

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number 001-37581

Aclaris Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(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 telephone number, including area code: (484) 324-7933

N/A

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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

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

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on August 2, 2018 was 30,980,663.

ACLARIS THERAPEUTICS, INC.

INDEX TO FORM 10-Q

	<u>PAGE</u>
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	2
<u>Unaudited Condensed Consolidated Balance Sheet as of June 30, 2018 and December 31, 2017</u>	2
<u>Unaudited Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and six months ended June 30, 2018 and 2017</u>	3
<u>Unaudited Condensed Consolidated Statement of Stockholders' Equity for the six months ended June 30, 2018</u>	4
<u>Unaudited Condensed Consolidated Statement of Cash Flows for the six months ended June 30, 2018 and 2017</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	39
<u>Item 4. Controls and Procedures</u>	40
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	41
<u>Item 1A. Risk Factors</u>	41
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	41
<u>Item 6. Exhibits</u>	42
<u>Signatures</u>	43

Part I. FINANCIAL INFORMATION**Item 1. Financial Statements**

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET
(Unaudited)

(In thousands, except share and per share data)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,035	\$ 20,202
Marketable securities	118,569	173,655
Accounts receivable, net	2,182	481
Inventory	1,026	—
Prepaid expenses and other current assets	3,360	5,883
Total current assets	171,172	200,221
Marketable securities	—	14,997
Property and equipment, net	4,375	2,159
Intangible assets	7,311	7,349
Goodwill	18,504	18,504
Other assets	457	279
Total assets	\$ 201,819	\$ 243,509
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 12,504	\$ 7,822
Accrued expenses	7,565	4,940
Total current liabilities	20,069	12,762
Contingent consideration	5,244	4,378
Other liabilities	1,754	558
Deferred tax liability	549	549
Total liabilities	27,616	18,247
Stockholders' Equity:		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.00001 par value; 100,000,000 shares authorized at June 30, 2018 and December 31, 2017; 30,965,296 and 30,856,505 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	395,273	384,943
Accumulated other comprehensive loss	(188)	(246)
Accumulated deficit	(220,882)	(159,435)
Total stockholders' equity	174,203	225,262
Total liabilities and stockholders' equity	\$ 201,819	\$ 243,509

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

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
ESKATA product sales, net	\$ 1,533	\$ —	\$ 1,533	\$ —
Contract research	1,143	—	2,261	—
Other revenue	1,000	—	1,000	—
Total revenue, net	3,676	—	4,794	—
Cost of revenue	1,181	—	2,148	—
Gross profit	2,495	—	2,646	—
Operating expenses:				
Research and development	13,984	7,965	27,590	15,737
Sales and marketing	12,368	2,188	23,601	3,626
General and administrative	8,121	5,142	14,381	8,862
Total operating expenses	34,473	15,295	65,572	28,225
Loss from operations	(31,978)	(15,295)	(62,926)	(28,225)
Other income, net	760	457	1,479	828
Net loss	\$ (31,218)	\$ (14,838)	\$ (61,447)	\$ (27,397)
Net loss per share, basic and diluted	\$ (1.01)	\$ (0.56)	\$ (1.99)	\$ (1.04)
Weighted average common shares outstanding, basic and diluted	30,944,899	26,594,854	30,915,577	26,339,250
Other comprehensive income:				
Unrealized gain (loss) on marketable securities, net of tax of \$0	\$ 111	\$ (4)	\$ 46	\$ (56)
Foreign currency translation adjustments	28	87	12	159
Total other comprehensive income	139	83	58	103
Comprehensive loss	\$ (31,079)	\$ (14,755)	\$ (61,389)	\$ (27,294)

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

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

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2017	30,856,505	\$ —	\$ 384,943	\$ (246)	\$ (159,435)	\$ 225,262
Exercise of stock options and vesting of RSUs	108,791	—	(62)	—	—	(62)
Unrealized gain on marketable securities	—	—	—	46	—	46
Foreign currency translation adjustment	—	—	—	12	—	12
Stock-based compensation expense	—	—	10,392	—	—	10,392
Net loss	—	—	—	—	(61,447)	(61,447)
Balance at June 30, 2018	30,965,296	\$ —	\$ 395,273	\$ (188)	\$ (220,882)	\$ 174,203

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

ACLARIS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

(In thousands)

	Six Months Ended	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (61,447)	\$ (27,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	537	105
Stock-based compensation expense	10,392	6,457
Change in fair value of contingent consideration	866	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,701)	—
Inventory	(1,026)	—
Prepaid expenses and other assets	2,345	(3,897)
Accounts payable	4,693	3,161
Accrued expenses	1,636	(1,168)
Net cash used in operating activities	<u>(43,705)</u>	<u>(22,739)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(650)	(388)
Purchases of marketable securities	(74,246)	(41,534)
Proceeds from sales and maturities of marketable securities	144,375	47,652
Net cash provided by investing activities	<u>69,479</u>	<u>5,730</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	19,311
Capital lease payments	(335)	—
Proceeds from the exercise of employee stock options	394	235
Net cash provided by financing activities	<u>59</u>	<u>19,546</u>
Net increase in cash and cash equivalents	25,833	2,537
Cash and cash equivalents at beginning of period	20,202	30,171
Cash and cash equivalents at end of period	<u>\$ 46,035</u>	<u>\$ 32,708</u>
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	\$ 442	\$ 190
Property and equipment obtained pursuant to capital lease financing arrangements	\$ 1,896	\$ —
Offering costs included in accounts payable	\$ 20	\$ —

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

ACLARIS THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

1. Organization and Nature of Business

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. 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. In August 2017, Aclaris Life Sciences Inc. (formerly known as Confluence Life Sciences Inc.) (“Confluence”) was acquired by Aclaris Therapeutics, Inc. and became a wholly-owned subsidiary thereof (see Note 3). Aclaris Therapeutics, Inc., ATIL, Vixen and Confluence are referred to collectively as the “Company”. The Company is a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. The Company’s lead drug, ESKATA (hydrogen peroxide) Topical Solution, 40% (w/w) (“ESKATA”), is a proprietary high-concentration formulation of hydrogen peroxide that the Company is commercializing as an office-based prescription treatment for raised seborrheic keratosis (“SK”), a common non-malignant skin tumor. The Company submitted a New Drug Application (“NDA”) for ESKATA to the U.S. Food and Drug Administration (“FDA”) in February 2017, and it was approved in December 2017. The Company launched ESKATA in May 2018.

Liquidity

The Company’s condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. At June 30, 2018, the Company had cash, cash equivalents and marketable securities of \$164,604 and an accumulated deficit of \$220,882. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, and the commercial launch of ESKATA in May 2018, the Company had never generated any revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing of the Company’s drug candidates, and commercialization of the Company’s products will require significant additional financing. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company’s failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

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 June 30, 2018, the condensed consolidated statement of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017, the condensed consolidated statement of stockholders' equity for the six months ended June 30, 2018, and the condensed consolidated statement of cash flows for the six months ended June 30, 2018 and 2017 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements contained in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 12, 2018 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position as of June 30, 2018, the results of its operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017 and its cash flows for the six months ended June 30, 2018 and 2017. The condensed consolidated balance sheet data as of December 31, 2017 was derived from audited financial statements but does not include all disclosures required by GAAP. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2018 and 2017 are unaudited. The results for the three and six months ended June 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period. The unaudited interim financial statements of the Company included herein have been prepared, pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2017 included in the Company's annual report on Form 10-K filed with the SEC on March 12, 2018.

Significant Accounting Policies

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

In February 2017, the Company paid a \$2.0 million Prescription Drug User Fee Act ("PDUFA") fee to the FDA in conjunction with the filing of its NDA for ESKATA. The Company requested a waiver and refund of this PDUFA fee, which was approved by the FDA in December 2017, and was received by the Company in January 2018.

Revenue Recognition

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

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

performance obligation is satisfied. The Company only recognizes revenue when collection of the consideration it is entitled to under a contract with a customer is probable.

ESKATA Product Sales

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

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

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

Contract Research

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

The Company also receives revenue from grants under the Small Business Innovation Research program of the National Institutes of Health (“NIH”). During the six months ended June 30, 2018, the Company, through Confluence, its wholly-owned subsidiary, had two active grants from NIH which were related to early-stage research. The Company recognizes revenue related to grants as amounts become reimbursable under each grant, which is generally when research is performed, and the related costs are incurred.

Inventory

Inventory includes the third-party cost of manufacturing and assembly of the finished product form of ESKATA, quality control and other overhead costs. Inventory is stated at the lower of cost or market. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. The Company had \$1,026 and \$0 of inventory as of June 30, 2018 and December 31, 2017, respectively, which was comprised solely of finished goods.

Contingent Consideration

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

Recently Issued Accounting Pronouncements

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

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

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Under this ASU, entities should recognize revenue in an amount that reflects the consideration to which they expect to be entitled to in exchange for goods and services provided. ASU 2014-09 is effective for annual reporting periods beginning after 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	<u>\$ 24,322</u>

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	\$ 3,676	\$ 1,067	\$ 4,794	\$ 2,303
Gross profit	995	243	1,146	805
Total operating expenses	32,973	16,133	64,072	29,449
Net loss	(31,218)	(15,432)	(61,447)	(28,106)

The supplemental unaudited pro forma financial results for the three and six months ended June 30, 2017 include adjustments to exclude \$370 and \$670, respectively, of revenue billed to the Company by Confluence. The supplemental unaudited pro forma financial results for the three and six months ended June 30, 2017 also include an adjustment for amortization expense related to the other intangible asset 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:

	June 30, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 33,722	\$ 11,182	\$ —	\$ 44,904
Marketable securities	—	118,569	—	118,569
Total Assets	<u>\$ 33,722</u>	<u>\$ 129,751</u>	<u>\$ —</u>	<u>\$ 163,473</u>
Liabilities:				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 5,244	\$ 5,244
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,244</u>	<u>\$ 5,244</u>

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 19,339	\$ —	\$ —	\$ 19,339
Marketable securities	—	188,652	—	188,652
Total Assets	\$ 19,339	\$ 188,652	\$ —	\$ 207,991
Liabilities:				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 4,378	\$ 4,378
Total liabilities	\$ —	\$ —	\$ 4,378	\$ 4,378

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

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

	June 30, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 18,084	\$ —	\$ (59)	\$ 18,025
Commercial paper	53,626	—	—	53,626
Asset-backed securities	22,021	—	(16)	22,005
U.S. government agency debt securities	24,962	1	(50)	24,913
Total marketable securities	\$ 118,693	\$ 1	\$ (125)	\$ 118,569

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

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	June 30, 2018	December 31, 2017
Computer equipment	\$ 1,276	\$ 650
Fleet vehicles	1,896	—
Manufacturing equipment	562	511
Lab equipment	838	721
Furniture and fixtures	523	327
Leasehold improvements	259	430
Property and equipment, gross	5,354	2,639
Accumulated depreciation	(979)	(480)
Property and equipment, net	\$ 4,375	\$ 2,159

Depreciation expense was \$296 and \$55 for the three months ended June 30, 2018 and 2017, respectively, and \$499 and \$105 for the six months ended June 30, 2018 and 2017, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2018	December 31, 2017
Employee compensation expenses	\$ 3,922	\$ 3,010
Sales and marketing expenses	1,237	39
Research and development expenses	938	627
Capital leases, current portion	552	142
Professional fees	389	108
Payable to NST	—	590
Other	527	424
Total accrued expenses	\$ 7,565	\$ 4,940

7. Stockholders' Equity**Preferred Stock**

As of June 30, 2018 and December 31, 2017, the Company's amended and restated certificate of incorporation authorized the Company to issue 10,000,000 shares of undesignated preferred stock. No shares of preferred stock were outstanding as of June 30, 2018 or December 31, 2017.

Common Stock

As of June 30, 2018 and December 31, 2017, the Company's amended and restated certificate of incorporation authorized the Company to issue 100,000,000 shares of \$0.00001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to any preferential dividend rights of any series of preferred stock that may be outstanding. The Company did not declare any dividends through June 30, 2018.

At-The-Market Equity Offering

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

Public 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 listing rules, generally including individuals who were not previously an employee or director of the Company. Under the terms of the 2017 Inducement Plan upon adoption, the Company may grant up to 1,000,000 shares of common stock pursuant to nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, and other stock awards. The shares of common stock underlying any awards that expire, or are otherwise terminated, settled in cash or repurchased by the Company under the 2017 Inducement Plan will be added back to the shares of common stock available for issuance under the 2017 Inducement Plan. As of June 30, 2018, 112,224 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 June 30, 2018, 1,671,239 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 June 30, 2018 and December 31, 2017, respectively. Stock options granted under the 2012 Plan vest over four years and expire after ten years. As required, the exercise price for the stock options granted under the 2012 Plan was not less than the fair value of the shares of common stock underlying the awards as determined by the Company as of the date of grant.

Stock Option Valuation

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

	Six Months Ended June 30,	
	2018	2017
Risk-free interest rate	2.63 %	1.93 %
Expected term (in years)	6.3	6.0
Expected volatility	95.78 %	94.09 %
Expected dividend yield	0 %	0 %

The Company recognizes compensation expense for awards over their vesting period. Compensation expense for awards includes the impact of forfeitures in the period when they occur.

Stock Options

The following table summarizes stock option activity from January 1, 2018 through June 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	3,328,757	\$ 20.69	8.28	\$ 19,812
Granted	1,215,000	21.70		
Exercised	(46,700)	8.43		
Forfeited and cancelled	(181,115)	24.79		
Outstanding as of June 30, 2018	4,315,942	\$ 20.93	8.34	\$ 13,650
Options vested and expected to vest as of June 30, 2018	4,315,942	\$ 20.93	8.34	\$ 13,650
Options exercisable as of June 30, 2018	1,377,080 ⁽¹⁾	\$ 15.25	7.21	\$ 10,725

(1) All options granted under the 2012 Plan are exercisable immediately, subject to a repurchase right in the Company's favor that lapses as the option vests. This amount reflects the number of shares under options that were vested, as opposed to exercisable, as of June 30, 2018.

The weighted average grant date fair value of stock options granted during the six months ended June 30, 2018 was \$17.04 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 June 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2017	283,553	\$ 27.02
Granted	357,360	21.62
Vested	(87,357)	27.13
Forfeited and cancelled	(20,800)	23.70
Outstanding as of June 30, 2018	<u>532,756</u>	<u>\$ 23.51</u>

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Cost of revenue	\$ 190	\$ —	\$ 366	\$ —
Research and development	1,756	1,304	3,483	2,521
Sales and marketing	1,020	400	1,927	780
General and administrative	2,283	1,600	4,616	3,156
Total stock-based compensation expense	<u>\$ 5,249</u>	<u>\$ 3,304</u>	<u>\$ 10,392</u>	<u>\$ 6,457</u>

As of June 30, 2018, the Company had unrecognized stock-based compensation expense for stock options and RSUs of \$45,446 and \$10,760, respectively, which is expected to be recognized over weighted average periods of 2.88 years and 3.25 years, respectively.

9. Net Loss per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	\$ (31,218)	\$ (14,838)	\$ (61,447)	\$ (27,397)
Denominator:				
Weighted average shares of common stock outstanding	30,944,899	26,594,854	30,915,577	26,339,250
Net loss per share, basic and diluted	\$ (1.01)	\$ (0.56)	\$ (1.99)	\$ (1.04)

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 and six months ended June 30, 2018 and 2017. All share amounts presented in the table below represent the total number outstanding as of June 30, 2018 and 2017.

	June 30,	
	2018	2017
Options to purchase common stock	4,315,942	2,773,066
Restricted stock unit awards	532,756	222,886
Total potential shares of common stock	4,848,698	2,995,952

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 \$201 and \$90 for the three months ended June 30, 2018 and 2017, respectively, and was \$478 and \$174 for the six months ended June 30, 2018 and 2017, respectively. The Company recognizes rent expense on a straight-line basis over the term of the lease and has accrued for rent expense incurred but not yet paid.

Capital Leases

Laboratory Equipment

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

Fleet Vehicles

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

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

Year Ending December 31,	
2018	\$ 603
2019	1,061
2020	998
2021	1,015
2022	765
Thereafter	533
Total	\$ 4,975

11. Related Party Transactions

In August 2013, the Company entered into a sublease agreement with NeXeption, Inc. ("NeXeption"), which was subsequently assigned to NST Consulting, LLC, a wholly-owned subsidiary of NST, LLC. In November 2017, the Company terminated the sublease with NST Consulting, LLC effective March 31, 2018. The Company paid \$590 to NST Consulting, LLC, which amount represented accelerated rent payments. Total payments made under the sublease during the six months ended June 30, 2018 and 2017 were \$570 and \$124, respectively.

In February 2014, the Company entered into a services agreement with NST, LLC (the "NST Services Agreement"), pursuant to which NST, LLC provided certain pharmaceutical development, management and other administrative services to the Company. Under the same agreement, the Company also provided services to another company under common control with the Company and NST, LLC and was reimbursed by NST, LLC for those services. In November 2017, the Company terminated the NST Services Agreement effective December 31, 2017.

Mr. Stephen Tullman, the chairman of the Company's board of directors, was an executive officer of NeXeption and is also the manager of NST Consulting, LLC and NST, LLC, and three of the Company's executive officers are and have been members of entities affiliated with NST, LLC.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Services provided by NST Consulting, LLC	\$ —	\$ 56	\$ —	\$ 112
Services provided to NST Consulting, LLC	—	(7)	—	(18)
General and administrative expense, net	\$ —	\$ 49	\$ —	\$ 94
Net payments made to NST Consulting, LLC				
	\$ —	\$ 47	\$ —	\$ 182

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

12. Agreements Related to Intellectual Property

License, Development and Commercialization Agreement – Cipher Pharmaceuticals Inc.

