.
- (c) <u>Third Party Infringement of James Alexander's Intellectual Property</u>. James Alexander shall retain the intellectual property rights to any of James Alexander's Intellectual Property, including but not limited to its Manufacturing processes or improvements thereto and shall be solely responsible for the prosecution of any Third Party that infringes any of James Alexander's Intellectual Property rights and any such prosecution shall be in the sole discretion of James Alexander.
- (d) <u>Trademarks</u>. All rights to either Party's Intellectual Property rights including but not limited to trademarks, trade names, trade secrets, brands, patents, patent applications, and copyrights shall remain that Party's absolute property during and after the Term of this Agreement. Neither Party shall apply for registration of any trademarks, trade names, or brand names of the other Party and each Party hereby renounces all rights that it may acquire to such trademarks, trade names or brand names according to law or customs because of this Agreement or because of its use of such trademarks, trade names, or brand names under this Agreement.\_
- (e) <u>Proprietary Information</u>, <u>etc</u>. In no event shall any of James Alexander's Proprietary Information (as defined below), technology, know-how, Intellectual Property (or rights thereto) become the property of Aclaris. In no event shall any of Aclaris' Proprietary Information (as defined below), technology, know-how, Intellectual Property (or rights thereto) become the property of James Alexander.

#### (f) <u>Grant of License</u>.

- (i) <u>Drug Product License</u>. Solely to the extent necessary to enable James Alexander to Manufacture the Drug Product for Aclaris and provide the Manufacturing services to Aclaris in accordance with the terms herein, Aclaris hereby grants James Alexander a royalty-free, non-exclusive, non-transferable license (without the right to grant licenses) under the Aclaris Intellectual Property to Manufacture the Drug Product for Aclaris in the Territory and/or provide the Manufacturing services as set forth in this Agreement.
- (ii) <u>Covenant Not to Sue</u>. Aclaris hereby covenants and agrees that Aclaris, its Affiliates and each successor in interest to the Aclaris Intellectual Property shall not bring any action before any legal, judicial, arbital, administrative, executive or other tribunal that has authority to adjudicate such action which asserts a claim of patent infringement of any Aclaris Intellectual Property against James Alexander for the manufacture, use, sale or offer for sale of a Non-Competitive Product in the Territory.
- (iii) No right, title or interest is granted by Aclaris to James Alexander whether expressly or by implication to or under any Aclaris Intellectual Property, other than those rights and licenses expressly granted in this Agreement. Aclaris reserves to itself all rights not expressly granted under

Execution Copy this Agreement. Without limiting the generality of the foregoing, and notwithstanding anything express or implied in this Agreement, nothing herein shall give James Alexander any right, title or interest in or any right to use any of Aclaris' or Aclaris' Affiliates intellectual property, including the Aclaris Intellectual Property or any trademarks or trade names that may be used in connection with the Drug Product except for Manufacturing the Drug Product as specified in the Specifications.

<u>Intellectual Property Ownership.</u> James Alexander agrees that all Intellectual Property (whether or not protectable by a patent or a copyright) related to the business of Aclaris and/or Drug Product ("Aclaris Technology"), which are conceived of, made, reduced to practice, created, written, designed or developed, authored or made by James Alexander specifically related to the Drug Product or the Manufacturing services provided by James Alexander under this Agreement (but not any generally applicable manufacturing processes or improvements which shall remain the Intellectual Property of James Alexander) shall be the sole and exclusive property of Aclaris. Subject to Section 10 (f) (ii), no rights are hereby given to Aclaris in any inventions conceived and evidenced in an invention record or disclosure, or under any patents or patent applications that James Alexander may own prior to the Effective Date of this Agreement or may subsequently acquire which do not arise out of and are not derived from the performance of the Manufacturing services under this Agreement. James Alexander hereby irrevocably assigns to Aclaris any and all rights or interests in the Aclaris Technology and will provide reasonable assistance, at Aclaris' expense, to obtain intellectual property protection, including but not limited to, causing the execution of any and all applications, assignments, or other instruments, and give testimony which Aclaris shall deem necessary to apply for and obtain patent protections in the United States and any foreign country or to otherwise protect Aclaris' interest in such Intellectual Property.

