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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2019

OR

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

For the transition period from _____ to _____

Commission File Number 001-37581

Aclaris Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	46-0571712
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
640 Lee Road, Suite 200 Wayne, PA (Address of principal executive offices)	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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, $0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

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

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

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

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

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

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

The number of outstanding shares of the registrant's common stock, par value $0.00001 per share, as of the close of business on November 7, 2019 was 41,388,432.

ACLARIS THERAPEUTICS, INC.

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Part I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

(In thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 29,898	$ 57,019
Marketable securities	61,530	110,953
Accounts receivable, net	673	563
Inventory	—	—
Prepaid expenses and other current assets	2,089	4,802
Discontinued operations - current assets	51,180	6,162
Total current assets	145,370	179,499
Property and equipment, net	2,854	2,287
Intangible assets	7,217	7,273
Goodwill	—	18,504
Other assets	4,975	332
Discontinued operations - non-current assets	—	67,671
Total assets	$ 160,416	$ 275,566
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 17,780	$ 14,755
Accrued expenses	6,066	8,090
Current portion of lease liabilities	642	142
Discontinued operations - current liabilities	14,501	4,355
Total current liabilities	38,989	27,342
Other liabilities	4,005	476
Long-term debt	29,930	29,914
Contingent consideration	1,668	934
Deferred tax liability	549	549
Discontinued operations - non-current liabilities	—	1,227
Total liabilities	75,141	60,442
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at September 30, 2019 and December 31, 2018; 41,380,811 and 41,210,725 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	520,209	507,366
Accumulated other comprehensive loss	(1)	(69)
Accumulated deficit	(434,933)	(292,173)
Total stockholders' equity	85,275	215,124
Total liabilities and stockholders' equity	$ 160,416	$ 275,566

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

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

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	$ —	$ —	$ —	$ —
Contract research	983	1,118	3,132	3,379
Other revenue	—	—	—	1,000
Total revenue, net	983	1,118	3,132	4,379
Costs and expenses:				
Cost of revenue	826	1,067	3,028	3,063
Research and development	16,183	15,189	53,334	41,482
Sales and marketing	112	63	629	89
General and administrative	6,726	6,141	21,142	20,481
Goodwill impairment	—	—	18,504	—
Amortization of definite-lived intangible	—	—	—	—
Total costs and expenses	23,847	22,460	96,637	65,115
Loss from operations	(22,864)	(21,342)	(93,505)	(60,736)
Other income (expense), net	(274)	710	(589)	2,189
Loss from continuing operations	(23,138)	(20,632)	(94,094)	(58,547)
Loss from discontinued operations	(32,181)	(12,108)	(48,666)	(35,640)
Net loss	$ (55,319)	$ (32,740)	$ (142,760)	$ (94,187)
Net loss per share, basic and diluted	$ (1.34)	$ (1.06)	$ (3.46)	$ (3.04)
Weighted average common shares outstanding, basic and diluted	41,364,387	30,982,192	41,296,377	30,938,026
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net of tax of $0	$ (23)	$ 65	$ 41	$ 111
Foreign currency translation adjustments	14	7	27	19
Total other comprehensive income (loss)	(9)	72	68	130
Comprehensive loss	$ (55,328)	$ (32,668)	$ (142,692)	$ (94,057)