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

Assignment Agreement – Estate of Mickey Miller and Finder’s Services Agreement – KPT Consulting, LLC

In August 2012, the Company entered into an assignment agreement with the Estate of Mickey Miller (the “Miller Estate”), under which the Company acquired some of the intellectual property rights covering A-101. In connection with obtaining the assignment of the intellectual property from the Miller Estate, the Company also entered into a separate finder’s services agreement with KPT Consulting, LLC. Under the terms of the finder’s services agreement, the Company made a milestone payment of \$1,000 upon the achievement of specified regulatory milestones in April 2017 and a milestone payment of \$1,500 upon the achievement of specified commercial milestones in May 2018. The payments were recorded as general and administrative expenses in the Company’s condensed consolidated statement of operations.

Under the finder’s services agreement, the Company is obligated to make additional milestone payments of up to \$3,000 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 and six months ended June 30, 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 therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. The Company's lead drug, ESKATA, is a proprietary formulation of high-concentration hydrogen peroxide topical solution that the Company is commercializing as an office-based prescription treatment for raised SKs, a common non-malignant skin tumor, and which is distributed by a wholesaler. The contract research segment earns revenue from the provision of laboratory services to clients through Confluence, the Company's wholly-owned subsidiary. Laboratory service revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis. Corporate and other includes general and administrative expenses as well as eliminations of intercompany transactions. The Company does not report balance sheet information by segment since it is not reviewed by the chief operating decision maker, and all of the Company's tangible assets are held in the United States.

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

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Three Months Ended June 30, 2018				
Revenue, net	\$ 2,533	\$ 3,053	\$ (1,910)	\$ 3,676
Cost of revenue	152	2,621	(1,592)	1,181
Research and development	13,984	—	—	13,984
Sales and marketing	12,360	8	—	12,368
General and administrative	—	521	7,600	8,121
Loss from operations	\$ (23,963)	\$ (97)	\$ (7,918)	\$ (31,978)
Three Months Ended June 30, 2017				
Revenue, net	\$ —	\$ —	\$ —	\$ —
Cost of revenue	—	—	—	—
Research and development	7,965	—	—	7,965
Sales and marketing	2,188	—	—	2,188
General and administrative	58	—	5,084	5,142
Loss from operations	\$ (10,211)	\$ —	\$ (5,084)	\$ (15,295)

	Dermatology	Contract	Corporate	Total
Six Months Ended June 30, 2018	Therapeutics	Research	and Other	Company
Revenue, net	\$ 2,533	\$ 5,554	\$ (3,293)	\$ 4,794
Cost of revenue	152	4,740	(2,744)	2,148
Research and development	27,590	—	—	27,590
Sales and marketing	23,581	20	—	23,601
General and administrative	—	992	13,389	14,381
Loss from operations	\$ (48,790)	\$ (198)	\$ (13,938)	\$ (62,926)

	Dermatology	Contract	Corporate	Total
Six Months Ended June 30, 2017	Therapeutics	Research	and Other	Company
Revenue, net	\$ —	\$ —	\$ —	\$ —
Cost of revenue	—	—	—	—
Research and development	15,737	—	—	15,737
Sales and marketing	3,626	—	—	3,626
General and administrative	151	—	8,711	8,862
Loss from operations	\$ (19,514)	\$ —	\$ (8,711)	\$ (28,225)

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 \$77 and \$175 of net assets, composed principally of cash, as of June 30, 2018 and December 31, 2017, respectively.

Intersegment Revenue

Revenue for the contract research segment includes \$1,910 and \$3,293 for services performed on behalf of the dermatology therapeutics segment for the three and six months ended June 30, 2018, respectively. The Company did not generate any revenue in the three and six months ended June 30, 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 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 launch in the United States, which occurred in May 2018. We have also hired a targeted field sales force of 50 sales representatives which we believe will allow us to reach the approximately 6,000 health care providers in the United States with the highest potential for using ESKATA. In April 2018, we licensed the rights to commercialize A-101 40% Topical Solution in Canada for the treatment of SK to Cipher Pharmaceuticals Inc., or Cipher. Under the terms of the license agreement, we received an up-front payment of \$1.0 million, and may receive additional milestone payments upon the achievement of specified regulatory and commercial milestones, and royalties from the sale of A-101 40% Topical Solution in Canada. Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada.

We are developing A-101 45% Topical Solution for the treatment of common warts. In June 2017, we commenced two Phase 2 clinical trials, WART-202 and WART-203, of A-101 45% topical solution to assess the dose frequency in adult and pediatric patients with common warts. Both trials evaluated the safety and efficacy of A-101 45%

Topical Solution as compared to placebo, or vehicle. The two randomized, double-blind, vehicle-controlled trials were designed to evaluate the effects of dose frequency and to explore additional clinical endpoints that will be further evaluated in a planned Phase 3 development program. We enrolled a total of 316 patients at 34 investigational centers in the United States across both trials. In January 2018, we reported top line results from these two Phase 2 clinical trials of A-101 45% Topical Solution. In March 2018, we reported final results, which included a 3-month drug-free follow-up phase, from the WART-203 clinical trial. In addition, in April 2018, we concluded the WART-202 clinical trial, in which we evaluated a different dosing regimen from the one used in the WART-203 clinical trial. In both of these clinical trials, patients treated with A-101 45% Topical Solution achieved clinically and statistically significant outcomes for the primary, secondary and exploratory endpoints of the trial. Based on the results from these clinical trials, we held an end of Phase 2 meeting with the FDA and we plan to use a twice-weekly dosing regimen in our 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 licensed from Rigel Pharmaceuticals, Inc., or Rigel, as an oral treatment for AA. AA is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include total scalp hair loss, known as alopecia totalis, or AT, and total hair loss on the scalp and body, known as alopecia universalis, or AU. We submitted an investigational new drug application, or IND, to the FDA for ATI-501 for the treatment of AA in October 2016. Since the filing of the IND, we have conducted several Phase 1 clinical trials to evaluate the pharmacokinetic and pharmacodynamic, or PK/PD, properties of various formulations of ATI-501. Based on the results from these clinical trials, we selected an oral suspension and have initiated a Phase 2 dose-response clinical trial of ATI-501.

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

Study	Indication	Objective	Patients	Initiation	Preliminary Results Expected
<u>ATI-501</u>					
AUAT-201	AA	Dose-ranging	80	Initiated	2H 2019
<u>ATI-502</u>					
AA-201	AA	Dose-ranging	120	Initiated	1H 2019
AA-202	AA	PK/PD	11	Initiated	1H 2018 ⁽¹⁾
AUATB-201	AA (Eyebrow)	Open-label study	12	Initiated	2H 2018
VITI-201	Vitiligo	Open-label study	24	Initiated	1H 2019
AGA-201	AGA	Open-label study	24	Initiated	1H 2019
AD-201	Atopic Dermatitis	Open-label study	30	Initiated	Mid-2019

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

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 are considering developing ATI-450 for the treatment of psoriasis, hidradenitis suppurativa, cryopyrin-associated periodic syndrome, and pyoderma gangrenosum. We are considering developing our soft-JAK inhibitors for the treatment of dermatological conditions. We are considering developing our ITK inhibitors for the treatment of atopic dermatitis and psoriasis.

We have also been issued a U.S. patent with claims directed to methods of treating SK in a human by topically administering 40% hydrogen peroxide containing certain stabilizers, including ESKATA, which is scheduled to expire in 2035.

Since our inception in July 2012, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, developing ESKATA for the treatment of raised SKs, building our intellectual property portfolio, developing our supply chain and engaging in other discovery and clinical activities in dermatology. We have 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 \$61.4 million for the six months ended June 30, 2018 and \$68.5 million for the year ended December 31, 2017. As of June 30, 2018, we had an accumulated deficit of \$220.9 million. We expect to incur significant expenses and operating losses related to product manufacturing, marketing, sales and distribution over the next several years as we continue to commercialize ESKATA. In addition, ESKATA, and our drug candidates if approved, may not achieve commercial success. Though we have 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

ESKATA Product Sales

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

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

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

Contract Research

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

We 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 had two grants from NIH which were related to early-stage research which were active during the six months ended June 30, 2018. We recognize revenue related to grants as amounts become reimbursable under each grant, which is generally when research is performed, and the related costs are incurred.

Cost of Revenue

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

ESKATA Product Sales

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

Contract Research

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

Research and Development Expenses

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

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

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

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

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

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

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

Sales and Marketing Expenses

Sales and marketing expenses include salaries and related costs for our field sales force, as well as personnel in our marketing and sales operations functions, including stock-based compensation, travel expenses and recruiting expenses. Sales and marketing expenses also include costs of content development, advertising, sponsorships and attendance at dermatology conferences as well as costs related to developing our direct-to-consumer advertising campaign, which we 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 commercial launch 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 with KPT Consulting, LLC, or KPT, or Finder's Services Agreement. We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company.

Other Income, Net

Other income, net consists of interest earned on our cash, cash equivalents and marketable securities, interest expense, and gains and losses on transactions denominated in foreign currencies.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, contingent consideration and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Except as described below, we believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in the footnotes to our audited consolidated financial statements for the year ended December 31, 2017 included in our 2017 Annual Report on Form 10-K filed with the SEC on March 12, 2018.

Revenue

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

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

Inventory

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

Contingent Consideration

We initially recorded the contingent consideration related to future potential payments based upon the achievement of certain development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. For example, if the timing of the development of an acquired drug candidate, or the size of potential commercial opportunities related to an acquired drug, differ from our 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 June 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-07, Compensation-Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with non-employees except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 is effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year, and early adoption is permitted. We are evaluating the impact of ASU 2018-07 on our consolidated financial statements.

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

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

Results of Operations**Comparison of Three Months Ended June 30, 2018 and 2017**

	Three Months Ended June 30,		Change
	2018	2017	
	(In thousands)		
Revenues:			
ESKATA product sales, net	\$ 1,533	\$ —	\$ 1,533
Contract research	1,143	—	1,143
Other revenue	1,000	—	1,000
Total revenue, net	3,676	—	3,676
Cost of revenue	1,181	—	1,181
Gross profit	2,495	—	2,495
Operating expenses:			
Research and development	13,984	7,965	6,019
Sales and marketing	12,368	2,188	10,180
General and administrative	8,121	5,142	2,979
Total operating expenses	34,473	15,295	19,178
Loss from operations	(31,978)	(15,295)	(16,683)
Other income, net	760	457	303
Net loss	\$ (31,218)	\$ (14,838)	\$ (16,380)

Revenue

Revenue was \$3.7 million for the three months ended June 30, 2018, and we did not generate any revenue in the three months ended June 30, 2017. ESKATA product sales, net included \$1.6 million of gross revenue from sales of product to McKesson, our only customer, during the three months ended June 30, 2018, offset by \$0.1 million of deductions for distribution and credit card fees. Contract research revenue of \$1.1 million was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. Other revenue included an up-front payment of \$1.0 million we received upon signing of the license agreement with Cipher in April 2018.

Cost of Revenue

Cost of revenue was \$1.2 million for the three months ended June 30, 2018, and was comprised of \$0.2 million of costs related to ESKATA product sales, net and \$1.0 million of costs incurred to provide laboratory services to our clients through Confluence, which we acquired in August 2017. We did not incur any cost of revenue in the three months ended June 30, 2017.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended		
	June 30,		
	2018	2017	Change
	(In thousands)		
ESKATA	\$ 563	\$ 1,243	\$ (680)
A-101 45% Topical Solution	507	675	(168)
JAK inhibitors	6,434	2,331	4,103
Personnel expenses	2,378	1,552	826
Other research and development expenses	2,346	860	1,486
Stock-based compensation	1,756	1,304	452
Total research and development expenses	\$ 13,984	\$ 7,965	\$ 6,019

The decrease in expenses associated with the development of ESKATA resulted primarily from the filing of our NDA in February 2017 following the completion of clinical trials. Expenses related to A-101 45% Topical Solution decreased primarily due to our Phase 2 clinical trials for the treatment of common warts which were initiated in June 2017 and concluded during the first quarter of 2018. Development expenses for our JAK inhibitors increased due to continued growth in both preclinical and clinical trial expenses as we continue to conduct multiple Phase 2 clinical trials of ATI-501 and ATI-502. The increase in personnel expenses was primarily the result of increased headcount. The increase in stock-based compensation expense was primarily the result of new awards granted after June 30, 2017. Other research and development expenses 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 June 30, 2017.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Three Months Ended		
	June 30,		
	2018	2017	Change
	(In thousands)		
Direct marketing and professional fees	\$ 4,651	\$ 1,183	\$ 3,468
Personnel expenses	3,786	466	3,320
Other sales and marketing expenses	2,911	139	2,772
Stock-based compensation	1,020	400	620
Total sales and marketing expenses	\$ 12,368	\$ 2,188	\$ 10,180

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

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended		Change
	2018	2017	
	June 30,		
	(In thousands)		
Personnel expenses	\$ 1,756	\$ 903	\$ 853
Professional and legal fees	1,566	1,106	460
Facility and support services	571	313	258
Milestone payments	1,500	1,000	500
Other general and administrative expenses	445	220	225
Stock-based compensation	2,283	1,600	683
Total general and administrative expenses	\$ 8,121	\$ 5,142	\$ 2,979

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

Other Income, Net

The \$0.3 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, as well as higher yields on those invested balances.

Comparison of Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,		Change
	2018	2017	
	(In thousands)		
Revenues:			
ESKATA product sales, net	\$ 1,533	\$ —	\$ 1,533
Contract research	2,261	—	2,261
Other revenue	1,000	—	1,000
Total revenue, net	4,794	—	4,794
Cost of revenue	2,148	—	2,148
Gross profit	2,646	—	2,646
Operating expenses:			
Research and development	27,590	15,737	11,853
Sales and marketing	23,601	3,626	19,975
General and administrative	14,381	8,862	5,519
Total operating expenses	65,572	28,225	37,347
Loss from operations	(62,926)	(28,225)	(34,701)
Other income, net	1,479	828	651
Net loss	\$ (61,447)	\$ (27,397)	\$ (34,050)

Revenue

Revenue was \$4.8 million for the six months ended June 30, 2018, and we did not generate any revenue in the six months ended June 30, 2017. ESKATA product sales, net included \$1.6 million of gross revenue from sales of product to McKesson, our only customer, during the six months ended June 30, 2018, offset by \$0.1 million of deductions for distribution and credit card fees. Contract research revenue of \$2.3 million was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. Other revenue included an up-front payment of \$1.0 million we received upon signing of the license agreement with Ciper in April 2018.

Cost of Revenue

Cost of revenue was \$2.1 million for the six months ended June 30, 2018, and was comprised of \$0.2 million of costs related to ESKATA product sales, net and \$1.9 million 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 six months ended June 30, 2017.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Six Months Ended June 30,		Change
	2018	2017	
	(In thousands)		
ESKATA	\$ 1,248	\$ 2,410	\$ (1,162)
A-101 45% Topical Solution	1,526	871	655
JAK inhibitors	11,715	4,887	6,828
Personnel expenses	4,345	2,814	1,531
Change in contingent consideration	866	—	866
Other research and development expenses	4,407	2,234	2,173
Stock-based compensation	3,483	2,521	962
Total research and development expenses	\$ 27,590	\$ 15,737	\$ 11,853

The decrease in costs associated with the development of ESKATA resulted primarily from the filing of our NDA in February 2017 following the completion of clinical trials. Expenses related to A-101 45% Topical Solution decreased primarily due to our Phase 2 clinical trials for the treatment of common warts which were initiated in June 2017 and concluded during the first quarter of 2018. Development expenses for our JAK inhibitors increased due to continued growth in both preclinical and clinical trial expenses as we continue to conduct multiple Phase 2 clinical trials of ATI-501 and ATI-502. The increase in personnel expenses was primarily the result of increased headcount. The increase in stock-based compensation expense was primarily the result of new awards granted after June 30, 2017. The change in contingent consideration was the result of updates to our assumptions related to drug discovery research on our soft-JAK inhibitors, which progressed more quickly than originally planned. Other research and development expenses primarily included expenses 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 six months ended June 30, 2017.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Six Months Ended June 30,		Change
	2018	2017	
	(In thousands)		
Direct marketing and professional fees	\$ 9,010	\$ 1,812	\$ 7,198
Personnel expenses	7,658	825	6,833
Other sales and marketing expenses	5,006	209	4,797
Stock-based compensation	1,927	780	1,147
Total sales and marketing expenses	\$ 23,601	\$ 3,626	\$ 19,975

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

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Six Months Ended		Change
	2018	2017	
		(In thousands)	
Personnel expenses	\$ 3,553	\$ 1,851	\$ 1,702
Professional and legal fees	2,685	1,810	875
Facility and support services	1,208	605	603
Milestone payments	1,500	1,000	500
Other general and administrative expenses	819	440	379
Stock-based compensation	4,616	3,156	1,460
Total general and administrative expenses	\$ 14,381	\$ 8,862	\$ 5,519

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

Other Income, Net

The \$0.7 million increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our financing transactions in 2017, as well as higher yields on those invested balances.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Prior to our acquisition of Confluence in August 2017, we did not generate any revenue. We have financed our operations since inception primarily through sales of our convertible preferred stock, as well as net proceeds from the sale of our common stock in public offerings and a private placement transaction.

As of June 30, 2018, we had cash, cash equivalents and marketable securities of \$164.6 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:

	<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>
	(In thousands)	
Net cash used in operating activities	\$ (43,705)	\$ (22,739)
Net cash provided by investing activities	69,479	5,730
Net cash provided by financing activities	59	19,546
Net increase in cash and cash equivalents	<u>\$ 25,833</u>	<u>\$ 2,537</u>

Operating Activities

During the six months ended June 30, 2018, operating activities used \$43.7 million of cash primarily resulting from our net loss of \$61.4 million, partially offset by changes in our operating assets and liabilities of \$5.9 million, and non-cash adjustments of \$11.8 million. Net cash provided by changes in our operating assets and liabilities during the six months ended June 30, 2018 consisted of a \$2.3 million decrease in prepaid expenses and other current assets and a \$6.3 million increase in accounts payable and accrued expenses, which were partially offset by a \$1.7 million increase in accounts receivable and a \$1.0 million increase in inventory. The decrease in prepaid expenses and other current assets was primarily due to a \$2.0 million Prescription Drug User Fee Act, or PDUFA, fee paid to the FDA in conjunction with the filing of the NDA for ESKATA, for which we received a refund during the six months ended June 30, 2018. The increase in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of June 30, 2018, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of June 30, 2018 primarily included sales and marketing expenses related to the commercial launch of ESKATA in May 2018, as well as expenses related our Phase 2 clinical trials for A-101 45% Topical Solution, ATI-501 and ATI-502. The increases in accounts receivable and inventory were the result of the commercial launch of ESKATA in May 2018. Non-cash expenses of \$11.8 million were primarily composed of stock-based compensation expense.