#### 11. **CONFIDENTIALITY/OWNERSHIP**

- (a) <u>Confidentiality Agreement</u>. James Alexander and Aclaris agree to keep confidential any and all information, including but not limited to formulations, methods, processes, chemical structures, know-how and marketing plans ("Proprietary Information") either disclosed hereunder or through any prior disclosure and not to disclose such Proprietary Information to any Person or entity, except to employees or contractors of each Party having a need to know the information in order to fulfill such Party's obligations hereunder. The Parties shall use the Proprietary Information solely for the purpose of carrying out the obligations contained in this Agreement. In the event that a Party has knowledge of any breach of the provision contained in this Section 11, the Party shall promptly give notice thereof to the other Party. Without prejudice to the rights and remedies otherwise available to a Party at law or in equity, the Parties agree that a non-breaching Party shall be entitled to seek equitable relief by way of specific performance and injunction or otherwise if the other Party breaches or threaten to breach any of the provisions of this Section 11. The obligations imposed by this Section 11 shall not apply to any Proprietary Information which:
  - (i) at the time of disclosure is in the public domain;
- (ii) after disclosure becomes part of the public domain by publication or otherwise, through no fault of the receiving Party;

- (iii) at the time of disclosure is already in the receiving Party's possession, except through prior disclosure by James Alexander, Aclaris or an Affiliate of either of them, and such possession can be properly documented by the receiving Party in its written records, and was not made available to the receiving Party by anyone owing an obligation of confidentiality to the disclosing Party;
- (iv) is rightfully made available to the receiving Party from sources independent of the disclosing Party; or
- (v) is legally required to be disclosed in the course of litigation or other legal or administrative proceedings or otherwise as required by law including without limitation disclosures required in connection with securities filings; provided that, in all cases, the Party receiving the Proprietary Information shall, to the extent permitted, give the other Party prompt written notice of the pending disclosure and shall cooperate in such other Party's attempts, at such other Party's sole expense, to seek an order maintaining the confidentiality of the Proprietary Information.
- (b) <u>Term of Confidentiality Agreement</u>. The obligation of confidentiality and nonuse set forth in this Article shall survive for a period of three (3) years beyond the termination or expiration of this Agreement and indefinitely with respect to trade secrets.
- (c) <u>Ownership of Proprietary Information</u>. Proprietary Information shall remain the exclusive property of the disclosing Party.

#### 12. **TERM AND TERMINATION**

- (a) <u>Term</u>. This Agreement shall commence on the Effective Date and shall continue until the close of business on the fifth anniversary of the date of First Commercial Sale of the Drug Product in the Territory (the "Term"). Thereafter, this Agreement shall be renewed automatically, upon the same terms and conditions contained herein, for periods of one (1) year unless written notice of termination has been given by either Party at least one hundred eighty (180) days prior to the end of the Term or any extensions or renewals thereof. Termination of this Agreement shall not affect the status of any shipping instructions outstanding as of the effective date of such termination.
- (b) <u>Immediate Termination</u>. Either Party shall have the right to immediately terminate this Agreement if (i) the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within thirty (30) calendar days; (ii) the other Party materially breaches any of the provisions of this Agreement and such breach is not cured within thirty (30) calendar days after the giving of written notice, or in the case of a breach by James Alexander, such breach is not cured in a reasonable timeframe not to exceed six (6) months; or (iii) any required license, permit or certificate required of the other Party to perform its obligations under this Agreement is not approved and/or issued, or is revoked, by any applicable Agency. James Alexander's obligations to perform under this Agreement shall automatically terminate if Aclaris has not paid any invoice within thirty (30) calendar days after such invoice is due.

- (c) <u>Termination Upon Notice</u>. Either Party shall have the right to terminate this Agreement for any reason or no reason upon one hundred eighty (180) calendar days' prior written notice to the other Party of its intention to terminate this Agreement.
- Duties Upon Termination. In the event of any termination, James Alexander shall, subject to the following sentence, promptly return to Aclaris at a location specified by Aclaris at Aclaris' expense (i) any remaining inventory of Manufacturing materials received from Aclaris or Aclaris' suppliers, (ii) all Manufacturing components paid for by Aclaris, (iii) all remaining inventories of the Drug Product and (iv) any other Manufacturing material being stored for Aclaris. James Alexander shall have no obligation to return the foregoing until all outstanding invoices sent by James Alexander to Aclaris have been paid in full. Aclaris shall also be required to pay, at the applicable price set forth in Appendix 2, for completed but not vet shipped Drug Product, Drug Product in process and Drug Product shipped but not yet invoiced. Aclaris will also be required to pay James Alexander for its indirect and direct costs of all non-refundable or noncancellable Manufacturing materials purchased or ordered based on Aclaris' forecasts by James Alexander for Manufacturing of the Drug Product and all Drug Product-specific tooling that has been, or remains to be, amortized. Aclaris shall specify the location in the continental United States to which delivery, at Aclaris' expense, of the foregoing is to be made. Proprietary Information exchanged between Aclaris and James Alexander shall be promptly returned upon termination or expiration of this Agreement. Further, upon termination or expiration of this Agreement, James Alexander shall cease using Aclaris' Intellectual Property rights for any purpose.
- (e) <u>Continuing Obligations</u>. The rights and obligations of each of the Parties under the provisions of Sections 3, 4, 6, 8, 9(e), 10, 11, 12(d) and (e), 14, 15, 16, 17, 18, 19, 20 and 21 of this Agreement shall continue notwithstanding the expiration or termination, for any reason, of this Agreement.