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

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

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2018	41,210,725	$ —	$ 507,366	$ (69)	$ (292,173)	$ 215,124
Vesting of RSUs	58,918	—	(188)	—	—	(188)
Unrealized gain on marketable securities	—	—	—	34	—	34
Foreign currency translation adjustment	—	—	—	(14)	—	(14)
Stock-based compensation expense	—	—	4,862	—	—	4,862
Net loss	—	—	—	—	(37,565)	(37,565)
Balance at March 31, 2019	41,269,643	—	512,040	(49)	(329,738)	182,253
Exercise of stock options and vesting of RSUs	8,927	—	(18)	—	—	(18)
Unrealized gain on marketable securities	—	—	—	30	—	30
Foreign currency translation adjustment	—	—	—	27	—	27
Stock-based compensation expense	—	—	4,814	—	—	4,814
Net loss	—	—	—	—	(49,876)	(49,876)
Balance at June 30, 2019	41,278,570	—	516,836	8	(379,614)	137,230
Exercise of stock options and vesting of RSUs	102,241	—	53	—	—	53
Unrealized loss on marketable securities	—	—	—	(23)	—	(23)
Foreign currency translation adjustment	—	—	—	14	—	14
Stock-based compensation expense	—	—	3,320	—	—	3,320
Net loss	—	—	—	—	(55,319)	(55,319)
Balance at September 30, 2019	41,380,811	$ —	$ 520,209	$ (1)	$ (434,933)	$ 85,275

	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	49,124	—	378	—	—	378
Unrealized loss on marketable securities	—	—	—	(65)	—	(65)
Foreign currency translation adjustment	—	—	—	(17)	—	(17)
Stock-based compensation expense	—	—	5,143	—	—	5,143
Net loss	—	—	—	—	(30,229)	(30,229)
Balance at March 31, 2018	30,905,629	—	390,464	(328)	(189,664)	200,472
Exercise of stock options and vesting of RSUs	59,667	—	(440)	—	—	(440)
Unrealized gain on marketable securities	—	—	—	111	—	111
Foreign currency translation adjustment	—	—	—	29	—	29
Stock-based compensation expense	—	—	5,249	—	—	5,249
Net loss	—	—	—	—	(31,218)	(31,218)
Balance at June 30, 2018	30,965,296	—	395,273	(188)	(220,882)	174,203
Exercise of stock options and vesting of RSUs	25,764	—	86	—	—	86
Unrealized gain on marketable securities	—	—	—	65	—	65
Foreign currency translation adjustment	—	—	—	7	—	7
Stock-based compensation expense	—	—	4,707	—	—	4,707
Net loss	—	—	—	—	(32,740)	(32,740)
Balance at September 30, 2018	30,991,060	$ —	$ 400,066	$ (116)	$ (253,622)	$ 146,328

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

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

(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (142,760)	$ (94,187)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,089	921
Stock-based compensation expense	12,996	15,099
Change in fair value of contingent consideration	734	866
Goodwill impairment charge	18,504	—
Intangible asset impairment charge	27,638	—
Changes in operating assets and liabilities:		
Accounts receivable	(13,003)	(552)
Inventory	602	(1,044)
Prepaid expenses and other assets	3,278	(3,461)
Accounts payable	3,050	5,932
Accrued expenses	6,817	2,863
Net cash used in operating activities	(76,055)	(73,563)
Cash flows from investing activities:		
Purchases of property and equipment	(1,347)	(1,210)
Purchases of marketable securities	(121,303)	(112,344)
Proceeds from sales and maturities of marketable securities	171,891	193,427
Net cash provided by investing activities	49,241	79,873
Cash flows from financing activities:		
Finance lease payments	(392)	(499)
Proceeds from the exercise of employee stock options	85	577
Net cash (used in) provided by financing activities	(307)	78
Net increase (decrease) in cash and cash equivalents	(27,121)	6,388
Cash and cash equivalents at beginning of period	57,019	20,202
Cash and cash equivalents at end of period	$ 29,898	$ 26,590
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	$ 207	$ 102
Property and equipment obtained pursuant to capital lease financing arrangements	$ —	$ 2,076
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