During the six months ended June 30, 2017, operating activities used \$22.7 million of cash primarily resulting from our net loss of \$27.4 million and by cash used by changes in our operating assets and liabilities of \$1.9 million, partially offset by non-cash adjustments of \$6.6 million. Net cash used by changes in our operating assets and liabilities during the six months ended June 30, 2017 consisted of a \$3.9 million increase in prepaid expenses and other current assets partially offset by a \$2.0 million increase in accounts payable and accrued expenses. The increase in prepaid expenses and other current assets was primarily due to a \$2.0 million PDUFA fee paid to the FDA in conjunction with the filing of the NDA for ESKATA, as well as deposits made for clinical supplies and development activities which were incurred during the second half of 2017. The increase in accounts payable and accrued expenses was primarily due to deposits and expenses incurred, but not yet paid, in connection with the commencement of 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 \$6.6 million were primarily composed of stock-based compensation expense.

Investing Activities

During the six months ended June 30, 2018, investing activities provided \$69.5 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$144.4 million, partially offset by purchases of marketable securities of \$74.2 million, and purchases of equipment of \$0.7 million.

During the six months ended June 30, 2017, investing activities provided \$5.7 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$47.7 million, partially offset by purchases of marketable securities of \$41.5 million and purchases of equipment of \$0.4 million.

Financing Activities

During the six months ended June 30, 2018, financing activities provided \$0.1 million of cash and included \$0.4 million from the exercise of employee stock options, partially offset by \$0.3 million of capital lease payments.

During the six months ended June 30, 2017, financing activities provided \$19.3 million of net proceeds from the sale of 635,000 shares of our common stock in April 2017 pursuant to a sales agreement with Cowen dated November 2, 2016, and \$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 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 LLC, requires public companies to implement specified corporate governance practices that were not applicable to us prior to our IPO. We expect ongoing compliance with these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe our existing cash, cash equivalents and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of our unaudited condensed consolidated financial statements that appear in Item 1 of this Quarterly Report on Form 10-Q based on our current operating assumptions including the commercialization of ESKATA, initiation of Phase 3 clinical trials for A-101 45% Topical Solution for the treatment of common warts, the continued development of ATI-501 and ATI-502 as potential treatments for AA and other indications, and the development of ATI-450 as a potential treatment for psoriasis and other dermatologic conditions. These assumptions may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to 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, to support our discovery efforts, to develop our preclinical compounds, 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.

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

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

Under the assignment agreement with the Estate of Mickey Miller pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of ESKATA or related products at rates ranging in low single-digit percentages of net sales, as defined in the agreement. Under the related Finder's Services Agreement, we have agreed to make aggregate remaining payments of up to \$3.0 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 June 30, 2018, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level.

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 \$2.0 million as of June 30, 2018 and Confluence’s total revenues were \$2.3 million during the six months ended June 30, 2018.

(b) Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting during our fiscal quarter ended June 30, 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*+	Distribution Agreement, by and between the Registrant and McKesson Specialty Care Distribution Corporation, dated as of October 13, 2017, as amended by Amendment No. 1, dated as of March 6, 2018.
10.2*+	First Amendment to License Agreement, by and between The Trustees of Columbia University in the City of New York and the Registrant, dated as of June 27, 2018.
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

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

+ 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: August 3, 2018

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

Date: August 3, 2018

By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer
(Principal Financial Officer)

DISTRIBUTION AGREEMENT

BY AND BETWEEN

MCKESSON SPECIALTY CARE DISTRIBUTION CORPORATION

AND

ACLARIS THERAPEUTICS, INC.

DATED: October 13, 2017

TABLE OF CONTENTS

ARTICLE I: INTERPRETATION AND DEFINITIONS	3
ARTICLE II: SCOPE OF SERVICES	9
ARTICLE III: OBLIGATIONS OF DISTRIBUTOR	10
ARTICLE IV: SHIPPING AND DATA REPORTING	14
ARTICLE V: GOVERNMENT APPROVALS AND COMPLIANCE BY SUPPLIER	17
ARTICLE VI: TERMS OF SALE AND PAYMENT	18
ARTICLE VII: REPRESENTATIONS, WARRANTIES AND COVENANTS	20
ARTICLE VIII: CONFIDENTIALITY; PROPRIETARY RIGHTS; INTELLECTUAL PROPERTY	23
ARTICLE IX: TERM AND TERMINATION	25
ARTICLE X: LIMITATION OF LIABILITY AND INDEMNIFICATION	27
ARTICLE XI : INSURANCE	29
ARTICLE XII: FORCE MAJEURE	30
ARTICLE XIII: NOTICES	31
ARTICLE XIV: GENERAL PROVISIONS	32
EXHIBIT A: PRODUCTS	37
EXHIBIT B: SERVICE FEES	38
EXHIBIT C: RETURNED GOODS POLICY	39
EXHIBIT D: PACKING AND SHIPPING REQUIREMENTS	42
EXHIBIT E: QUALITY ASSURANCE/QUALITY CONTROL PROGRAM	44
EXHIBIT F: PERFORMANCE METRICS	52
EXHIBIT G: DATA REPORTING	53
EXHIBIT I: DISTRIBUTION SERVICE LEVEL	58

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

DISTRIBUTION AGREEMENT

THIS DISTRIBUTION AGREEMENT (the "**Agreement**") is by and between McKesson Specialty Care Distribution Corporation, a Delaware corporation with offices at 10101 Woodloch Forest, The Woodlands, Texas 77380 ("**Distributor**") and Aclaris Therapeutics, Inc., with offices at 101 Lindenwood Drive, Suite 400, Malvern, Pennsylvania 19355 ("**Supplier**") is dated and effective this 13th day of October 2017 (the "**Effective Date**"). Distributor and Supplier are sometimes hereinafter referred to collectively as "**Parties**" and individually as a "**Party**".

WHEREAS, Supplier is licensed to distribute and market those certain products and devices set forth in Exhibit A annexed hereto (collectively referred to herein as the "**Products**") in the Territory; and

WHEREAS, Supplier desires to enter into a relationship with Distributor for the provision of a comprehensive array of distribution services in connection with the Products, including, without limitation, distribution, packing, shipping, finance, account accreditation, call center, data reporting, return and chargeback services (the "**Services**"); and

WHEREAS, Distributor wishes to perform the Services on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I: INTERPRETATION AND DEFINITIONS

1.1 **Definitions.** The terms listed in this Section 1.0 shall, for the purpose of interpreting and construing this Agreement, have the meanings indicated herein.

1.0.1 "**ADR**" has the meaning assigned to such term in Section 5.3.

1.0.2 "**Affiliate**" means a person or entity that directly or indirectly controls, is controlled by, or is under common control with another person or entity, whether directly or through one or more intermediaries. For purposes, hereof "control" shall be deemed to exist when one person or entity: (i) owns fifty percent (50%) or more of the equity of another person or entity; (ii) has the right to receive fifty percent (50%) or more of the dividends or other distributions of profits of another person or entity; or (iii) has the right to elect or select fifty percent (50%) or more of the board of directors, board of managers or other managerial personnel of another person or business entity. "Controlled" and "controls" shall be construed accordingly.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 1.0.3 “**Agreement**” means this Distribution Agreement and any annex, exhibit, attachment or schedule annexed hereto and incorporated by reference herein, and any amendments to any of the same.
- 1.0.4 “**Applicable Laws**” means all state and federal laws, rules, statutes, codes, orders, decrees, permits, consents, approvals, agreements or regulations applicable to the performance by the Parties of their respective obligations under this Agreement, including but not limited to and to the extent applicable to a Party, compliance with the Federal Food, Drug, and Cosmetic Act and the PDMA, as well as their implementing regulations.
- 1.0.5 “**Applicable Permits**” means all permits, authorizations, licenses, certificates, approvals or similar requirements of or from any Government Authority or any other organization having the power to regulate or decide on any matter arising out of or in connection with this Agreement or otherwise having jurisdiction over such matters relating to or connected with the activities under this Agreement.
- 1.0.6 “**Change Order**” has the meaning assigned to such term in [Section 3.15](#).
- 1.0.7 “**Chargeback**” means a reimbursement paid by Supplier to Distributor by means of a credit memorandum or other payment method, of the positive difference between the WAC in effect as of the applicable invoice date of sale of Product to a Customer and the Contract Price negotiated between Supplier and such Customer in effect on such invoice date.
- 1.0.8 “**Claim**” means any claims, demands, litigation, actions, suits, administrative proceedings or causes of action brought or asserted by a third party and any liabilities, judgments, settlements, costs, losses or expenses including attorney’s and expert’s fees and costs of litigation resulting therefrom, and any attorneys’ fees, penalties, damages or Claim paid to any third party.
- 1.0.9 “**Confidential Information**” means and includes all non-published patents, know-how, designs, plans, including product development and marketing plans, cost information, advertising programs, data, software, names and information relating to customers, manufacturers, suppliers, and shippers and all other information designated in writing as confidential and relating to the Products, as well as financial information, plans, strategies, know-how, operations, summaries, notes, analyses and/or studies thereof or relating thereto, and all pricing of Services and Products, and any other information relating to the business of Supplier or Distributor that may be divulged in the course of Supplier and Distributor’s performance of this Agreement, whether written or recorded in electronic or other format and on whatever media. For the avoidance of doubt, Supplier’s designated products, product information, healthcare provider information and customer sales

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

data provided by Supplier to Distributor or collected by Distributor in connection with the provision of Services to Supplier pursuant to this Agreement is considered Supplier's Confidential Information.

- 1.0.10 "Contract Price" means a [***].
- 1.0.11 "CPI" means the Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average published from time to time by the United States Bureau of Labor Statistics or any successor index thereto if the United States Bureau of Labor Statistics ceases the publication of the CPI.
- 1.0.12 "Customer(s)" means any physician practice, buying groups, group purchasing organizations, clinics, pharmacies and hospitals, licensed healthcare professional (including physicians, nurse practitioners or dentists), *provided, however*, that the Parties may agree from time to time in writing (including any such agreement reflected in an exchange of electronic mail) to include or exclude certain entities or classes of entities from the definition of "Customer" set forth herein.
- 1.0.12 "Data Reports" has the meaning assigned to such term in [Section 4.1.1](#).
- 1.0.13 "Data Reporting Service" has the meaning assigned to such term in [Section 4.1.2](#).
- 1.0.14 "Distribution Center" means the location or locations at which Distributor, an Affiliate or a Subcontractor of Distributor will receive, store, and/or ship Products.
- 1.0.15 "Distributor" means McKesson Specialty Care Distribution Corporation and its successors and permitted assigns.
- 1.0.16 "Distributor QA/QC Representative" has the meaning assigned to such term in [Section 2.5.1](#).
- 1.0.17 "Diversion" shall mean: (i) any unauthorized purchase by Distributor of Products from any person or entity other than Supplier; (ii) any sale of Products purchased hereunder outside the Territory by Distributor; or (iii) any sale or transfer of Products into the market by Distributor that have been manufactured by Supplier but have expired, are defective, or have been withdrawn by Supplier from the market. For the avoidance of doubt, nothing herein: (a) prohibits sale of Products by Distributor to licensed distributors and resellers, customers such as closed network or self-warehousing pharmacies who may resell or redistribute Products in compliance with Applicable Laws or any inter or intra divisional or inter or intra affiliate transfers of Product; or (b) requires Distributor to monitor Customers with regard to their sale or use of Products.
- 1.0.18 "Effective Date" is as set forth in the preamble hereto.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 1.0.19 "**Escalation Quotient**" means, for any Year, the quotient of the CPI as of the first day of the current Year divided by the CPI as of the first day of the immediately preceding Year; *provided, however*, that in no event shall the quotient be less than one (1.0) for any particular Year.
- 1.0.20 "**FDA**" means the Food and Drug Administration of the United States or any successor agency thereto.
- 1.0.21 "**Fulfillment Error**" has the meaning given such term in Section 4.04.
- 1.0.22 "**GAAP**" means Generally Accepted Accounting Principles in the United States of America.
- 1.0.23 "**Government Authority**" means any court or tribunal of competent jurisdiction, any state or national agency or any governmental authority, department, legislature, agency, council, department, or official person of any state or national organization that has the power to regulate or decide on any matter arising out of or in connection with this Agreement or which otherwise has jurisdiction over such matters.
- 1.0.24 "**Insolvency**" means that: (i) a Party makes an assignment for the benefit of creditors, or petitions or applies for or arranges for the appointment of a trustee, liquidator or receiver, or commences any proceeding relating to itself under any bankruptcy, reorganization, arrangement, insolvency, readjustment of debt, dissolution or liquidation or similar law of the state in which the insolvent Party is organized or a state in which the insolvent Party conducts business, now or hereafter in effect (collectively "**Bankruptcy Laws**"), or shall be adjudicated bankrupt or insolvent in such a country; or (ii) a Party gives its approval of, consent to, or acquiesces in, any of the following for a period of sixty (60) days: the filing of a petition or application for the appointment of a trustee, liquidator or receiver against that Party; the commencement of any proceeding under any Bankruptcy Laws against that Party; or the entry of an order appointing any trustee, liquidator or receiver; or (iii) a Party is generally unable to pay its debts when due.
- 1.0.25 "**Logistics Contractor**" has the meaning given such term in Section 2.6.
- 1.0.26 "**Party**" means either Supplier or Distributor, depending on the context in which it is used, and "**Parties**" shall mean both Supplier and Distributor.
- 1.0.27 "**PDMA**" means the Prescription Drug Marketing Act of 1987 (as amended by the Prescription Drug Amendments of 1992 ("**PDA**")).
- 1.0.28 "**Products**" are as set forth in Exhibit A, as the same may be amended from time to time by the mutual written agreement of the Parties.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 1.0.29 **"Prudent Industry Practices"** means the practices, methods, specifications, and standards of care, skill, safety and diligence, as the same may change from time to time, but applied in light of the facts known at the time, as are generally applied or utilized under comparable circumstances by experienced and prudent professionals in respect of the pharmaceutical distribution industry in the United States of America. **"Prudent Industry Practices"** does not necessarily mean the best practice, method, or standard of care, skill, safety and diligence in all cases, but is instead intended to encompass a range of acceptable practices, methods, and standards.
- 1.0.30 **"Qualified Customer"** is a Customer who: (i) meets Distributor's customary creditworthiness standards; and (ii) has no history (to Distributor's actual knowledge) of non-payment or late payments for Products.
- 1.0.31 **"Reference Rate"** means the thirty (30) day LIBOR rate. "LIBOR" shall mean the London Interbank Offering Rate per annum (rounded upwards, if necessary, to the nearest 1/16th of 1%) appearing in *The Wall Street Journal*, or if such publication is not available, any successor or similar service for deposits in U.S. Dollars having a thirty (30) day term.
- 1.0.32 **"Renewal Term"** has the meaning given such term in Section 9.0.
- 1.0.33 **"Returned Goods Policy"** has the meaning given such term in Exhibit D.
- 1.0.34 **"Services"** has the meaning given such term in the preamble.
- 1.0.35 **"Service Fee"** has the meaning given such term in Exhibit B.
- 1.0.36 **"Shipping Companies"** has the meaning given such term in Section 2.6.
- 1.0.37 **"Short Dated Product"** has the meaning given such term in Section 4.02.
- 1.0.38 **"Standard Dated Product"** has the meaning given such term in Section 4.02.
- 1.0.39 **"Subcontractor"** means, as applicable, a person or entity engaged by Distributor for the performance of any portion of the Services in accordance with Section 2.6, or a person or entity engaged by Supplier for the performance of any of its obligations hereunder in accordance with the provisions of Section 2.6.
- 1.0.40 **"Supplier"** means Aclaris Therapeutics, Inc. and its successors and permitted assigns in accordance with the provisions of Section 14.3 hereof.
- 1.0.41 **"TAA"** has the meaning given such term in Section 5.5.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 1.0.42 "**Taxes**" means all levies, fees, charges, duties, tariffs and taxes, including sales taxes, value added taxes, use taxes, excise taxes and stamp taxes, imposed by a Government Authority other than income or franchise taxes imposed on or measured by the net income, net profits or capital of Distributor or Supplier, as applicable.
- 1.0.43 "**Term**" shall be as set forth in Section 9.0.
- 1.0.44 "**Territory**" means the forty-eight (48) contiguous United States, the District of Columbia, the Commonwealth of Puerto Rico and the states of Alaska and Hawaii and shall include, solely with respect to shipments of Products to the U.S. Veterans Administration and the U.S. Department of Defense, any location in the world to which such Customer may direct Products be shipped.
- 1.0.45 "**WAC**" means the current wholesale acquisition cost to wholesalers for any of the Products without regard to prompt payment or other discounts, rebates, or Chargebacks.
- 1.0.46 "**Year**" shall be as set forth in Section 9.0.
- 1.1 **Interpretation.** For the purposes of interpreting and construing this Agreement, unless the context indicates otherwise:
- 1.1.1 words denoting gender within this Agreement shall be construed to include any other gender;
- 1.1.2 the word "including" means including without limitation;
- 1.1.3 references to Articles, sections and Exhibits are, unless the context otherwise requires, references to Articles, sections of and Exhibits to this Agreement;
- 1.1.4 Articles, sections and Exhibits headings are for ease of reference only;
- 1.1.5 any reference to a statute, regulation or other legal instrument having the force of law shall be construed as a reference to such statute, regulation or other legal instrument having the force of law as the same may have been, or may from time to time be, amended or re-enacted;
- 1.1.6 words in the singular case shall be construed to include the plural;
- 1.1.7 unless expressly stated otherwise, when a time limit is stated in days, it shall mean calendar days (including weekends and public holidays);
- 1.1.8 the calculation of all dates and periods shall be calculated in accordance with the Gregorian calendar; and

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

1.1.9 provisions including the word "agree", "agreed" or "agreement" require the agreement to be recorded in writing and signed by the agreeing parties.