#### 13. **FORCE MAJEURE**

If James Alexander or Aclaris are delayed in performing any of their respective obligations under this Agreement (except in respect of any obligation to pay money), in each case in whole or in part, by reason of Force Majeure, such delay shall be excused during the continuance of and to the extent of such Force Majeure; provided that if, as a consequence of any such Force Majeure, the total demand for James Alexander's services cannot be supplied by James Alexander, James Alexander may, at its option, allocate its services among Aclaris and its other customers on such basis as James Alexander may deem fair and practicable, without liability for any failure to perform this Agreement. The Party claiming Force Majeure shall promptly notify the other Party of the termination of such event. During the period that the performance by one of the Parties of its obligations under this Agreement has been suspended by reason of an event of Force Majeure, the other Party may likewise suspend the performance of all or part of its obligations hereunder to the extent that such suspension is commercially reasonable. Resumption of obligations shall be made as soon as reasonably possible after the removal of such Force Majeure event and the time for performance of this Agreement shall be extended for a period equal to the duration of such cause and the time reasonably necessary to effect a cure of the Force Majeure event. Notwithstanding the foregoing, in the event of a Force Majeure event that will, or continues to, prevent performance (in

Execution Copy whole or substantial part) of this Agreement by a Party for a period of at least ninety (90) calendar days, the other Party shall be entitled to terminate this Agreement upon prior written notice to the other Party subject to Section 12(d).

#### 14. **INDEMNIFICATION**

(a) <u>Indemnification by Aclaris</u>. Aclaris agrees to indemnify, defend and hold James Alexander, its Affiliates, and their respective agents, employees, officers, directors, and representatives ("James Alexander Parties") harmless from and against any and all third party claims, demands and actions and resulting costs, expenses, liabilities, damages, losses and fees, including reasonable attorneys' fees and costs (collectively, "Losses") arising from (i) Aclaris' breach of any of its obligations under this Agreement, including but not limited to its warranties; or (ii) Aclaris' negligent acts or negligent omissions or willful misconduct, other than as a result of James Alexander's breach of any of its obligations under this Agreement, including but not limited to its warranties, and James Alexander's negligent acts, negligent omissions or willful misconduct.

Aclaris further agrees to indemnify, defend and hold James Alexander Parties harmless from and against any and all third party claims, demands and actions and resulting costs, expenses, liabilities, damages, losses and fees, including reasonable attorneys' fees and costs or recall costs (collectively, "[\*\*\*]") that may be sustained, suffered or incurred by James Alexander arising out of, or resulting from, or in connection with any defect or claim of defect in [\*\*\*]. The foregoing does not apply to [\*\*\*] arising out of, or resulting from, or in connection with James Alexander's negligent acts, negligent omissions or willful misconduct in connection with any defect in the [\*\*\*] which may be attributable to James Alexander in connection with James Alexander's Manufacturing process.

- (b) <u>Indemnification by James Alexander</u>. James Alexander agrees to indemnify, defend and hold Aclaris, its Affiliates, and their respective agents, employees, officers, directors, and representatives ("Aclaris Parties") harmless from and against any and all Losses to the extent arising from (i) James Alexander's breach of any of its obligations under this Agreement, including but not limited to its warranties; and (ii) James Alexander's negligent acts or negligent omissions or willful misconduct, other than as a result of Aclaris' breach of any of its obligations under this Agreement, including but not limited to its warranties, and Aclaris' negligent acts or negligent omissions or willful misconduct.
- (c) Procedure for Indemnification. Upon receiving notice of any claim for liability under this provision, the indemnified Party shall promptly notify the indemnifying Party in writing; provided, however, that failure to give notice shall not limit or otherwise reduce the indemnity provided for in this Agreement except to the extent that failure to give notice materially prejudices the rights of the indemnifying Party. The indemnifying Party will assume and conduct the legal defense of the indemnified Party in any suit that could result in claims under this provision. Indemnifying Party will not settle any case without the prior written consent of the indemnified Party and such consent shall not be unreasonably withheld.