Overview

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. In July 2015, Aclaris Therapeutics International Limited ("ATIL") was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. In March 2016, Vixen Pharmaceuticals, Inc. ("Vixen") became a wholly-owned subsidiary of Aclaris Therapeutics, Inc., and in September 2018, Vixen was dissolved. In August 2017, Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) ("Confluence") was acquired by Aclaris Therapeutics, Inc. and became a wholly-owned subsidiary thereof. Aclaris Therapeutics, Inc., ATIL, Vixen and Confluence are referred to collectively as the "Company." The Company is a physician-led biopharmaceutical company focused on immuno-inflammatory diseases. The Company currently has one commercial product and a diverse pipeline of drug candidates, including one late-stage investigational drug candidate. In October 2019, the Company sold the worldwide rights to one of its commercial products, RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE"), which includes the assignment of certain licenses for related intellectual property assets (see Note 19). The Company's other commercial product, ESKATA (hydrogen peroxide) topical solution, 40% (w/w) ("ESKATA"), is a proprietary formulation of high concentration hydrogen peroxide which was approved by the U.S. Food and Drug Administration ("FDA") as an office-based prescription treatment for raised seborrheic keratosis ("SK"), a common non-malignant skin tumor. In August 2019, the Company voluntarily discontinued the commercialization of ESKATA in the United States and withdrew the marketing authorizations it had previously received for the product in all countries outside of the United States. The Company continues to maintain the New Drug Application ("NDA") for ESKATA in the United States. The Company is currently seeking a strategic partner to commercialize ESKATA worldwide.

Liquidity

The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. At September 30, 2019, the Company had cash, cash equivalents and marketable securities of $91,428 and an accumulated deficit of $434,933. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, the Company had never generated any revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, research and development activities, including preclinical and clinical testing of the Company's drug candidates will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its drug candidates and generate revenue from identifying and consummating transactions with potential third-party partners to further develop, obtain marketing approval for and/or commercialize its development assets 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. Based upon the revenue from contract research services, the Company believes that gross profit does not provide a meaningful measure of profitability and, therefore, has not included a line item for gross profit on the condensed consolidated statement of operations.

Discontinued Operations

On September 5, 2019, the Company announced the completion of a strategic review and its decision to refocus its resources on its immuno-inflammatory development programs and to actively seek partners for its commercial products. The Company also announced a plan to terminate 86 employees (see Note 16).

The accompanying condensed consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to the Company's commercial products as discontinued operations (see Note 15). The accompanying condensed consolidated financial statements are generally presented in conformity with the Company's historical format, even in situations where reclassifications to discontinued operations have resulted in $0 values being presented. The Company believes this format provides comparability with its previously filed financial statements.

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, variable consideration included in product sales, net, research and development expenses, contingent consideration and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2019, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2019 and 2018, the condensed consolidated statement of stockholders' equity for the three and nine months ended September 30, 2019 and 2018, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2019 and 2018 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 18, 2019 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position as of September 30, 2019, the results of its operations and comprehensive loss for the three and nine months ended September 30, 2019 and 2018, its changes in stockholders' equity for the three and nine months ended September 30, 2019 and 2018 and its cash flows for the nine months ended September 30, 2019 and 2018. The condensed consolidated balance sheet data as of December 31, 2018 was derived from audited financial statements but does not include all disclosures required by GAAP. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2019 and 2018 are unaudited. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the year ending December 31, 2019, 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, 2018 included in the Company's annual report on Form 10-K filed with the SEC on March 18, 2019.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2018 included in the Company's annual report on Form 10-K filed with the SEC on March 18, 2019. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

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.

Product Sales, net

The Company sold RHOFADE during the nine months ended September 30, 2019 and sold ESKATA during the nine months ended September 30, 2019 and 2018 to a limited number of wholesalers in the United States (collectively, its "Customers"). These Customers subsequently resold the Company's products to pharmacies and health care providers. In addition to distribution agreements with Customers, the Company entered into arrangements with third-party payors, including pharmacy benefit managers and government agencies, and group purchasing organizations ("GPOs"), which provided for government mandated or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's commercial products. The Company discontinued selling ESKATA in August 2019. The Company sold the worldwide rights to RHOFADE in October 2019 (see Note 19). Product sales, net has been reclassified to discontinued operations for all periods presented.