ARTICLE II: SCOPE OF SERVICES

- 2.0 **Engagement of Distributor.** Supplier engages Distributor to be the exclusive distributor of the Products in the Territory and to perform the Services during the Term. Distributor accepts this engagement and agrees to perform the Services during the Term in conformity with the requirements of this Agreement.
- 2.1 **Limited Distribution.** Distributor shall only sell and/or distribute Product(s) to Qualified Customers. Distributor and Supplier shall periodically review and update the list of Qualified Customers.
- 2.1 **Standard of Performance.** Distributor shall perform the Services (including, without limitation, all storage, handling, shipping and distribution) in accordance with Prudent Industry Practices, all Applicable Laws and the applicable provisions of this Agreement.
- 2.2 **Independent Contractor.** Distributor is an independent purchaser and reseller of the Products. Distributor is an independent contractor of Supplier that has been engaged for the sale and distribution of the Products. No other relationship is intended to be created between the Parties. Nothing herein shall be interpreted as creating any partnership between the Parties, and neither shall have the right to act on behalf of the other except as expressly provided in this Agreement.
- 2.3 **Expenses.** Distributor shall incur no expense chargeable to Supplier, except as may be specifically authorized in advance in writing by Supplier or as may be specifically provided for herein.
- 2.4 **Representative of Supplier.** Promptly after execution of this Agreement, Supplier shall appoint an individual (the "Supplier Representative"), who shall be authorized to act for and on behalf of Supplier concerning the day-to-day administration of this Agreement. Supplier shall notify Supplier in writing upon the appointment of the Supplier's Representative, and of his/her successor(s), if changed.
- 2.5 **Representative of Distributor.** Promptly after execution of this Agreement, Distributor shall appoint an individual (the "Distributor's Representative") who shall be authorized to act for and on behalf of Distributor on all matters concerning the day-to-day administration of this Agreement. Distributor shall notify Supplier in writing upon the appointment of the Distributor's Representative, and of his/her successor(s), if changed.
- 2.5.1 **QA/QC Representative of Distributor.** Promptly after execution of this Agreement, Distributor shall also appoint an individual (the "Distributor QA/QC Representative"), who shall be authorized and empowered to act for and on behalf

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

of Distributor concerning the administration of the quality assurance/quality control system to be established by Distributor pursuant to Section 3.12 hereof. The Distributor QA/QC Representative shall be responsible for and shall be the sole point of contact with respect to quality assurance/quality control matters hereunder. Distributor shall notify Supplier in writing upon the appointment of the Distributor's QA/QC Representative, and of his/her successor(s), if changed.

- 2.6 **Distributor Subcontractors.** Some of the Services to be provided hereunder by Distributor may be performed by Subcontractors engaged by Distributor including: (a) freight forwarding or shipping companies to ship Products ("**Shipping Companies**"); and (b) contractors who provide human resources for logistics services including picking, packing, shipping and returns processing ("**Logistics Contractors**"). Supplier understands and agrees that such Subcontractors are independent contractors with exclusive control over their respective employees, and not agents, employees or authorized representatives of Distributor. At all times during the Term, Distributor shall be responsible for payments to Subcontractors, including without limitation, freight charges and any other charges or compensation as required by Applicable Laws. For the avoidance of doubt, and notwithstanding the preceding sentences, Distributor agrees that it is not relieved of any of its obligations hereunder, including any obligations performed by any Distributor Subcontractor, and Distributor shall remain responsible for any breach of the terms of this Agreement by any such Subcontractor.

ARTICLE III: OBLIGATIONS OF DISTRIBUTOR

- 3.0 **Sales.** Distributor shall:
- 3.0.1 offer, sell, and ship the Products to Qualified Customers;
 - 3.0.2 store and warehouse the Products in suitable storage facilities and distribute the Products, each in accordance with: (i) Applicable Laws; (ii) Prudent Industry Practices; and (iii) Product specifications and labeling of which Distributor has been previously apprised in writing by Supplier;
 - 3.0.3 reasonably endeavor to cause Supplier to be apprised of information that comes to Distributor's attention that indicates a Product manufacturing/packaging defect, Product contamination, or Product tampering;
 - 3.0.4 provide service incident to the sale of the Products by Distributor consistent with Prudent Industry Practices which shall include, without limitation, distribution, order entry, invoicing and collection, and appropriate Supplier service and support;
 - 3.0.5 maintain trained and qualified personnel for selling the Products to Customers or prospective Customers;

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 3.0.6 furnish to Supplier such information as required by Section 4.1 and any other information and reports as shall be mutually agreed upon by the Parties in writing (including as may be provided for in electronic mail) from time to time; and
- 3.0.7 cause its employees and agents to materially comply with all sales policies of Supplier and its suppliers of which Distributor has been previously apprised in writing.
- 3.1 **Governmental Approvals; Compliance.**
- 3.1.1 Distributor shall, at its expense, obtain and maintain all Applicable Permits that may be necessary to permit the sale and distribution of the Products by Distributor to Customers within the Territory, but Distributor disclaims any responsibility for any Applicable Permits required to be procured, obtained or maintained by Supplier or any of its suppliers or Subcontractors.
- 3.1.2 Distributor shall comply with Applicable Laws applicable to Distributor's performance of the Services, including, but not limited to, those with respect to the marketing, sale or distribution of the Products, including the Federal Food, Drug and Cosmetic Act and the PDMA.
- 3.2 **Recall or Market Withdrawal.** Supplier may elect to recall or withdraw any of the Products from the market because of: (i) a request, instruction or other action of any Governmental Authority; or (ii) a determination by Supplier for reasons associated with safety, quality or technical issues directly affecting the Products or otherwise.
- 3.2.1 In the event of such a withdrawal or recall, Supplier shall promptly provide Distributor with reasonable advance written notice of such recall or withdrawal (such notice to include the reasons for such recall or withdrawal and any notices or other communications from any Governmental Authority in relation thereto).
- 3.2.3 Distributor shall comply with Supplier's reasonable instructions regarding the recall or withdrawal of Products from Distributor's stock, Customers, or from other persons or entities requested by Supplier, and shall use commercially reasonable efforts to retain records sufficient to effectuate such recall or withdrawal pursuant to Supplier's recall or withdrawal policy, including, but not limited to, maintaining records that document the lot numbers of Products stored or distributed by Distributor (including to which Customers Products were distributed).
- 3.2.4 Supplier shall reimburse Distributor for all its demonstrable direct and indirect costs incurred in connection with such recall or withdrawal, except to the extent such costs are directly attributable to a failure of Distributor to comply with and adhere

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

to any instructions of Supplier or Applicable Laws relating to the storage, handling, shipping or distribution of the affected Products.

- 3.2.4 Distributor shall maintain all records relating to recalled or withdrawn Product during the Term and for a period of at least two (2) Years thereafter. Distributor shall notify Supplier in writing prior to any destruction or other permanent disposition of any records retained under this Section 3.2.4, and, if requested by Supplier, shall transfer such records to Supplier at its expense.
- 3.3 **Audits, Records and Inspection.** During the Term and for such longer period as may be required by Applicable Law, Distributor shall maintain records in accordance with GAAP, consistently applied, which shall document its performance and compliance in accordance with this Agreement. Upon not less than ten (10) business days' prior written notice, Supplier may perform an audit of the foregoing records at its' sole expense during the Term and for one (1) calendar year after the termination of this Agreement (or such longer period as may be required by Applicable Law). Such audits shall be performed during regular business hours using the services of a third-party independent professional auditor mutually acceptable to the Parties. Distributor shall not unreasonably withhold or condition its approval of any auditor acceptable to Supplier. No auditor shall be allowed to perform an audit without first executing a confidentiality agreement reasonably acceptable to the Distributor and Supplier. Any such audit shall be completed within thirty (30) calendar days of the date that Distributor provides the available documentation to the auditor. Any information obtained by the audit shall be kept confidential and shall not be disclosed to a third party unless disclosure is required by Applicable Laws. Supplier may not conduct more than one (1) audit in each calendar year and the scope of the audit shall be limited to records relating to the immediately preceding twelve (12) calendar months.
- 3.4 **Customer Returns.** Unless mutually agreed to in writing by the Parties (including by electronic mail), Distributor shall not accept the physical return of Products from Customers on behalf of Supplier. If Supplier requests Distributor to issue to Customers credits for returns which are managed by Supplier, or its designee, such credits will be issued by Distributor in accordance with Distributor's standard procedures for third party customer returns. Distributor shall be entitled to charge a non-refundable fee of [***] for the processing of each return authorization or returned order at the time any return is processed by Distributor.
- 3.6 **Business Continuity Planning.** Distributor shall maintain a business continuity plan in place to avoid or reasonably mitigate disruptions of the sales and distribution of the Products.
- 3.7 **Storage.** Distributor shall maintain the Products at one or more Distribution Centers in accordance with Applicable Laws and the Product specifications, both in storage and in transit, including such refrigeration and/or climate controlled storage as may be: (i) dictated

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

by Prudent Industry Practices; and (ii) reasonably specified in the relevant Product's labeling and package insert(s).

- 3.8 **Distribution of Samples.** Supplier may, from time to time, request that Distributor deliver or cause to be delivered one or more units of samples of Products to Suppliers and to sales representatives of Supplier. Upon receipt of any such request, Distributor shall undertake to effect such deliveries promptly and with all reasonable diligence, *provided, however*, that for each units of samples of Product so delivered by Distributor, Distributor shall be entitled to charge Supplier a delivery and processing fee of [***]. Notwithstanding the foregoing, if Distributor delivers or causes to be delivered one or more units of samples of Products to Suppliers and to sales representatives of Supplier at the same time that Distributor ships units of Product that are not samples, such processing fee shall not be charged to Supplier.
- 3.9 **Distribution of Replacements.** Supplier may, from time to time, authorize Distributor to ship replacement Product to Suppliers for quality or other reasons. Upon receipt of any request, Distributor shall undertake to effect such deliveries promptly and with all reasonable diligence, provided however, that for each package of replacement Product so delivered by Distributor, Distributor shall be entitled to charge Supplier a delivery and processing fee of [***]. For calculating Service Fees associated with replacement Products, a no-cost or reduced-cost replacement Product shipped by Supplier to Distributor will be subject to the same Service Fee as if the replacement Product was purchased by Distributor at WAC.
- 3.10 **Credit Card Fees.** Supplier shall reimburse Distributor for any credit card fees, charges or associated costs incurred in connection with the sale and delivery of Products. Such fees, charges and costs shall be invoiced on a monthly basis.
- 3.11 **Supplier Performance Metrics.** Distributor shall endeavor to achieve the Supplier Performance Metrics set forth in Exhibit F annexed hereto.
- 3.12 **Quality Assurance/Quality Control (QA/QC).** Distributor shall institute a quality assurance/quality control system to demonstrate compliance with the requirements of this Agreement and Applicable Laws and Applicable Permits.
- 3.13 **Adverse Event and Other Reports.** If Distributor receives any written report of any adverse event or other safety-related event, or any quality complaints associated with the Products, Distributor will use commercially reasonable efforts to cause any such report to be delivered to Supplier promptly after receipt thereof. If Distributor receives follow-up information with respect to any adverse event or Product quality complaint after initial reporting of an adverse event or Product quality complaint, Distributor shall use commercially reasonable efforts to report such new information to Supplier promptly after receipt thereof.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 3.14 **Pharmacovigilance.** All pharmacovigilance activities for the Products, including submission of reports to any Government Authority and verification of and follow-up for reports provided by Distributor are the sole and exclusive responsibility of Supplier. Notwithstanding anything else contained herein, Supplier acknowledges that: (i) Distributor does not have a centralized reporting function or formalized pharmacovigilance program; (ii) as a result Distributor may not be able to notify Supplier of all adverse events and Product quality complaints; and (iii) nothing herein shall require Distributor to implement any such centralized reporting function or pharmacovigilance program.
- 3.15 **Change Orders.** Subject to Applicable Laws and Applicable Permits, Supplier may request changes in the Services through the issuance of a Change Order (a “**Change Order**”). If Distributor reasonably believes that the Supplier has requested or required services which are not otherwise provided for herein, Distributor may propose a Change Order to Supplier. A Change Order signed by Supplier and Distributor indicates an agreement to the changes in the Services and increases in the fees and charges payable hereunder reflected in such Change Order. Supplier and Distributor shall use their good faith efforts to agree on the price and time adjustments for such changes prior to the issuance of such Change Order. If, however, the Parties cannot agree on the adjustment to be made, then Distributor shall nevertheless proceed to execute the changed Services described in the Change Order and shall charge for such changed Services in accordance with Exhibit B and Supplier shall pay such charges in accordance herewith.

ARTICLE IV: SHIPPING AND DATA REPORTING

4.0 **Quantity and Delivery.**

- 4.01 Supplier shall be responsible, at its cost, for delivering or causing to be delivered to Distributor the amount of Products ordered by Distributor within Distributor’s stated receiving hours of 6am to 12pm CST Monday through Friday with “First Expiration, First Out” methodology. Distributor shall be responsible for determining the amount of the Products to be shipped to Distributor at such location or locations as may be designated by Distributor; *provided however*, that, upon receipt of such orders from Distributor, if Supplier is unable to deliver the quantities of Product requested at the time requested, it will promptly notify Distributor in writing and will provide a schedule for delivery of such amounts. In the event of any insufficiency in the supply of Products, Supplier and Distributor shall cooperate to determine an optimum allocation of Products. All Products ordered by Distributor shall be delivered FOB Distributor’s designated delivery location(s) and Supplier shall be responsible for all insurance and shipping costs until the Products are delivered and accepted at such location. All costs of shipping from such designated location, including from such designated location to a Distribution Center, shall be borne by Distributor. Title and risk of loss for each shipment of

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Products shall pass to Distributor upon arrival and acceptance pursuant to Section 4.04 hereof at Distributor's designated delivery location.

- 4.02 All Products shall have a shelf life of not less than [***] from the date of shipment (“**Standard Dated Product**”). Notwithstanding the foregoing, Supplier may ship Products with an earlier expiration date of at least [***] from the date of shipment (“**Short Dated Product**”) provided that: (i) Supplier does not have a sufficient quantity of Standard Dated Product to fill Distributor's orders; (ii) Supplier provides Distributor with written notice of its shortage of Standard Dated Product as promptly as practicable after becoming aware of such anticipated shortage; (iii) Supplier communicates in writing to Distributor in advance of each shipment that includes Short Dated Product that such shipment includes Short Dated Product; and (iv) the Short Dated Product will be subject to return by Supplier for full credit. Supplier shall ensure that all Products are delivered to Distributor within seven (7) days of the date of order entry. Any reasonable expenses incurred by Distributor to the extent resulting from a late shipment by Supplier shall be borne by Supplier. Notwithstanding anything to the contrary in this Agreement, Supplier may reject any purchase orders for Products that Supplier, in its sole discretion, believes would cause Distributor's inventory of such Product to exceed the reasonable inventory thresholds for the applicable Products.
- 4.03 Following delivery to Distributor's designated location(s), the costs of storage shall be borne by Distributor. The costs of shipping Products from Distributor's warehouse to Customers shall be borne by Distributor. All shipping material shall comply with the Applicable Laws and the packing and shipping requirements set forth in Exhibit E hereto (if any) and with such other shipping specifications as the Parties shall from time to time agree.
- 4.04 Upon receipt of each shipment of Products at the designated delivery location or locations, Distributor shall promptly inspect it, or cause it to be promptly inspected, for any apparent physical damage, shortages, or inconsistencies with the packing list, inventory and bill of lading that is to accompany each shipment. Distributor may reject any shipment or portion thereof of Products received in damaged condition, products shipped in error, Products shipped in quantities more than what was ordered, or Products which do not comply with Section 4.02 or 7.1 (each, a “**Fulfillment Error**”). Distributor shall notify Supplier in writing within five (5) business days after each such delivery of Products of any Fulfillment Error and of its rejection of the applicable shipment or shipments, unless such Fulfillment Error is not apparent, in which case Distributor shall notify Supplier in writing within five (5) business days after discovery thereof. Any Products not so rejected shall be deemed to have been accepted by Distributor.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 4.05 Products properly rejected by Distributor in accordance with [Section 4.04](#) shall be returned by Distributor to Supplier at Supplier's sole risk and expense in accordance with the Returned Goods Policy. Supplier shall promptly replace any properly rejected Products with the same Products and any such substitute Product shall be subject to the same shipment, delivery and acceptance criteria set forth in [Section 4.02](#) and [Section 4.04](#), but in each case, subject to the provisions of [Section 4.06](#). Notwithstanding anything to the contrary, including without limitation, the Return Goods Policy, Fulfillment Errors will be replaced, or credited at Distributor's full purchase price, as applicable, without the assessment by Supplier of any restocking fees and the cost of shipment and any insurance and risk of loss associated therewith, will be borne solely by Supplier.
- 4.06 If Supplier disagrees with the rejection of Product by Distributor, it will so notify Distributor within seven (7) days of receipt of such rejection notice. If the Parties cannot agree as to whether a shipped Product has been properly rejected, the Parties shall mutually designate an independent party to determine whether the relevant Product is damaged, defective or wrong, the findings of which shall be binding on the Parties, absent manifest error. All costs and expenses of such third party shall be borne by the Party whose position is determined to have been in error. If any Product is ultimately agreed or found not to be damaged, defective or the wrong item and if Supplier has replaced such Product, then Distributor shall be obligated to pay the shipping costs associated with the return of the rejected Product and the delivery of the replacement Product.
- 4.07 Distributor will manage the on-hand supply and safety-stock of Products. Distributor shall, at all times, maintain an on-hand inventory at its Distribution Centers sufficient, in Distributor's discretion, to satisfy its projections of orders of Products from Qualified Customers without any further deliveries from Supplier. Distributor will perform physical inventory counts for on-hand boxes of Products and determine monthly utilization.
- 4.08 Distributor acknowledges that Supplier may modify its Returned Goods Policy from time-to-time in its reasonable discretion upon at least thirty (30) days advanced written notice, *provided, however*, that any modification of the Returned Goods Policy that may have a negative financial impact on Distributor will require Distributor's written consent, with such consent not to be unreasonably withheld.
- 4.1 **Data Reporting.**
- 4.1.1 Subject to Applicable Laws, during the Term, Distributor shall provide [***] to Supplier pursuant to the specifications set forth in [Exhibit G](#) (the "Data Reports"). Distributor shall communicate as needed with Supplier regarding delivery of and data elements contained in each Data Report specified in [Exhibit H](#).