#### 15. **ADVERSE EVENTS**

- (a) <u>Duty to Inform</u>. Aclaris shall inform James Alexander immediately of any important information relating to the activity, side effects, toxicity and/or safety of the Drug Product that becomes known to Aclaris during the Term of this Agreement and that is relevant to the performance of the Manufacturing services by James Alexander under this Agreement.
- (b) Recall. In the event that a recall of any Drug Product is required by an Agency, or if a recall of a Drug Product is deemed advisable by Aclaris, in its sole discretion, such recall shall be implemented and administered in a manner which is appropriate and reasonable under the circumstances and in conformity with any requests or orders of the applicable Agency, as well as accepted trade practices. The costs and expenses in connection with a recall shall be paid by Aclaris, including without limitation the costs and expenses related to the dissemination of information set forth below, unless such recall is due to James Alexander's gross negligence, willful misconduct or negligent omission. In the event that a Drug Product is recalled as a result of the Drug Product Manufactured pursuant to this Agreement or Aclaris is required to disseminate information relating to the Drug Product Manufactured pursuant to this Agreement, Aclaris shall so notify James Alexander within a reasonable time so as to enable James Alexander to provide Aclaris with such assistance in connection with such recall as may reasonably be requested by Aclaris. James Alexander will comply with all such reasonable requests from Aclaris. Aclaris shall handle exclusively the organization and implementation of all recalls of Drug Product.
- (c) <u>Insurance</u>. As of the Effective Date, Aclaris maintains a commercial general liability insurance policy with limits of [\*\*\*] per occurrence and [\*\*\*] annual aggregate, a product liability insurance policy with limits of [\*\*\*] per occurrence and [\*\*\*] annual aggregate and an umbrella liability insurance policy with limits of [\*\*\*] per occurrence and [\*\*\*] annual aggregate. James Alexander shall maintain a commercial general liability insurance policy covering product liability and personal injury damages with limits of [\*\*\*] per occurrence and [\*\*\*] annual aggregate. The policies of each Party shall remain in effect throughout the Term of this Agreement and shall not be canceled or subject to reduction or any other modification without thirty (30) calendar days prior written notice to the other Party. Both Parties shall also carry and maintain in force at all times relevant hereto all other insurance required by law or statute.

#### 16. **NOTICES**

Notices or other communications required or permitted by this Agreement shall be given in writing, and shall be deemed to have been given when deposited in the United States mail, return receipt requested and postage prepaid, or on the day following delivery of such notice to a major overnight delivery service or by facsimile or electronic communication, if receipt of delivery is confirmed in writing. All notices shall be addressed to the parties as follows:

To: James Alexander

James Alexander 845 Route 94 Blairstown, New Jersey 07825 Attn: David Robinson, President Email: dave\_robinson@james-alexander.com

To: Aclaris:

Aclaris Therapeutics, Inc. 101 Lindenwood Drive, Suite 400 Malvern, Pennsylvania 19355 Attn: Chief Legal Officer kalijackson@aclaristx.com

#### 17. CHOICE OF LAW

The formation, existence, construction, performance, validity of this Agreement shall be governed by the laws of the state of Delaware without regard to conflict of laws provisions. For any and all claims or disputes between the Parties that arise out of this Agreement, the parties hereby consent to the jurisdiction of the federal and state courts located in the State of Delaware.

#### 18. ASSIGNMENT

Neither this Agreement, nor any rights or obligations hereunder, may be assigned by either Party hereto without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part: (a) in connection with the transfer or sale of all or substantially all of the capital stock or assets of such Party or the line of business or the products to which this Agreement relates including without limitation the Drug Product; (b) to the successor entity or acquirer in the event of the merger, consolidation or change of control of a Party hereto; or (c) to any Affiliate of the assigning Party. Any subsequent assignee Aclaris or transferee shall be bound by the terms of this Agreement.

#### 19. REMEDIES

EXCEPT FOR INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION LOST REVENUES OR PROFITS.

#### 20. RELATIONSHIP OF THE PARTIES

Nothing contained in this Agreement shall create a joint venture or partnership between the Parties. James Alexander shall be an independent contractor in performing its obligations. Neither Party shall be liable for any of the debts or obligations of the other and neither Party shall have any authority or right to act for or incur any liability of any kind, express or implied, in the name of or on behalf of the other Party except as may otherwise be set forth in this Agreement.