The Company recognizes revenue from product sales at the point the Customer obtains control of the product, which generally occurs upon delivery, and includes estimates of variable consideration in the same period revenue is recognized. Components of variable consideration include trade discounts and allowances, product returns, government rebates, discounts and rebates, other incentives such as patient co-pay assistance, and other fee for service amounts. Variable consideration is recorded on the condensed consolidated balance sheet as either a reduction of accounts receivable, if payable to a Customer, or as a current liability, if payable to a third party other than a Customer. The Company considers all relevant information when estimating variable consideration such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of net revenue the Company can recognize is constrained by estimates of variable consideration which are included in the transaction price. Payment terms with Customers do not exceed one year and, therefore, the Company does not account for a financing component in its arrangements. The Company expenses incremental costs of obtaining a contract with a Customer, including sales commissions, when incurred as the period of benefit is less than one year. Shipping and handling costs for product shipments to Customers are recorded as sales and marketing expenses in the condensed consolidated statement of operations.

Trade Discounts and Allowances - The Company provided Customers with trade discounts, rebates, allowances and other incentives. The Company records an estimate for these items as a reduction of revenue in the same period the revenue is recognized.

Government and Payor Rebates - The Company contracted with certain third-party payors, including pharmacy benefit managers and government agencies, for the payment of rebates with respect to utilization of its commercial products. The Company also entered into agreements with GPOs that provided for administrative fees and discounted pricing in the form of volume-based rebates. The Company is also subject to discount and rebate obligations under state Medicaid programs and Medicare. The Company records an estimate for these discounts and rebates as a reduction of revenue in the same period the revenue is recognized.

Other Incentives - Other incentives include the Company's co-pay assistance program which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by third-party payors. The Company estimates and records an accrual for these incentives as a reduction of revenue in the period the revenue is recognized. The Company estimates amounts for co-pay assistance based upon the number of claims and the cost per claim that the Company expects to receive associated with product that has been sold to Customers but remains in the distribution channel at the end of each reporting period.

Product Returns - Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the product to a patient. The Company records an estimate for the amount of its products which may be returned as a reduction of revenue in the period the related revenue is recognized. The Company's estimate for product returns are based upon available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. There is no returns liability associated with sales of ESKATA as the Company has a no returns policy for this product.

Contract Research

The Company earns contract research revenue from the provision of laboratory services to clients through Confluence, its wholly-owned subsidiary. Contract research 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 contract research revenue. The Company recognizes contract research revenue in the amount to which it has the right to invoice.

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

Other Revenue

Licenses of Intellectual Property – The Company recognizes revenue received from non-refundable, upfront fees related to the licensing of intellectual property when the intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the license has been transferred to the customer, and the customer is able to use and benefit from the license.

Milestone Payments - At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the amount allocated to the license of intellectual property. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

Inventory

Inventory includes the third-party cost of manufacturing and assembly of finished product, quality control and other overhead costs. Inventory is stated at the lower of cost or net realizable value. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. The Company had $189 and $791 of inventory as of September 30, 2019 and December 31, 2018, respectively, which was comprised primarily of finished goods and has been reclassified to discontinued operations for all periods presented.

Intangible Assets

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

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

During the three months ended September 30, 2019, the Company performed an interim impairment analysis of the RHOFADE intangible asset due to its decision to discontinue commercial operations and actively seek a commercialization partner for RHOFADE. The Company classified the RHOFADE intangible asset as held for sale, in discontinued operations, on its condensed consolidated balance sheet as of September 30, 2019. The Company's impairment analysis, which primarily utilized a market-participant's indication of fair value, resulted in a fair value for the RHOFADE intangible asset which was less than its carrying value. As a result, the Company recorded an impairment charge of $27,638 to adjust the carrying value of the RHOFADE intangible asset to its net realizable value as of September 30, 2019 (see Note 19).

Goodwill

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

During the nine months ended September 30, 2019, the Company performed an interim impairment analysis due to the decline in its stock price, which was considered a triggering event to evaluate goodwill for impairment. The Company's impairment analysis, using a market approach, noted that its stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, the Company recorded an impairment charge of $18,504, the full balance of goodwill, in the nine months ended September 30, 2019.