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Communications may involve but not be limited to discussions on Data Report delivery or content error resolution.

- 4.1.2 Distributor agrees to not disclose any data related to warehouse Product withdrawal, Product sales, or other Product data included in the Data Reports to: (i) any third party pharmaceutical data reporting services provider (each a “**Data Reporting Service**”); or (ii) to any Affiliate or other third-party, which to Distributor’s actual knowledge, intends to disclose such data to a Data Reporting Service, without Supplier’s prior written consent (which shall not be unreasonably withheld or conditioned), unless in each case, such data is aggregated with similar data from other suppliers and manufacturers in a manner that does not specifically identify either the Supplier or any of the Products. For the avoidance of doubt, nothing herein is intended to limit Distributor’s right to notify a third-party that, pursuant to this Agreement, Distributor is bound by certain restrictions relating to the disclosure of data relating to the Products.

ARTICLE V: GOVERNMENT APPROVALS AND COMPLIANCE BY SUPPLIER

- 5.0 **Governmental Permits.** Supplier shall, at its expense, obtain and maintain, and shall ensure that its’ suppliers and Subcontractors obtain and maintain, all Applicable Permits that may be necessary to permit the performance by Supplier of its obligations hereunder within the Territory.
- 5.1 **Compliance with Applicable Laws.** Supplier shall comply in all material respects with all Applicable Laws that are applicable to Supplier, including, but not limited to, those with respect to the marketing, sale or distribution of the Products, including the Federal Food, Drug and Cosmetic Act and the PDMA.
- 5.3 **Authorized Distributor of Record.** To the extent not already so provided for as of the Effective Date, Supplier shall promptly arrange for the manufacturer of each of the Products to designate Distributor and any Affiliate so designated by Distributor as an Authorized Distributor of Record (“**ADR**”) for the Products in accordance with the PDMA.
- 5.4 **Labeling and Purchasing.** Supplier shall ensure that the Products are labeled and packaged in accordance with applicable FDA labeling requirements and other requirements of Applicable Laws.
- 5.5 **Trade Agreement Act.** Supplier understands that any of the Products offered for sale to the United States Government under this Agreement are subject to the United States Trade Agreements Act (“**TAA**”) (19 U.S. C. 2501, et seq.). Supplier agrees to provide TAA certifications and related information applicable to the Products in a manner mutually agreed to by the Parties. If Supplier is not the actual manufacturer of a Product supplied to

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Distributor, Supplier certifies that it has appropriate information on file from the manufacturer of the Product to support the TAA certification provided to Distributor.

- 5.6 **Product Marking Requirements.** Supplier certifies that all the Products sold to Distributor pursuant to this Agreement are marked (e.g., "Made in Germany") with the country of origin as required by 19 U.S.C. 1304 and related regulations issued by U.S. Customs and Border Protection. Supplier certifies that the Products are compliant with the U.S. Federal Trade Commission's rules governing the use of "Made in the USA" or similar phrases.

ARTICLE VI: TERMS OF SALE AND PAYMENT

6.0 **Sale of Product.**

- 6.0.1 **Price and Terms of Sale.** Distributor shall remit payments for the Products on a net [***] calendar day basis for payment by check or on a net [***] day basis for payment by EFT. All remittances by Distributor will be transmitted electronically, in accordance with then current NACHA guidelines. Distributor will manage billing and collection of payments from Suppliers incident to the provisions of this Agreement.
- 6.0.2 **Discount Pricing.** For any discount of any kind or character (including rebates and guarantees that operate as a discount to the WAC) given by Supplier to a Customer, Distributor shall have the right to charge back that amount to Supplier.
- 6.0.3 **Changes to the WAC.** Supplier may change the WAC price for Products in its sole discretion at any time. Supplier shall notify Distributor in writing (including via email or other electronic communication) by no later than 2 PM CST on the business day immediately preceding the effective date of any Product WAC change. Any inventory held by Distributor as of the effective date of any WAC reduction will be eligible for a price adjustment for each unit of Product on hand at, in transit to, or on order by Distributor on the date of the price reduction in an amount equal to the difference between: (i) the reduced WAC; and (ii) the WAC in effect before the price reduction.
- 6.0.4 **Changes to the Contract Price.** Supplier may amend the Contract Price for Products in its' sole discretion at any time upon seven (7) business days prior written notice to Distributor.
- 6.1 **Payment for the Services.** The fees for the Services (and any other fees or charges due pursuant to the provisions of this Agreement) shall be as set forth in Exhibit B. Distributor shall invoice Supplier for all sums due hereunder on a calendar monthly basis. Supplier shall pay each such invoice thirty (30) calendar days after the date of the invoice. Any invoice for fees for Services that are not subject to a good faith dispute by Supplier and

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

which remains unpaid for more than thirty (30) days from date of invoice will be deducted by Distributor from any amounts owed by Distributor to Supplier. Should Supplier in good faith contest the validity, reasonableness or accuracy of any invoice or part thereof submitted to it for payment, it shall pay the undisputed portion thereof and notify Distributor in writing within five (5) business days of its receipt of the same explaining in detail the reasons for its refusal to honor the invoice in whole or in part. Upon resolution of the dispute, the disputed sum that is properly due (if any) shall be promptly paid with the next invoice due to be paid to Distributor. Past due and undisputed invoices shall bear interest at the lesser of: (i) the Reference Rate; or (ii) the maximum rate permitted by Applicable Law. For the avoidance of doubt, the due date for any amount that has been disputed but was ultimately determined to have been properly payable shall be the date on which such amount was originally due to be paid by Supplier. The Parties agree and acknowledge that: (a) unless otherwise agreed in writing, the fees provided hereunder will be Distributor's sole, full and complete form of compensation provided by Supplier for the Services; (b) the fees for services and have been negotiated at arm's-length, in good faith by the Parties; (c) Supplier has determined that service fees represent fair market value for the Services; (d) the fees are not intended in any way as a payment related to a drug formulary or drug formulary activities and have not been negotiated or discussed between the Parties in connection with any such drug formulary or formulary activities; (e) the fees are not intended to constitute a discount or other form of compensation that must be included in best price, AMP, or ASP reporting; and (f) the fees are not intended in any way as remuneration for referrals or for other business generated. For avoidance of doubt, nothing herein precludes Distributor from taking into consideration all its revenues, including the service fees earned under this Agreement, when pricing its products or services to Customers.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

6.2 **Taxes.**

- 6.2.1 **Taxes for Services.** Supplier shall pay, or, as applicable, reimburse Distributor on demand for all Taxes that are imposed on Distributor by a Government Authority in connection with the performance of the Services, *provided, however,* Distributor shall be fully responsible for and is not entitled to any reimbursement for any taxes imposed upon Distributor's net income. If Supplier is exempt from the payment of any applicable sales and/or use Taxes or has a direct payment permit with respect to such Taxes, Supplier shall provide Distributor with a copy of the certificate or permit, duly executed and issued by the appropriate Government Authority. Request for payment and/or reimbursement of any Taxes shall be included in the invoices tendered to Supplier pursuant to Section 6.1 hereof. Each request for reimbursement and/or payment shall be separately stated thereupon as a line item and shall be contemporaneously supported by reasonable documentation reflecting the Taxes to be reimbursed and/or paid.
- 6.2.2 **Taxes on Product Sales.** Distributor shall pay, or, as applicable, reimburse Supplier on demand for all Taxes that are imposed on Supplier by a Government Authority in connection with the sale of Products to Distributor hereunder, *provided, however,* Supplier shall be fully responsible for and not entitled to any reimbursement for any taxes imposed upon Supplier's net income. If Distributor is exempt from the payment of any applicable sales and/or use Taxes or has a direct payment permit with respect to such Taxes, Distributor shall provide Supplier with a copy of the certificate or permit, duly executed and issued by the appropriate Government Authority. Request for payment and/or reimbursement of any Taxes shall be included in the invoices tendered to Distributor pursuant to Section 6.1 hereof. Each request for reimbursement and/or payment shall be separately stated thereupon as a line item and shall be contemporaneously supported by reasonable documentation reflecting the Taxes to be reimbursed and/or paid. Notwithstanding anything to the contrary, Distributor will not be liable to pay, or as applicable, reimburse Supplier for any Taxes relating to the sale of Products by Supplier to Distributor which cannot in accordance with Applicable Laws be fully passed on by Distributor to Customers when the Products are sold by Distributor to Customers.

ARTICLE VII: REPRESENTATIONS, WARRANTIES AND COVENANTS

7.0 Each of the Parties warrants and represents that:

- 7.0.1 It is duly organized and validly existing under the laws of the State of its formation, with full legal right, power and authority to enter into and to perform its obligations hereunder;

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 7.0.2 It has duly authorized, executed and delivered this Agreement and this Agreement constitutes a legal, valid and binding obligation, enforceable against it in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally, by general equitable principles or by principles of good faith and fair dealing;
- 7.0.3 Neither the execution nor delivery by it of this Agreement, nor the performance by it of its obligations hereunder conflicts with, violates or results in a breach of any Applicable Laws, or conflicts with, violates or results in a breach of any term or condition of any order, judgment or decree or any agreement or instrument to which it is a party or by which it or any of its properties or assets are bound, or constitutes a default thereunder;
- 7.0.4 No approval, authorization, order, consent, declaration, registration or filing with any Government Authority is required for the valid execution and delivery of this Agreement; and
- 7.0.5 It has no knowledge of any action, suit or proceeding, at law or in equity, before or by any court or governmental authority, pending against it, in which an unfavorable decision, ruling or finding would adversely affect the performance by it of its obligations hereunder, or that, in any way, would materially adversely affect the validity or enforceability of this Agreement.
- 7.0.6 **Where required by Applicable Laws, Distributor and Supplier shall each abide by the requirements of 41 CFR §§ 60-1.4(a), 60-300.5(a) and 60-741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, or national origin. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, national origin, protected veteran status or disability.**
- 7.0.8 It qualifies as an authorized trading partner of the other Party and has implemented a system to support suspect product verification and disposal, each as may be defined or required by the Drug Supply Chain Security Act ("DSCSA") (21 U.S.C. §§ 360eee et seq.).
- 7.1 Supplier represents and warrants and covenants, as applicable, to Distributor that:
- 7.1.1 It holds the right to distribute, sell and market the Products in the Territory, including the right to grant to Distributor the rights or licenses granted hereunder;

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 7.1.3 The Products are and will be sold to Distributor in compliance with Applicable Laws;
 - 7.1.4 Products will not be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act ("FDCA"), or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the FDCA, or will be an article which may not, under the provisions of Sections 404 or 505 of said Act, be introduced into interstate commerce;
 - 7.1.6 To the knowledge of Supplier, the Products do not infringe upon the patents, copyrights, trademarks or any other intellectual property rights of any third party;
 - 7.1.8 There is no existing agreement, understanding, letter of intent or other commitment or arrangement of any kind between it and any other person, firm, or corporation, concerning the distribution of Products which conflict with the rights granted hereunder or the provision to Supplier of services for Products similar to the Services discussed herein; and
 - 7.1.9 During the Term, Supplier will not grant any other third party any rights to distribute the Products in the United States which conflict with the rights granted hereunder.
- 7.2 Distributor represents and warrants and covenants, as applicable, to Supplier that:
- 7.2.1 As of the Effective Date, neither Distributor nor any of its then-current officers, directors or employees has been debarred pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA") or been excluded from participating in a federal health care program, including without limitation the Medicare or Medicaid programs. If Distributor or any of its then-current officers, directors and employees is or are subsequently debarred under the FDCA or excluded from a federal health care program, Distributor agrees promptly to notify Supplier of such action;
 - 7.2.3 Distributor has obtained, and shall maintain, all necessary Applicable Permits to perform its obligations hereunder;
 - 7.2.4 The Products will be stored and distributed by Distributor in compliance with Applicable Laws and the Product specifications and Product labeling; and
 - 7.2.5 It will comply with the applicable provisions of 42 U.S.C. Section 1320a-7b and 42 C.F.R. § 1001.952(h) in connection with all sales of Product by Distributor to Customers, and none of its personnel performing any of the Services are excluded

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 7.3 **EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY HERETO MAKES ANY OTHER EXPRESS WARRANTIES OR REPRESENTATIONS, STATUTORY WARRANTIES, OR ANY IMPLIED WARRANTIES OR REPRESENTATIONS, OF ANY KIND WHATSOEVER RELATING EITHER TO THE PRODUCTS OR THE SERVICES, INCLUDING (WITHOUT LIMITATION) ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALL SUCH OTHER WARRANTIES AND REPRESENTATIONS ARE HEREBY DISCLAIMED.**

ARTICLE VIII: CONFIDENTIALITY; PROPRIETARY RIGHTS; INTELLECTUAL PROPERTY

- 8.0 **Confidential Information.** The Parties acknowledge that the Confidential Information comprises valuable trade secrets and is proprietary and the exclusive property of the disclosing Party and its Affiliates. During the Term and for a period of one (1) Year thereafter, the receiving Party shall hold the Confidential Information supplied by the disclosing Party hereunder in strict confidence, and shall use such Confidential Information solely for the purposes of performing its obligations hereunder. The receiving Party may only disclose Confidential Information to those directors, officers, employees, attorneys, contractors, agents and Affiliates (each a "**Representative**") who have a need to know and who are bound by obligations of confidentiality and non-use with respect to such Confidential Information that are at least as restrictive as those set forth herein. Each of the Parties agrees to: (i) advise their Representatives of the proprietary nature of the Confidential Information and the terms and conditions of this Agreement requiring that the confidentiality of such information be maintained; and (ii) use reasonable safeguards to prevent unauthorized use by such Representatives. Each Party shall be responsible for any breach of this Agreement by its respective Representatives.
- 8.1 **Agreement Confidentiality.** Neither Party hereto shall disclose the terms of this Agreement to any other person or entity other than such Party's Representatives, or as may otherwise be required by Applicable Laws. In the event a Party reasonably believes it is required by Applicable Laws to disclose any terms of this Agreement, prior to any proposed disclosure of any of the terms of this Agreement, such Party shall allow and reasonably assist the other Party in taking any action to lawfully prevent or limit any such disclosure.
- 8.2 For the purposes of this Agreement, "Confidential Information" shall not include:
- 8.2.1 Confidential Information which is or becomes public knowledge (through no fault of the Parties or their Representatives in violation hereof); or

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 8.2.2 Confidential Information which is lawfully made available to a Party by an independent third party (and such lawful availability can be properly demonstrated); or
- 8.2.3 Confidential Information which is already in a Party's possession at the time of initial receipt from the other Party (and such prior possession can be demonstrated by competent evidence); or
- 8.2.4 Confidential Information which is independently developed by a Party or its Representatives and such independent development can be demonstrated by competent evidence.
- 8.3 **Disclosures Required by Applicable Law.** Either Party may disclose Confidential Information which is required to be disclosed by Applicable Laws or order of any Government Authority to be disclosed; *provided, however*, that the Party so disclosing shall give the other Party advance written notice to permit it to seek a protective order or other similar order with respect to the Confidential Information and, thereafter, shall disclose only the minimum Confidential Information required to be disclosed in order to comply, whether or not the other Party seeks or obtains any such protective or other similar order. Notwithstanding the foregoing, information disclosed as set forth in this Section 8.3 shall not be disclosed to any other third party without the prior written consent of the disclosing Party.
- 8.3 **Injunctive Relief.** Each Party acknowledges and agrees that its breach of the confidentiality and non-use obligations set forth herein would cause irreparable harm to the disclosing Party which would not be fully compensable by payment of money damages alone, and that in the event of such a breach or threatened breach the disclosing Party shall be entitled to seek equitable relief (including without limitation injunctive relief), without the necessity of proving actual damages or posting a bond. Such equitable relief shall be in addition to and not in lieu of any other relief available to the disclosing party at law or in equity.
- 8.4 All Confidential Information which either Party or any of its Representatives shall obtain or to which either Party or any such Representative shall be given access pursuant to or in connection with this Agreement, shall be and remain the sole property of the disclosing Party, and the receiving Party shall have no rights or interests (except as expressly provided herein) to or in such Confidential Information. Notwithstanding the foregoing, information generated, compiled or stored by Distributor reflecting the purchase and resale of Products to Customers, including the information included in the Data Reports, constitutes the Confidential Information of Supplier and, subject to Section 4.1.2, Supplier will be entitled to utilize all such information for its business purposes.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 8.5 Immediately upon the expiration or earlier termination of this Agreement, the receiving Party shall, at the other Party's option, return to the disclosing Party, or provide a certificate of one of its executive officers as to the destruction of all Confidential Information (including all copies thereof) then in the possession of the receiving Party or any of its Representatives. Each Party may retain one (1) archival copy of such Confidential Information.
- 8.6 Distributor shall not use the Confidential Information of Supplier for any other purpose other than for the purpose of Distributor providing the Services to Supplier pursuant to this Agreement. For the avoidance of doubt, Distributor may not disclose, transfer, sell or otherwise use Supplier's Confidential Information for any purpose other than purpose of performing its obligations under this Agreement, without the prior written consent of Supplier.
- 8.7 **Intellectual Property.** Neither Party shall obtain any rights to any trademarks, service names or service marks of the other Party, nor shall either Party conduct any activity or make any statement, written or oral, which in any manner infringement upon the use of such trademarks, service names or service marks by the other Party. The infringing party shall indemnify and hold harmless the non-infringing party against any action, claim or loss arising from any such infringement, including all costs and reasonable attorneys' fees.