#### 21. MISCELLANEOUS

- (a) Entire Agreement. This Agreement, together with the Quality Agreement, constitutes the entire agreement between the Parties pertaining to the subject matter hereof and supersedes all prior agreements, understandings, negotiations and discussions, whether oral or written, of the Parties, excluding the [\*\*\*] and there are no warranties, representations or other agreements between the Parties except as specifically set forth herein. All Appendices to this Agreement are part of this Agreement to the same effect as if such terms had been included herein. To the extent of any conflict or inconsistency between this Agreement and any purchase order, invoice, confirmation, acceptance or any similar document, the terms of this Agreement shall govern in all respects.
- (b) <u>Counterparts, Signature by Facsimile and Electronic Transmission</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one agreement. The parties agree that execution of this Agreement by industry standard electronic signature software and /or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.
- (c) <u>Titles</u>. The headings appearing at the beginning of the numbered Articles and at the beginning of paragraphs have been inserted for convenience only and do not constitute any part of this Agreement.
- (d) <u>Amendments</u>. No changes or modifications or waivers are to be made to this Agreement unless evidenced in writing and signed for and on behalf of both Parties.
- (e) <u>Severability</u>. In the event that any provision of this Agreement shall be determined to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.
- (f) <u>Waiver</u>. The failure on the part of any Party to exercise or enforce any rights conferred upon it hereunder shall not be deemed to be a waiver of any such rights nor operate to bar the exercise or enforcement thereof at any time or times thereafter.
- (g) <u>No Strict Construction</u>. The language used in this Agreement will be deemed to be the language chosen by the Parties to express their mutual intent, and no rules of strict construction will be applied against any Party.
- (h) <u>Publicity</u>. Neither Party shall issue any publicity, news release, or other announcement regarding this Agreement, the terms of this Agreement or the relationship or activities of the Parties thereunder, written or oral, whether to the public press, the trade, its customers, or the other Party's customers without the other Party's prior written consent; provided, however, either Party may issue such publicity, news release, or other announcement regarding this Agreement, the terms of this Agreement or the relationship or activities of the Parties thereunder, written or oral, as required by Applicable Laws and Regulations.

(i) Review by Legal Counsel. Each Party has carefully reviewed this Agreement, and understands its terms. Each Party has been given sufficient opportunity to seek legal advice prior to signing this Agreement, and has either sought legal advice with counsel experienced in issues of confidentiality in regards to this Agreement, or has relied wholly upon that Party's own judgment and knowledge in executing this Agreement. Each Party fully understands and voluntarily accepts each and every provision contained in this Agreement. Failure to seek legal advice prior to signing this Agreement does not excuse either Party from failure to understand the terms and conditions set forth in this Agreement. This Agreement has been prepared on the basis of the mutual understanding of the Parties and in the event of an ambiguity; such ambiguity shall not be strictly construed against either Party as a drafter of this Agreement.

**Execution Copy** 

**IN WITNESS WHEREOF,** Aclaris and James Alexander have executed this Agreement on the date first set forth above.

JAMES ALEXANDER CORPORATION	ACLARIS THERAPEUTICS, INC.	
By:/s/ David Robinson Name:David Robinson Title: President and CEO	By: <u>/s/ Neal Walker</u> Name: <u>Neal Walker</u> Title:	<u>President</u>

# **APPENDIX 1**

### **SPECIFICATIONS**

Table 1 Specifications for A-101 (hydrogen peroxide) 40% Topical Solution Drug Product ([\*\*\*])

[\*\*\*]

**Execution Copy** 

Table 2 Specifications for A101 (hydrogen peroxide) 40% Topical Solution Drug Product ([\*\*\*])

[\*\*\*]

#### **APPENDIX 2**

### PRICE FOR COMMERCIAL SUPPLIES

Description:	Order Quantity:	Price:
Eskata [***]	[***]	[***]
Eskata [***]	[***]	[***]
Eskata [***]	[***]	[***]

## **Current Pricing Assumptions:**

Aclaris to supply the following components: [\*\*\*]

James Alexander to supply the following components: [\*\*\*]

Items omitted from this production quote:

[\*\*\*]

# **APPENDIX 3**

Calendar Year	Quantity (number of Drug Product units not including Drug Product validation units):
2018	[***]
2019	[***]
2020	[***]
2021	[***]
2022	[***]

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

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

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2018 of Aclaris Therapeutics, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation: and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2018

/s/ Neal Walker
Neal Walker
President and Chief Executive Officer
(principal executive officer)

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

#### I, Frank Ruffo, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2018 of Aclaris Therapeutics, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation: and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2018

/s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(principal financial officer)

# CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Neal Walker, President and Chief Executive Officer of Aclaris Therapeutics, Inc. (the "Company"), and Frank Ruffo, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

- 1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- **2.** The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 8<sup>th</sup> day of May, 2018.

/s/ Neal Walker/s/ Frank RuffoNeal WalkerFrank RuffoPresident and Chief Executive OfficerChief Financial Officer(principal executive officer)(principal financial officer)

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