Leases

Leases represent a company's right to use an underlying asset and a corresponding obligation to make payments to a lessor for the right to use those assets. The Company evaluates leases at their inception to determine if they are an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows are substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease.

The Company recognizes assets and liabilities for leases at their inception based upon the present value of all payments due under the lease. The Company uses an implicit interest rate to determine the present value of finance leases, and its incremental borrowing rate to determine the present value of operating leases. The Company determines incremental borrowing rates by referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. The Company recognizes expense for operating and finance leases on a straight-line basis over the term of each lease, and interest expense related to finance leases is recognized over the lease term based on the effective interest method. The Company includes estimates for any residual value guarantee obligations under its leases in lease liabilities recorded on its condensed consolidated balance sheet.

Right-of-use assets are included in other assets and property and equipment, net on the Company's condensed consolidated balance sheet for operating and finance leases, respectively. Obligations for lease payments are included in current portion of lease liabilities and other liabilities on the Company's condensed consolidated balance sheet for both operating and finance leases.

Contingent Consideration

The Company initially recorded the contingent consideration related to future potential payments based upon the achievement of certain development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. Future changes in the fair value of the contingent

consideration, if any, will be recorded as income or expense in the Company's condensed consolidated statement of operations.

Concentration of Credit Risk and of Significant Customers and Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds all cash, cash equivalents and marketable securities balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company's top five customers represented 67% and 85% of contract research revenue for the nine months ended September 30, 2019 and 2018, respectively.

The Company is dependent on third-party manufacturers to supply drug product, including all underlying components, for its research and development activities, including preclinical and clinical testing. These activities could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients or other components.

Recently Issued Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is evaluating the impact of ASU 2018-18 on its consolidated financial statements.

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

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

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with nonemployees except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 is effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year. The Company adopted the provisions of this standard on January 1, 2019, the impact of which on its consolidated financial statements was not significant.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, and 2018-11, Targeted Improvements, which included a number of technical corrections and improvements, including additional options for transition. The new standard establishes a right-of-use model that requires a lessee to record a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods. The amendments in ASU 2016-02 must be applied to all leases existing at the date a company initially applies the standard.

The Company adopted the new standard on January 1, 2019, using the effective date as the date of its initial application, and used the modified retrospective approach. In addition, the Company elected the practical expedients permitted under the transition guidance within the new standard which, among other things, allowed the Company to carry forward the historical lease identification and classification. The Company also elected the practical expedient to not separate lease and non-lease components, as well as the short-term lease practical expedient which allowed the Company to not capitalize leases with terms less than 12 months that do not contain a reasonably certain purchase option. The Company's consolidated financial statements have not been restated, and disclosures required by the new standard have not been provided, for periods before January 1, 2019.

The adoption of ASU 2016-02 resulted in recording additional assets and liabilities of $2,132 and $2,317, respectively upon adoption on January 1, 2019. The adoption of ASU 2016-02 did not have a material impact on the Company's consolidated statement of operations or cash flows.

3. Fair Value of Financial Assets and Liabilities

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

	September 30, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 23,567	$ —	$ —	$ 23,567
Marketable securities	—	61,530	—	61,530
Total assets	$ 23,567	$ 61,530	$ —	$ 85,097
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 1,668	$ 1,668
Total liabilities	$ —	$ —	$ 1,668	$ 1,668

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 49,766	$ 4,992	$ —	$ 54,758
Marketable securities	—	110,953	—	110,953
Total assets	$ 49,766	$ 115,945	$ —	$ 165,711
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 934	$ 934
Total liabilities	$ —	$ —	$ 934	$ 934

As of September 30, 2019 and December 31, 2018, the Company's cash equivalents consisted of investments with maturities of less than three months and included a money market fund and commercial paper, which were valued based upon Level 1 inputs. The Company's marketable securities consisted of investments with maturities of more than three months and included commercial paper, corporate debt and government obligations, which were valued based upon Level 2 inputs. In determining the fair value of its Level 2 investments, the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. On a quarterly basis, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of those quoted prices. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to the quoted prices obtained from the third-party pricing service. During the nine months ended September 30, 2019 and the year ended December 31, 2018, there were no transfers between Level 1, Level 2 and Level 3. The change in acquisition-related contingent consideration related to Confluence of $734 was the result of updates to the Company's assumptions as a result of the filing of an Investigational New Drug Application ("IND") for ATI-450 during the nine months ended September 30, 2019.