ARTICLE IX: TERM AND TERMINATION

- 9.0 **Term.** The term of this Agreement shall commence on the Effective Date and continue in full force and effect for a period of three (3) Years, unless otherwise terminated as set out in this Agreement (the "**Term**"). For purposes of this Agreement, a "**Year**" is a period of twelve (12) consecutive calendar months. If the Term or any renewal term commences on any day other than the first day of a calendar month, such month shall be deemed to constitute a complete calendar month. At the end of the Term, this Agreement will automatically renew for additional consecutive one (1) Year renewal terms (each, a "**Renewal Term**") unless either Party provides the other with written notice of non-renewal of this Agreement at least ninety (90) calendar days before the end of the Term or any Renewal Term, or unless otherwise terminated as provided herein.
- 9.1 **Termination for Convenience.** Either Party hereto has the right to terminate this Agreement for its convenience at any time by not less than ninety (90) calendar days' prior written notice to the either Party. If a Party terminates the Agreement under this Section 9.1, the terminating Party shall pay all direct winding-down fees, noncancelable and nonrefundable costs and expenses reasonably incurred through the effective date of termination by the non-terminating Party in connection with the termination in accordance with such terminating Party's instructions, as substantiated by documentation reasonably satisfactory to the terminating Party.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

9.2 **Termination for Breach.**

9.2.1 Either Party may terminate this Agreement in the event of a material breach by the other Party of any material obligation of this Agreement on thirty (30) days' prior written notice to the other, specifying the nature of the breach, unless such other Party shall cure such default within such sixty (60) day period

9.2.2 Notwithstanding the provisions of Section 9.2.1, either Party may terminate this Agreement on written notice with immediate effect upon the occurrence of any of the following to or by the other Party:

9.2.2.1 a transfer or assignment of this Agreement without the prior written consent of the non-transferring Party not otherwise permitted or provided for by the provisions of this Agreement; or

9.2.2.2 the Insolvency of the other Party; *provided, however*, that the Party which is not Insolvent may waive such termination right.

9.3 **Rights of Parties on Termination or Expiration.** The following provisions shall apply to any termination or expiration of this Agreement; *provided, however*, that the termination or expiration of this Agreement for any reason shall not affect any obligations accrued or amounts owed hereunder before the date of such expiration or termination:

9.3.1 Distributor shall cease all sales and other activities under this Agreement, but shall fulfill all Supplier orders submitted prior to the effective date of termination;

9.3.2 Each Party shall return to the other Party or destroy all Confidential Information, and all summaries, compendiums, reports, analyses and other materials prepared with the use of such Confidential Information, in accordance with Section 8.4;

9.3.3 All Supplier orders for Products received after the effective date of termination will be promptly referred to Supplier;

9.3.4 Each Party will cease holding itself out as being in any way connected with the other Party;

9.3.5 The Parties shall cooperate to prepare a reasonably detailed, written transition and wind-down plan to coordinate an orderly cessation of the activities provided for under this Agreement; and

9.3.6 Other than with respect to matters in dispute, all indebtedness of the Parties to each other shall become immediately due and payable without further notice or demand.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

ARTICLE X: LIMITATION OF LIABILITY AND INDEMNIFICATION

- 10.0 Distributor shall indemnify, defend and hold harmless Supplier and its Affiliates and its and their shareholders, directors, officers, employees, agents and representatives and insurers (the “**Indemnified Persons**”) from and against all Claims that may arise directly or indirectly as a result of: (i) the negligence or willful or wrongful acts or omissions of Distributor; (ii) a breach by Distributor of any of its representations or warranties under this Agreement; (iii) the failure of Distributor to comply with Applicable Laws; or (iv) Distributor’s storage, handling or distribution of the Products, except to the extent such Claim arises directly or indirectly as a result of any of the matters for which Supplier is providing indemnification pursuant to Section 10.2.
- 10.1 Supplier shall promptly notify Distributor in writing of any Claim for which indemnity may be sought and will thereafter keep Distributor reasonably informed with respect thereto. Supplier shall fully cooperate with Distributor and shall permit Distributor to conduct and control the defense and disposition of such Claims, *provided, however*, that Distributor shall not admit fault on behalf of Supplier without Supplier’s prior written consent. Distributor shall promptly assume, at its cost and expense, the sole defense of such Claim through counsel selected by Distributor and reasonably acceptable to Supplier, *provided that* in the event that Distributor does not assume the defense on a timely basis or reasonably maintain the defense, then, without prejudice to any other rights and remedies available to Supplier under this Agreement, Supplier may take over such defense with counsel of its choosing at Distributor’s cost and expense. If the Distributor assumes the defense of any Claim as provided in this Section 10.1, Supplier shall provide reasonable assistance to Distributor in its efforts to investigate and defend the Claim, including, without limitation, providing reasonable access to the indemnifying party to such documentary evidence and witnesses as are available to Supplier. If a conflict of interest arises, which, under applicable principles of legal ethics prevents a single legal counsel from representing both Supplier and Distributor; Supplier may take over its defense with counsel of its choosing at Distributor’s cost and expense.
- 10.2 Supplier shall indemnify, defend and hold harmless Distributor, its Affiliates and its and their respective shareholders, directors, officers, employees, agents and representatives from and against all Claims that may arise directly or indirectly as a result of: (i) the negligence or willful or wrongful acts or omissions of Supplier; (ii) a breach by Supplier of any of its representations or warranties under this Agreement; (iii) the failure of Supplier to comply with Applicable Laws; (iv) injury to a patient resulting from the purchase, use, consumption or recall of any Product, whether or not involving a defect in a Product, its labeling or packaging; or (v) the infringement by the Product or its packaging of the patent, copyright, trademark, trade secret or other intellectual property of any other person or entity, except to the extent such Claim arises directly or indirectly as a result of any of the matters for which Distributor is providing indemnification pursuant to Section 10.0, *provided, however*, that with respect to Claims arising pursuant to Section 10.2 (v),

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Supplier shall indemnify, defend and hold harmless Distributor, its Affiliates and its and their respective shareholders, directors, officers, employees, agents and representatives without regard to the negligence of any of them.

- 10.3 Distributor shall promptly notify Supplier in writing of any Claim for which indemnity may be sought and will thereafter keep Supplier reasonably informed with respect thereto. Distributor shall fully cooperate with Supplier and shall permit Supplier to conduct and control the defense and disposition of such Claims, *provided however*, that Supplier shall not admit fault on behalf of Distributor without Distributor's prior written consent. Supplier shall promptly assume, at its cost and expense, the sole defense of such Claim through counsel selected by Supplier and reasonably acceptable to Distributor, *provided that* in the event that Supplier does not assume the defense on a timely basis or reasonably maintain the defense, then, without prejudice to any other rights and remedies available to Distributor under this Agreement, Distributor may take over such defense with counsel of its choosing at Supplier's cost and expense. If Supplier assumes the defense of any Claim as provided in this Section 10.3, Distributor shall provide reasonable assistance to Supplier in its efforts to investigate and defend the Claim, including, without limitation, providing reasonable access to the indemnifying party to such documentary evidence and witnesses as are available to Distributor. If a conflict of interest arises, which, under applicable principles of legal ethics prevents a single legal counsel from representing both Supplier and Distributor; Distributor may take over its defense with counsel of its choosing at Supplier's cost and expense.
- 10.4 Neither Party shall, without the written consent of the other Party: (i) settle or compromise any Claim without including as an unconditional term thereof the giving of an unconditional release with respect to all liability under such Claim, or consent to the entry of any judgment which does not include a dismissal with prejudice of the indemnified party and indemnifying party; (ii) settle or compromise any Claim in any manner that may adversely affect the other Party other than as a result of money damages or other monetary payments; or (iii) settle or compromise any Claim in any manner that includes an admission of fault or liability on the part of the other Party.
- 10.5 **No Claims.** EXCEPT WITH RESPECT TO INDEMNIFICATION FOR THIRD PARTY CLAIMS UNDER THIS AGREEMENT, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY HERETO BE LIABLE TO THE OTHER FOR ANY: (i) LOST PROFITS; (ii) LOSS OF PROSPECTIVE COMPENSATION OR UNJUST ENRICHMENT; (iii) GOODWILL OR LOSS THEREOF; OR (iv) CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OF ANY KIND OR CHARACTER, WHETHER ARISING IN TORT, CONTRACT, INDEMNITY, STRICT LIABILITY OR ANY OTHER THEORY OF RECOVERY.
- 10.6 **Maximum Liability.** Distributor's total aggregate liability to Supplier arising out of or in connection with this Agreement and the Services, from any and all causes, whether based

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

on contract, tort (including negligence), strict liability, or any other cause of action, including claims for indemnification under Section 10.1, shall in no event exceed the aggregate of the fees paid to Supplier.

ARTICLE XI : INSURANCE

- 11.0 **Supplier Insurance.** Supplier agrees that during the Term it shall carry and maintain in full force and effect at its own expense the following insurance policies with insurers currently rated A-VII or better by A.M. Best:
- 11.0.1 Commercial General Liability insurance including coverage for premises and operations, products and completed operations, contractual liability, bodily injury, property damage, and personal injury and advertising injury with a minimum policy limit of [***] per occurrence and [***] in the annual aggregate. This coverage may be satisfied through a combination of Commercial General Liability and Commercial Umbrella or Excess policies; and
- 11.0.2 Products Liability insurance including bodily injury and property damage for all products and work supplied under this Agreement with a minimum policy limit of [***] per occurrence and [***] in the annual aggregate.
- 11.1 **Certificates of Insurance and Additional Insureds.** Each Party agrees to furnish the other Party with certificates of insurance for all required policies of insurance. Each Party shall cause insurer(s) to endorse all insurance policies to name the other Party and its Affiliates as Additional Named Insureds. Each Party shall use best efforts to provide the other Party with thirty (30) days advance written notice of any material changes of the required insurance coverage, cancellation or termination in coverage prior to policy expiration.
- 11.2 **Claims-Made Policies.** If any insurance policy is a “claims-made” policy, then such claims made policy shall be kept in force for not less than three (3) years immediately following termination or expiration of this Agreement. Evidence of successive policy periods shall be made by the annual issuance of a certificate of insurance to the other Party. Alternatively, each Party and/or each Party’s subcontractors shall purchase a three year “tail” policy including the same or broader coverage for any claim or circumstance occurring or taking place during the Term of this Agreement without regard to whether the claim is brought during the term of the insurance policy.
- 11.3 **Policy is Primary Cover.** All insurance policies afforded by a Party and a Party’s subcontractors shall be primary to and not contributing to any other insurance, self-insurance or captive insurance maintained by the other Party or its Affiliates.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 11.4 **Subrogation Waiver.** Each Party shall cause each insurer of coverage required under this Article 11 to endorse each insurance policy to waive its subrogation rights against the other Party and its Affiliates.
- 11.5 **Separation of Insureds.** As applicable, each Party shall include a separation of insured provisions under the Commercial General Liability, Excess and/or Umbrella Liability and Business Auto Liability insurance policies with no cross liability or cross suits exclusions.
- 11.6 **Satisfaction of Limits.** The limits required under this Agreement can be satisfied through any combination of primary and umbrella/excess insurance. No provision contained herein shall be construed as prohibiting either party from self-insuring in whole or part the insurance obligations contained herein.
- 11.7 **No Relief from Obligations.** Approval or acceptance of any of a Party's insurance policies by the other Party shall not relieve such first Party of any obligations contained herein, including such Party's obligations as part of this Agreement, whether claims are within, outside or in excess of such Party's policy limits, and regardless of solvency or insolvency of the insurer(s) that issues such coverage. Such insurance shall not preclude the other Party from taking any actions that are available to it under any provision of this Agreement or otherwise under applicable law. The failure to provide certificates or add the other Party or its Affiliates as Additional Insureds in accordance with this Article 11 will not release a Party in any manner of any liability arising under this Agreement.
- 11.8 **Distributor Insurance.** Distributor, at its sole cost and expense, shall procure and maintain such policies of general and professional liability and other insurance as are consistent with industry standards and are necessary to insure it and its employees against any type (not necessarily amount) of claim for damages arising by reason of personal injuries or death occasioned directly or indirectly by the providing of the Services by Distributor or with respect to their obligations under this agreement including, but not limited to, storage and distribution of the Products. The insurance coverage by Distributor shall not be construed to create a limit on Distributor's liability with respect to its' indemnification of Supplier. Distributor shall provide not less than thirty (30) days' notice of cancellation or any material modification of the foregoing policy of insurance. Distributor shall deliver or cause to be delivered to Distributor a certificate of insurance evidencing the foregoing coverages within thirty (30) days of the Effective Date.

ARTICLE XII: FORCE MAJEURE

- 12.0 **Force Majeure.** Other than with respect to any obligation to make payments hereunder, neither Party hereto shall be in default hereunder by reason of any failure or delay in the performance of any obligation under this Agreement where such failure or delay demonstrably arises out of any cause beyond the reasonable control of the Party claiming relief, including, without limitation, storms, floods, other acts of nature, fires, explosions,

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

shortage of raw materials, riots, war or civil disturbance, national strikes or other industry wide labor unrest, embargoes and other governmental actions, including the U.S. Food and Drug Administration decision not to approve Supplier's products that are to be distributed by Distributor pursuant to this Agreement, and any governmental regulations, that would prohibit the supply or distribution of Products or the performance of a Party's obligations hereunder, delays in transportation, inability to obtain necessary labor, supplies, or manufacturing facilities, *provided, however*, that in no event shall any event of Force Majeure operate to delay or otherwise excuse any payment obligations hereunder. The Party claiming to be delayed because of an event of Force Majeure shall promptly notify the other Party in writing of any actual or anticipated delays and take all necessary steps to avoid, overcome or end delays without additional cost to the other Party. The notice shall contain particulars as to the nature of the claimed event of Force Majeure, the date of commencement of the event and the anticipated date on which the event is anticipated to cease. The Party claiming to be delayed because of an event of Force Majeure shall take all reasonable steps to mitigate the effect of delays. Such steps shall include advanced planning and contingency planning. In the event of any event of Force Majeure extending for a period of more than thirty (30) consecutive calendar days and which materially and adversely affects the ability of Distributor to perform the Services provided for hereunder, Distributor shall have the right to submit a Change Order to Supplier for an equitable adjustment to the fees provided for in Exhibit B hereto to reflect the costs attributable to such Force Majeure event. Notwithstanding the foregoing, either Party has the right to terminate this Agreement in accordance with Section 9.1.

ARTICLE XIII: NOTICES

- 13.0 All notices pertaining to this Agreement shall be delivered in person, sent by certified mail, delivered by air courier, or transmitted by facsimile or electronic transmission and confirmed in writing (sent by air courier or certified mail) to a Party at the address or facsimile number shown in this Agreement, or such other address or facsimile number as a Party may notify the other Party from time to time. Notices delivered in person, and notices dispatched by facsimile prior to 4:00 PM, recipient's time, Monday through Friday (legal holidays excepted), shall be deemed received on the day sent. All other facsimiles and notices shall be deemed to have been received on the business day following receipt; *provided, however*, that if such day falls on a weekend or legal holiday, receipt shall be deemed to occur on the next business day. Notices may also be transmitted electronically between the Parties *provided that* mutually acceptable arrangements are made in advance to facilitate such communications and provide for their security and verification.

If to Distributor:

McKesson Specialty Care Distribution Corporation
10101 Woodloch Forest
The Woodlands, TX 77380

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Attention: General Counsel
Telephone: XXXXXXXX
Facsimile: XXXXXXXX

With a copy, which shall not constitute notice, to:
McKesson Corporation
One Post Street
San Francisco, CA 94104
Attention: General Counsel
Telephone: XXXXXXXX
Facsimile: XXXXXXXX

If to Supplier:

Aclaris Therapeutics, Inc.
101 Lindenwood Drive
Suite 400
Malvern, PA 19355
Telephone: 484-324-7933

With a copy, which shall not constitute notice, to:

Attention: Kamil Ali-Jackson

Chief Legal Officer

Aclaris Therapeutics, Inc.
101 Lindenwood Drive
Suite 400
Malvern, PA 19355
Email: XXXXXXXX

ARTICLE XIV: GENERAL PROVISIONS

- 14.0 **Entire Agreement.** This Agreement, together with the Exhibits and all written amendments, modifications and supplements thereto constitute the entire agreement between the Parties and all prior negotiations, proposals and writings pertaining to this Agreement or the subject matter thereof, are hereby superseded excluding any Confidentiality Agreements between the parties. No modification of this Agreement will be effective unless in writing and signed by both Parties.
- 14.1 **Severability.** In the event that any provision of the Agreement or the documents and instruments contemplated hereby is held by court of competent jurisdiction to be invalid, prohibited or unenforceable for any reason, unless narrowed by construction, the

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Agreement and the documents and instruments contemplated hereby shall be construed as if such invalid, prohibited or unenforceable provision had been more narrowly drawn so as not to be invalid, prohibited or unenforceable, or if such language cannot be drawn narrowly enough to satisfy such court, the court making any such determination shall have the power to modify in scope, duration or otherwise any such provision, but only to the extent necessary to make such provision or provisions enforceable in such court, and such provision then shall be applicable in such modified form. No narrowed construction, court modification, or invalidation of any provision of the Agreement and the documents and instruments contemplated hereby shall affect the construction, validity, or enforceability of such provision or of the Agreement and the documents and instruments contemplated hereby in any jurisdiction other than that upon which the decision of the court of competent jurisdiction shall govern.

- 14.2 **Assignment.** This Agreement may not be assigned to any person, firm, partnership, corporation or other entity (including by operation of law, judicial process or otherwise) without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party hereto may assign this Agreement, or any or all of the rights and obligations hereunder, to: (a) any of its Affiliates or (b) a third party who acquires the assets or stock of either Party but such assignment will not operate to discharge or otherwise relieve any assigning Party from its obligations hereunder. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns.
- 14.3 **Counterparts.** This Agreement may be executed simultaneously in several counterparts and by facsimile, each of which shall be an original and all of which shall constitute but one and the same instrument. 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.
- 14.4 **Not For Benefit Of Third Parties.** This Agreement and each and every provision hereof and thereof are for the exclusive benefit of the Parties hereto and not for the benefit of any third party.
- 14.5 **Applicable Law.** This Agreement shall be governed and controlled as to validity, enforcement, interpretation, construction, effect and in all other respects by the internal laws of the State of Delaware applicable to contracts made in that State.
- 14.6 **Waiver.** Neither Party's failure to insist on performance of any term, condition, or

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

instruction nor failure to exercise any right or privilege or its waiver of any breach, shall thereafter be construed to constitute a waiver of such term, condition, instruction, right or privilege. No consent or waiver, expressed or implied, by a Party to the performance by the other Party or of any breach or default by the other Party of its obligations hereunder shall be deemed or construed to be a consent or waiver to or of any other breach or default in the performance by such other Party of the same or any other obligations of such other Party hereunder. The giving of consent by a Party in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance. No waiver of any rights under this Agreement shall be binding unless it is in writing and signed by the Party waiving such rights.

14.7 **Dispute Resolution.**

14.7.1 **Administrative Committee Procedure.** If any dispute arises on any matters concerning this Agreement, either Party may initiate the dispute resolution procedures of this Section 14.7 by providing written notice to the other Party of the existence and nature of the dispute. The dispute shall be referred to representatives of each Party who shall attempt to resolve the dispute and if they are unable to do so, it will then be referred to senior management of both Parties. To aid the negotiation by the Parties' senior managers, the representatives shall promptly prepare and exchange memoranda stating the issues in dispute and their positions, summarizing the negotiations which have taken place and attaching relevant documents. If such senior managers can resolve the dispute, such resolution shall be reported in writing to and shall be binding upon the parties. If such senior managers cannot resolve the dispute within fifteen (15) days, or such other time as the representatives may mutually agree, then either Party may exercise its other rights under Sections 14.7.2 and 14.7.3.

14.7.2 **Judicial Process.** The procedures specified in this Section 14.7 shall be the sole and exclusive procedures for the resolution of claims, disputes and controversies between the Parties arising out of or relating to this Agreement or the breach thereof.

14.7.3 **Consent to Jurisdiction.** **EACH OF THE PARTIES HEREBY AGREES THAT ANY ACTION REFERRED TO JUDICIAL PROCESS UNDER OR RELATING TO THIS AGREEMENT SHALL BE INSTITUTED IN THE FEDERAL COURTS THEN SITTING IN THE STATE OF DELAWARE AND IN NO OTHER FORUM AND EACH OF THE PARTIES HEREBY IRREVOCABLY CONSENTS TO SUCH JURISDICTION AND IRREVOCABLY WAIVES ANY OBJECTIONS, INCLUDING, WITHOUT LIMITATION, ANY OBJECTION TO THE LAYING OF VENUE BASED ON THE GROUNDS OF FORUM NON CONVENIENS, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY SUCH**

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

ACTION OR PROCEEDING IN SUCH RESPECTIVE JURISDICTIONS. THE FOREGOING IS WITHOUT PREJUDICE TO THE RIGHT OF ANY PREVAILING PARTY TO SEEK ENFORCEMENT OF ANY JUDGMENT RENDERED IN A COURT IN ANY JURISDICTION WHERE THE LOSING PARTY OR ITS PROPERTY MAY BE LOCATED.

- 14.7.4 **Obligations to Pay Charges.** Pending the resolution of the dispute, each Party shall continue to perform the applicable provisions of this Agreement and each Party shall continue to pay all charges required in accordance with the applicable provisions of this Agreement.
- 14.8 **Headings.** Any headings used herein are for convenience in reference only and are not a part of this Agreement, nor shall they in any way affect the interpretation hereof.
- 14.9 **Construction.** Each Party has participated to a significant degree in the preparation of this Agreement. No provision of this Agreement shall be construed against any Party based on that Party having been, or been deemed, the "drafter."
- 14.10 **Amounts.** All amounts of money in this Agreement are denominated in United States of America Dollars.
- 14.11 **Further Assurances.** Each Party hereto agrees that they will without further consideration execute and deliver such other documents and take such other actions as may be reasonably requested by the other Party to consummate more effectively the transactions and agreements contemplated hereby.
- 14.12 **Survival.** The following provisions of this Agreement, as well as the provisions of this Agreement which by their nature are intended to survive the termination, cancellation, completion or expiration of this Agreement, shall continue as valid and enforceable obligations of the Parties notwithstanding any such termination, cancellation, completion or expiration.

IN WITNESS WHEREOF, Supplier and Distributor have caused this instrument to be executed by their duly authorized employees, as of the day and year first above written.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

DISTRIBUTOR

**MCKESSON SPECIALTY CARE
DISTRIBUTION CORPORATION**

By: ___/s/ Layne H Martin_____

Printed

Name: _Layne H Martin_____

Date: ___10/16/17_____

Title: ___Vice President/GM_____

SUPPLIER

ACLARIS THERAPEUTICS, INC.

By: _____/s/ Neal Walker_____

Printed

Name: ___Neal Walker_____

Date: ___10/16/17_____

Title: _____President & CEO_____

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT A: PRODUCTS

ESKATA™ (hydrogen peroxide) topical solution (40%)

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT B: SERVICE FEES

For Specialty Distribution Services and Logistics Services provided by McKesson Specialty Health Distribution and McKesson Specialty 3PL Services, hereunder Supplier (Aclaris Therapeutics) shall pay to Specialty Distributor an amount (the "Fee"), which shall be equal to [***] WAC for the Product, multiplied by the total units of Product purchased by the Specialty Distributor pursuant to this Agreement each month.

Additional fees include the following:

Description	Amount (US\$)
Credit Card Transactions	[***]
Dating	[***]

Pricing is based on [***] days on hand inventory level, and up to an additional 30 days of dating into the market. Inability of Supplier to meet inventory and dating terms agreed upon with the Specialty Distributor and Logistics Services Provider precludes continuation of services.

The following examples are for dating illustration purposes only:
[***]

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT C: RETURNED GOODS POLICY

McKesson's product returns policy applies to returns made by Customers who participate in McKesson Return Programs processed through McKesson's designated third party returns processor. Supplier shall send return policies or information pertaining to supplier's returns to XXXXXXXX.

Unsaleable/Outdated Returns

Customer Returns

McKesson Customers have a variety of programs to manage their product returns. Customers may choose a direct relationship with a third party returns processor whereas McKesson will administer issuing returns credits received from Supplier to the customer.

McKesson offers alternative return programs to Customers which are managed by the McKesson Reverse Logistics group. For these programs, the return policies follow the same guidelines as our DC returns. Suppliers will receive a monthly consolidated debit memo from McKesson's designated third party returns processor processed for each customer GPO.

Processing of Returns

McKesson's designated third party returns processor offers a valuable, streamlined service to the supply chain. Products from McKesson DCs and Customers who participate in McKesson Return Programs are aggregated at this central point for the Supplier and one convenient invoice for each program is prepared monthly. Many other services are, or can be provided, including extensive data analysis and local destruction of products. An appropriate fee will be assessed to the Supplier for such services used.

Third Party Returns processes are as follows:

- When product is available for return at the designated processing location, the Supplier will be notified with a debit memo. The debit memo which also serves as the request for return authorization or product disposition request.
- The debit will be generated at current WAC price and may include return processing and handling fees, per piece.
- If Supplier authorizes automatic destruction of product at the third party returns processor, McKesson will reduce the processing fee. (see fee schedule).
- Supplier agrees to issue product return credit at current WAC price at the time of return notification.
- Any return credit payment issued, if less than the debit memo amount requested, will require the submission of a short payment form (SPF) via the returns portal to explain the variance, which shall accompany Supplier credit memo.
- Unsaleable products debited to the Supplier and held at McKesson's designated third party returns processor will be destroyed within 60 days of request for return authorization if no response is received. The return deduction will not be subject to re-valuation and repayment.
- All products returned in full case/cartons and opened or unopened individual containers may be returned for credit.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- o Partial individual containers may be returned for credit.
- o Refrigerated product may be returned for credit.
- o All item categories (RX, OTC, Controlled, Class II) may be returned for credit.
- o Product is eligible for return six months prior to product expiration date and up to 12 months after expiration date.
- o McKesson does not pay supplier handling charges or restocking fees.
- o Due to Supplier request and/or McKesson discretion, McKesson reserves the right to block customer returns back to McKesson DCs.
- o Customers may return product directly to Supplier or designated third parties. Suppliers who do not issue credit or remit payment directly to customer will be subject to additional processing fees if McKesson is responsible for issuing credit to the individual pharmacy or customer (see Third Party Credits). Alternate return processes have been implemented to reduce inefficiencies in the supply chain, and, if approved by McKesson and they are utilized, this processing charge may be waived.
- o Hazardous items, as deemed by the EPA or DOT, will not be accepted from customers without proper reimbursement from Suppliers on disposition.
- o Product shipped to McKesson with less than 12 months dating which is consistently distributed with short dating, will be processed for return for credit at supplier's current WAC price, when product is rendered submitted for returnable.

Return Debit Memo/Credit Reconciliation

McKesson will generate a return debit made available on the supplier portal to serve as notification of a return request. Supplier agrees to manage their account on the supplier portal to identify debits posted. Supplier agrees to issue credit by posting a credit in the portal or click the VIC (vendor internal credit) link to resolve the debit. Should supplier issue credit less than the amount requested on the return debit, supplier agrees to complete McKesson's Returns Short Pay Form explaining the different of the requested value.

Should a dispute result from the supplier credits issued due to product quality, quantity, or otherwise defined policies. These disputes may result in secondary audit deductions. McKesson agrees to notify supplier of such disputes through McKesson's Supplier Resource Center (supplier portal) identifying the claim as "denied" returns claims.

McKesson reserves the right to request additional reconciliation or product quality evidence to understand reasons for suppliers' non issuance of credit. McKesson may deny suppliers product dispute claim within 30 days of the supplier issuing a short pay form through McKesson's supplier portal noting the reason for such denial and additional information requested to support the suppliers claim. McKesson commits not to request such product dispute evidence frivolously.

Inventory purchased from Supplier that expires before sold into the market place is eligible for return to Manufacturer for a full credit.

McKesson DCs Saleable Inventory, Overstock Inventory and Product Shipped to McKesson in Error

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Saleable product returned by McKesson to Supplier may occur due to:

- o Products shipped in error.
- o Excess inventory on new items and other marketing programs that do not yield forecasted sales.
- o Excess saleable products resulting from loss by Supplier of contract-priced sales.
- o Excess saleable products resulting from McKesson loss of customer business
- o Products discontinued by supplier where as demand does not support the sell-through of inventory on hand.
- o Marketability of the products is limited as a result of an act or omission of Supplier.
- o Products subject to an injunction or governmental order or regulation which limits the marketability of the product in any way.
- o Supplier requests a product or certain lot #s of a product to be completely withdrawn from a market or from the entire marketplace.
- o Any products received damaged will be returned to the Supplier, priced as invoiced and include any associated shipping or disposition expenses.
- o Supplier agrees to credit McKesson the current WAC price associated with all products within ten (10) days from the date product is received at Supplier's warehouse or Supplier's designated disposition facility.
- o Supplier agrees not to charge McKesson any fees or other charges associated with such returns including, and without limitation to, restocking or handling charges, unless McKesson agrees to such conditions on receiving the returns authorization from the Supplier.
- o In the event that a supplier informs McKesson customers that product is available with better dating than the oldest salable product in McKesson's warehouses, McKesson reserves the right to make a direct exchange from the supplier of the older product for the newer product.

Discontinued Product

Discontinued product is identified as any item that Supplier has communicated is no longer available for McKesson to purchase or product packaging changes or any change that requires new NDC or UPC.

Supplier agrees to provide communication to McKesson's national buyer, at least 90-days prior to formal trade discontinuation notification, to support inventory balancing to the lowest possible level of inventory,

Any product McKesson owns inventory for the greater of 90 days after formal Supplier discontinue notification, or after reasonable product demand has subsided, product will be considered for return to the Supplier. McKesson shall receive return credit at current WAC including any associated shipping expenses.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT D: PACKING AND SHIPPING REQUIREMENTS

The identification and counting of Product is performed by scanning the Product bar codes/identifiers on the cases, cartons or containers. The packing list is reference only as a tool for verification and discrepancy resolution.

The following shipping guidelines are recommended to insure receiving accuracy:

- Distributor generally references the packing list only to assist in the accuracy of receiving Product.

NOTE: Distributor's buyer does not see the packing slip. Therefore, any message regarding Product availability or expected shipping delays should be communicated separately to the buyer.

- Each packing list should have Distributor's PO number clearly noted and in a human readable font. The PO number should be included using HDMA's standard bar code format.

- Supplier's name, Supplier shipping address, DEA number and the Supplier's account number assigned by Distributor clearly noted on the package.

- The shipping packing list should list the status of ALL Products ordered on Distributor's PO:

¾ It should clearly list items and their quantity that are backordered, cancelled or shipped from another shipping point.

¾ It should clearly state as to whether to keep the PO open to receive further shipments in the event of back orders or in the event that Product is being shipped on the same PO from more than one distribution location.

- The ship to information should be clear and accurate.

- Note clearly the number of containers shipped and as well as the number of containers that have multiple items repacked into them.

- The list of Products shipped should have all information necessary to make it easy to identify them with the containers in the shipment. It is preferred that Product be listed in alphabetical order to support sorting processes.

- Package placards noting special Product information are recommended:

¾ Short Dated Product Policy: case placard noting "best dating available" for short dated Product (Product with less than 12 months' shelf life) is suggested.

NOTE: Product Dating Policy: Supplier shall obtain permission to ship Product that does not hold at least 12 months' shelf life to expiration. Such Product delivered without this required dating is subject to refusal or return to Supplier due to insufficient Product dating requirement. Communication with Distributor's buyer is required to facilitate receiving of all short-dated Product.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- ¾ Product requiring refrigeration for immediate handling on receiving.
- Tender delivery of Product in eaches, not in terms such as one pallet or one skid, which may lead to receiving errors such as quantity accuracy resulting in shortage claims on payment of the invoice.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

McKESSON QUALITY AGREEMENT

by and between

McKesson Specialty Distribution LLC [MSH]

4100 Quest Way

Memphis TN, 38115

and

Aclaris Therapeutics, Inc. [Rx Manufacturer/Customer]

640 Lee Rd., Suite 200

Wayne, PA 19087

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

1.0 Term of Quality Agreement

- 1.1 The Effective Date of this Quality Agreement shall be the date of last signature (“Effective Date”) as it appears in the Quality Agreement Approvals block in this Agreement.
- 1.2 MSH and/or Rx Manufacturer/Customer may terminate this Quality Agreement upon thirty (30) days written notice to the other party. Upon termination of this agreement, “Other Agreements” must be reviewed to determine effects of it Terms.
- 1.3 This Quality Agreement constitutes the written contract as required by FDA Good Manufacturing Practices between MSH and the Rx Manufacturer/Customer.

2.0 Purpose of Quality Agreement

- 2.1 This Quality Agreement outlines the responsibilities of MSH and the Rx Manufacturer/Customer regarding the quality assurance of receiving, storing and shipping of pharmaceutical drugs/medical devices to be shipped to the Rx Manufacturer/Customer customers.

3.0 Scope of the Quality Agreement

- 3.1 Unless otherwise specified in this Quality Agreement, this Agreement applies to all **pharmaceutical drugs/medical devices** received at MSH located at 4100 Quest Way Memphis TN from Rx Manufacturer/Customer for distribution to their customers.
- 3.2 Unless otherwise specified in this Agreement, no other McKesson locations are authorized to be used for the distribution of Rx Manufacturer/Customer pharmaceutical drugs/medical devices.

4.0 Other Related Agreements Pertaining to the Rx Manufacturer/Customer

- 4.1 This Quality Agreement, in addition to all other agreements between MSH and Rx Manufacturer/Customer, if any, (other agreements; “Supply Agreement,” “Trade Agreement,” “Market Agreement,” Commercial Agreement “Distribution Agreement”) regarding the subject matter hereinto, if there are any conflicts between the terms of this Quality Agreement and the “other agreements,” this Quality Agreement shall be binding.
- 4.2 Warranties, liabilities, insurance, and other legal matters shall not be stipulated in this Agreement.

5.0 Amendments to Quality Agreement

- 5.1 This Quality Agreement is subject to review and revise every two (2) years from the effective date or in the event of significant changes to processes, pharmaceutical drugs/medical devices and/or systems.
- 5.2 This Quality Agreement may be amended by mutual consent of both parties. If an amendment to this Quality Agreement is accepted, the amended Quality Agreement must be circulated for internal review and approval by MSH and Rx Manufacturer/Customer.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

5.3 Amendment notation shall document in the Amendment Block in this agreement.

6.0 Quality Agreement Contact List

6.1 MSH shall document appropriate contact person and the contact information responsible for the execution of this Quality Agreement in the Contact List block in this Agreement.

6.2 Rx Manufacturer/Customer shall document appropriate contact person and the contact information responsible for the execution of this Quality Agreement in the Contact List block in this Agreement.

7.0 Definitions

7.1 **Complaint:** Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product after it is released for distribution.

7.2 **GMP (Good Manufacturing Practices)** is sometimes referred to as "**cGMP**"(Current Good Manufacturing Practices): "c" stands for "current," reminding manufacturers that they must employ technologies and systems which are up-to-date to comply with the regulation GMP. GMP is a system for ensuring that **pharmaceutical drugs/medical devices** and/or services are consistently produced and controlled per quality standards.

7.3 **GDP (Good Distribution Practices):** Facility practices which ensures that pharmaceutical drugs/medical devices and/or services are consistently stored, transported and handled under suitable conditions as required by appropriate FDA, Drug Supply Chain Security Act (DSCSA), and U.S. Pharmacopeia (USP) Regulations/Standards.

7.4 **Management:** Executive responsibility means those senior employees of a manufacturer who have the authority to establish or make changes to the quality policy and quality system.

7.5 **Medical devices:** is any instrument, apparatus, appliance, software, material, or other article—whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application—intended by the manufacturer to be used for human beings for:

7.5.1 Diagnosis, prevention, monitoring, treatment, or alleviation of disease

7.5.2 Diagnosis, monitoring, treatment, alleviation, or compensation for an injury or handicap

7.5.3 Investigation, replacement, or modification of the anatomy or of a physiological process

7.5.4 Control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means

7.6 **Nonconformity:** The nonfulfillment of a specified requirement

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- 7.7 **Quality Agreement:** Is a document that defines both specific quality parameters for a project AND which party is responsible for the execution of those parameters. The level of detail may vary depending on the developmental stage of the project
- 7.8 **Qualified Person:** one who, “by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training and experience, has successfully demonstrated his/her ability to perform his/her task related to the distribution of pharmaceutical drugs/medical devices applicable SOPs, FDA, DSCSA and/or States BOP regulations.
- 7.9 **Quality Policy:** means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
- 7.10 **Quality Management System (QMS):** QMS means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. QMS systematic actions to ensure pharmaceutical drugs/medical devices and/or services will satisfy given requirements for quality per the terms and conditions of this Quality Agreement and applicable laws and regulations.
- 7.11 **Pharmaceutical drug:** (also referred to as medicine, medication, or simply as drug) is a drug used to diagnose, cure, treat, or prevent disease.
- 7.12 **Product Recall:** Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

8.0	Quality Agreement Tables of Responsibilities	MSH	Rx Mfger/Customer	NA
8.1 Qualified Person and Management				
a)	Maintain updated SOPs, WIs, and Forms to support appropriate FDA, DSCSA, and USP	X	X	
b)	Maintain robust Audit Program	X	X	
c)	Retain Qualified Person and Management to execute QMS	X	X	
d)	Staff affected by the Agreement shall be appropriately trained on applicable GMP/GDP requirements including but not limited to the specific holding and transportation conditions	X		
e)	Maintain training records	X		
f)	Maintain Business Continuity Plan	X		

8.2 Compliance		MSH	Rx Mfger/Customer	NA
a)	Comply with appropriate FDA, DSCSA, and USP Regulations and Standards applicable to distribution operations	X		
b)	Maintain licenses from States' Board of Pharmacy [equivalent agencies], and NABP - Verified-Accredited Wholesale Distributors (VAWD) holding and distribution of pharmaceuticals, in compliance with regulations.	X		
c)	Review and approval Document Change Requests and CAPAs.	X		
d)	Investigate non-conformance via CAPA process	X		
e)	Notification of Document Change Requests and CAPAs to Rx Mfger/Customer of mutual interest.	X		
f)	Routine or 'For Cause' audits of McKesson		X	
g)	Notification of FDA inspection at McKesson when the inspection involves Rx Mfger/Customer products	X		
h)	Provide Drug Regulatory Submission related documentation as approved by Management	X		
i)	Distribution documentation retention per McK RIM Policy	X		
j)	Right to audit MSH facilities, systems and documentation, at a mutually agreed upon time.		X	
k)	Provide, in advance of the audit, specificities of the audit		X	
l)	Provide formal agenda schedule includes, topics, time, and personnel and their title	X		
m)	Rx Mfger/Customer shall provide a written report of the audit findings within 30 days of the audit.		X	
n)	MSH shall provide a written response to Rx Mfger/Customer written report of the audit findings within 30 days	X		

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

8.3 Complaints and Recalls	MSH	Rx Mfger/Customer	NA
a) Document and notify incoming calls and notification of complaints or queries related to product safety, and efficacy or administration of use.	X		
b) Investigation of Adverse Events, Product Safety, Medical Related, Product Quality Concerns		X	
c) Investigation (CAPA and/or Productivity Metrics) of Shipment Complaints and report Shipment Complaints of mutual interest to Rx Mfger/Customers	X		
d) Provide distribution records to support recalls	X		
e) Provide instruction for recalling product from the market		X	
f) Provide recall closure and reporting to Rx Mfger/Customers	X		

8.4 Product Receiving and Inspection	MSH	Rx Mfger/Customer	NA
a) Retain all temperature records (temperature transport data/packout temperature devices) related to the incoming Lot/Batch shipments	X		
b) Maintain records related to expiry verification	X		
c) At the point of receipt, notify the Rx Mfger/Customer of receipt, including any non-conformance related to the Lot/Batch received including, but not limited to expiration information, damages, and improper shipping documentation.	X		
d) If quarantine of the Lot/Batch is required, Certificate of Analysis / Certificate of Conformance and/or other related technical documentation, shall be provided by Rx Mfger/Customer.		X	
e) Ensure physical segregation of rejected, expired, recalled or returned Products and suspected counterfeits to prevent the Product distribution	X		

8.5 Storage Facility	MSH	Rx Mfger/Customer	NA
a) Maintain facilities and systems to store pharmaceuticals according standards set-forth by USP <1079>. Notify Rx Mfger/Customer of any events with potential impact on drug storage (e.g., power outage, extreme weather conditions, etc.).	X		
b) Maintain robust Environmental Control, Monitoring, and Alarm system to support Rx Mfger/Customer pharmaceutical drug storage requirements.	X		

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

c) Provide Environmental Control, Monitoring, Temperature and Alarm data as required to support Rx Mfger/Customer pharmaceutical drug storage requirements. Notify Rx Mfger/Customer of any deviation in drug storage requirements lasting more than 4 hours.	X
d) Perform maintenance and calibration per predetermined Master Validation Plan	X
e) Ensure storage areas are cleaned regularly and pest control systems for insects and rodents are in operation	X
f) Ensure effective access control to the warehouse, as appropriate	X

8.6 Distribution	MSH	Rx Mfger/Customer	NA
a) Meet appropriate standards set-forth by DSCSA to ensure traceability of the products distributed	X	X	
b) Generate shipping documentation that accompanies shipment	X		
c) Provide qualified pack-out for distribution of pharmaceutical drugs	X		
d) Execute dispatch order	X		
e) Return of confirmation receipts from recipient to McKesson.	X		
f) Follow up with courier to ensure delivery of shipments not delivered by the standard time.			X

CONTACT LIST – Rx MANUFACTURER/CUSTOMER			
Position	Name	Telephone	E-mail

CONTACT LIST – MSH			
Position	Name	Telephone	E-mail

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT		
Rev	Description of Change	Initial and Date

QUALITY AGREEMENT APPROVALS

MSH		Signature:	Date:

Aclaris Therapeutics, Inc.		Signature:	Date:

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT F: PERFORMANCE METRICS

Distributor will endeavor to maintain a minimum performance level of [***] for Products on average each month for the following categories. Distributor will advise in writing to Supplier if the minimum performance level is not met for any month, within ten (10) days after the end of such month:

[***]

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT G: DATA REPORTING

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

CHARGEBACK POLICY

The following represents the policies regarding the submission, processing, reversal and audits of any chargeback related to sales, as well as certain other related matters. These policies may be subject to change from time to time upon mutual agreement of the parties.

I. Chargeback Processing

Specialty Distributor will recognize and administer contracts between Supplier and customers pursuant to those prices at which a customer may purchase Products have been established, subject to the continued validity of such contracts in accordance with applicable law.

To ensure accuracy, the Supplier will notify Specialty Distributor by EDI, email or fax, with at least five (5) days advance notice to update existing contracts or pricing arrangements, and ten (10) days advance notice for new contract or pricing arrangement loads. Specialty Distributor reserves the right to deduct for any chargeback pricing discrepancies that result from Supplier's inability to provide Specialty Distributor reasonable time to load contract pricing.

Chargebacks shall be calculated based upon the WAC of the Product on the date of the sale. Specialty Distributor will submit chargeback reimbursement claims via EDI transaction sets within thirty (30) days of the invoice date. The Supplier will respond to original chargeback debit memos within twenty (20) days of debit memo date and the Supplier will respond to re-submitted chargebacks within twenty (20) days from the date the re-submittal was processed. Specialty Distributor may deduct in the event the Supplier does not provide a response to an original or re-submitted chargeback claim after twenty (20) days, and such deduction will be considered authorized.

In the event that new information surfaces that causes corrections or adjustments to prior sales, chargeback claims can be reopened and resubmitted within twelve (12) months of the original sale date or

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

as otherwise may be required in a government contract. All chargebacks older than twelve (12) months must be approved by the Supplier before resubmitting. The Supplier will notify Specialty Distributor of rejection of chargeback submissions within twenty (20) days from the date of receipt of Specialty Distributor's original submission. Specialty Distributor may resubmit such rejected chargebacks with corrected information. Rejected claims not re-submitted within ninety (90) days of the date on the Supplier's credit memo will be considered to be waived.

Specialty Distributor will transmit all chargeback claims to Supplier electronically via electronic data interchange (EDI) in accordance with industry standards established by the Health Distribution Management Association (HDMA). If Supplier is not able to receive chargeback files via EDI, then Specialty Distributor shall send chargeback claims to Supplier as MS Excel files. Failure to receive and respond to chargebacks will result in automatic deduction of chargeback with no repayment. The Supplier must contact Specialty Distributor's contract department regarding any discrepancies to correct going forward. All appropriate fields (i.e., customer identifier, item, contract number, WAC or contract pricing information, and changes required per customer sales or credit transactions) shall be completed.

Specialty Distributor will inform Supplier of all chargeback discrepancies or disputes with sufficiently detailed supporting information, including all customer invoice level detail and valid dispute reasons sufficient to meet HDMA standards, within thirty (30) days from the date of Specialty Distributor's original chargeback submission. Supplier will apply chargeback debit claim amounts against Specialty Distributor's account with Supplier. Specialty Distributor may resubmit chargebacks with corrected information following Supplier notification of discrepancies. Supplier will respond to all Specialty Distributor resubmission requests within twenty (20) days from date of Specialty Distributor's chargeback resubmission.

Supplier shall provide the following contact information to Specialty Distributor:

- Primary Chargeback's contact and Manager
- Primary Pricing contact and Manager
- Membership contact and Manager
- Contract Manager

II. Chargeback Reversals on Contract Customer Returns

Upon the issuance of a credit by Specialty Distributor to a customer in connection with the prior sale of Product under contract (for which Specialty Distributor previously submitted and collected a

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

chargeback from Supplier), the applicable chargeback to that transaction shall be reversed and remitted to Supplier only when the following conditions are met:

- A. Specialty Distributor received back from customer merchantable product (i.e. Specialty Distributor must be able to return the item to its inventory for resale in the ordinary course of its business without special preparation, testing, handling or expense); and
- B. The customer's return of the Product was due to an ordering error by customer or a picking error by Specialty Distributor.

III. Supplier Chargeback Audits

Supplier shall have the right to audit, at its own expense, Specialty Distributor's compliance with respective contracts in force between Supplier and Specialty Distributor's customers and related chargeback matters (including compliance with the chargeback reversal policy stated above) subject to the following terms and conditions:

- A. The scope of each chargeback audit shall be limited to the twelve (12) month period immediately preceding the date such audit begins.
- B. Specialty Distributor shall have a reciprocal twelve (12) month period to reconcile any differences that may arise with the Supplier related to chargeback issues (including submission and other errors and regardless of whether such issues arise as part of a Supplier chargeback audit). Supplier shall notify Specialty Distributor of an intent to perform an audit at least (30) days prior to beginning the audit, specifying the location to be audited and the time period to be audited, subject to the limitations set forth in Paragraph A, above. In the event that such timing is expected to create undue disruption of Specialty Distributor's business, Specialty Distributor shall have the right to delay the start of the audit for up to 60 additional days.
- C. Audits shall be performed by any of: (1) bona fide, permanent employees of the party conducting such audit or inspection; (2) auditors from independent accounting firms of national recognition; or (3) such other representatives as the parties may mutually agree upon. Those persons performing the audit on behalf of the Supplier must enter into confidentiality agreements prepared by, and in a form acceptable to, Specialty Distributor signed by the Supplier and such persons prior to beginning the audit.
- D. Audits shall be performed at the Specialty Distributor's facility at 1220 Senlac Drive, Carrollton, TX 75006, or such alternate site where appropriate records are located as Specialty Distributor may designate.
- E. Audits shall be performed during the normal, customary office hours of the Specialty Distributor designated site.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

- F. The existing accounting records subject of the audit shall be made available for audit, subject to following limitations:
 - a. Electronic data shall not be specifically created; and
 - b. Specialty Distributor reserves the right to summarize the contents of all records containing sensitive or competitive information.
- G. Any Supplier claims arising from an audit must be supported by specific audit findings related to specific transactions. Extrapolation of results from one period to another shall not be accepted.
- H. Any Supplier claims arising from an audit must be submitted to Specialty Distributor within thirty (30) days of completing the audit. All claims must be accompanied by specific supporting details of the transactions that comprise the claim. Specialty Distributor shall then have sixty (60) days to review the claim and advise Supplier of acceptance of, or disagreement with the claim.
- I.

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT I

DISTRIBUTION SERVICE LEVEL

Aclaris Orders - Shipped within 1 Business Day				
Orders Received				Orders Shipped By Close of Business
From		To		
Day	Central Time	Day	Central Time	
Monday	3:01 PM	Tuesday	3:00 PM	Tuesday
Tuesday	3:01 PM	Wednesday	3:00 PM	Wednesday
Wednesday	3:01 PM	Thursday	3:00 PM	Thursday
Thursday	3:01 PM	Friday	3:00 PM	Friday
Friday	3:01 PM	Monday	3:00 PM	Monday

Note: All orders are shipped 4 day ground from the Specialty Distributor's warehouse. **There are no expedited ground shipments.**

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Amendment No. 1 to the Distribution Agreement

THIS AMENDMENT NO. 1 (the "Amendment"), dated and effective as of March 6, 2018 (the "Effective Date"), is entered into by and between McKesson Specialty Care Distribution Corporation, a Delaware corporation with offices at 10101 Woodloch Forest, The Woodlands, Texas 77380 ("**Specialty Distributor**"), and Aclaris Therapeutics, Inc., with offices at 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087 ("**Supplier**").

WHEREAS, Specialty Distributor and Supplier entered into that certain Distribution Agreement dated October 13, 2017 (the "Agreement"), which the parties desire to amend as set forth herein;

WHEREAS, Any terms used but not otherwise defined herein, shall have the same meaning given to such terms in the Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and for other good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

Exhibit F of the Agreement shall be replaced in its entirety and amended and to read as follows:

EXHIBIT F: Performance Metrics

Distributor will endeavor to maintain a minimum performance level of [***] for Products on average each month for the following categories. Distributor, will advise in writing to Supplier if the minimum performance level is not met for any month, within ten (10) days after the end of such month:

[***]

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Except as expressly amended herein, the Agreement shall remain unchanged and in full force and effect in accordance with its terms.

Intending to be bound by the provisions hereof, the parties hereto have caused this Amendment to be executed personally or by their duly authorized representatives, to be effective as of the Effective Date.

AGREED TO:

AGREED TO:

**MCKESSON SPECIALTY CARE
DISTRIBUTION CORPORATION**

ACLARIS THERAPEUTICS, INC.

By: /s/ Layne H Martin

By: /s/ Neal Walker

Printed

Printed

Name: Layne H Martin

Name: Neal Walker

Date: 3/6/2018

Date: 3/6/2018

Title: Vice President / General Manager

Title: President & CEO

Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

First Amendment to License Agreement

The License Agreement effective as of **December 31, 2015**, between

- A. Vixen Pharmaceuticals, a Delaware corporation, as assigned to and assumed by Aclaris Therapeutics Inc., having offices at 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087 (“RECIPIENT”) pursuant to the Stock Purchase Agreement signed by Vixen Pharmaceuticals and Aclaris Therapeutics Inc., dated March 24, 2015; and
- B. The Trustees of Columbia University in the City of New York, having an address at c/o Columbia Technology Ventures, 80 Claremont Avenue, Suite 4F, New York, New York 10027 (“Columbia”),

a copy of the License Agreement is attached herewith as Schedule A (the “Agreement”), is hereby amended as follows:

1. Please amend Exhibit A by adding the following Section:

IR	Docket	Patent/Application Title	Patent/Application No.	Filing Date	Status
[***]	[***]	[***]	[***]	[***]	[***]

- 2. This Amendment is effective as of June 27, 2018.
- 3. All other terms and conditions of the Agreement shall remain in full force and effect, except as expressly amended herein. If there is any inconsistency or conflict between this Amendment and the Agreement, the provisions of this Amendment shall govern and control. This Amendment shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and assigns.

AGREED:

RECIPIENT

/s/ Neal Walker

Printed Name: Neal Walker

Title: President and CEO

Date: 6/27/18

THE TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

/s/ Scot G. Hamilton

Printed Name: Scot G. Hamilton

Title: AVP for CTV at Columbia

Date: 6/28/2018

TT 52520

Attachments: Schedule A – the Agreement

**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 June 30, 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: August 3, 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 June 30, 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: August 3, 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 June 30, 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 3rd day of August, 2018.

/s/ Neal Walker

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

/s/ Frank Ruffo

Frank Ruffo
Chief Financial 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.