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

	September 30, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 14,359	$ 13	$ —	$ 14,372
Commercial paper	28,643	—	(1)	28,642
Asset-backed securities	5,998	4	—	6,002
U.S. government agency debt securities	12,514	—	—	12,514
Total marketable securities	$ 61,514	$ 17	$ (1)	$ 61,530

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 5,030	$ —	$ (14)	$ 5,016
Commercial paper	67,159	—	—	67,159
Asset-backed securities	21,745	—	(8)	21,737
U.S. government agency debt securities	17,044	—	(3)	17,041
Total marketable securities	$ 110,978	$ —	$ (25)	$ 110,953

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2019	December 31, 2018
Computer equipment	$ 1,362	$ 1,292
Fleet vehicles	—	—
Finance lease right-of-use assets	435	—
Manufacturing equipment	607	604
Lab equipment	1,067	1,068
Furniture and fixtures	647	313
Leasehold improvements	889	332
Property and equipment, gross	5,007	3,609
Accumulated depreciation	(2,153)	(1,322)
Property and equipment, net	$ 2,854	$ 2,287

Depreciation expense was $324 and $264 for the three months ended September 30, 2019 and 2018, respectively, and was $886 and $704 for the nine months ended September 30, 2019 and 2018, respectively.

5. Intangible Assets

Intangible assets consisted of the following:

		Gross Cost		Accumulated Amortization	
	Remaining Life (years)	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018
Other intangible assets	7.8	751	751	163	107
Total definite-lived intangible assets		751	751	163	107
IPR&D	na	6,629	6,629	—	—
Total intangible assets		$ 7,380	$ 7,380	$ 163	$ 107

As of September 30, 2019, estimated future amortization expenses are as follows:

Year Ending December 31,	
2019	$ 20
2020	75
2021	75
2022	75
2023	75
Thereafter	268
Total	$ 588

6. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2019	December 31, 2018
Employee compensation expenses	$ 2,665	$ 4,948
Sales discounts and allowances	—	—
Research and development expenses	2,045	1,437
Professional fees	276	1,123
Selling and marketing expenses	—	—
Other	1,080	582
Total accrued expenses	$ 6,066	$ 8,090

7. Debt

Loan and Security Agreement – Oxford Finance LLC

In October 2018, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Oxford Finance LLC, a Delaware limited liability company ("Oxford"). The Loan Agreement provided for up to $65,000 in term loans (the "Term Loan Facility"). Of the $65,000, the Company borrowed $30,000 in October 2018. In October 2019, the Company repaid in full the $30,000 that was outstanding under the Loan Agreement, together with all accrued and unpaid interest and fees (see Note 19).

The Loan Agreement provided for interest only payments through November 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 2021 and continuing through the maturity date of October 2023. The Loan Agreement provided for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate plus 6.25%. The Loan Agreement also provided for a final payment fee equal to 5.75% of the original principal amount of the term loans drawn under the Term Loan Facility.

The Company had the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of (i) 3% of the original principal amount of the aggregate term loans drawn for any prepayment prior to the first anniversary of the date such term loan was funded, (ii) 2% of the original principal amount of the aggregate term loans drawn for any prepayment between the first and second anniversaries of the date such term loan was funded or (iii) 1% of the original principal amount of the aggregate term loans drawn for any prepayment after the second anniversary of the funding date but before October 1, 2023.

The carrying value of the Loan Agreement approximated fair value because the interest rate was a floating rate based on the 30-day U.S. LIBOR rate and was therefore reflective of market rates.

8. Stockholders' Equity

Preferred Stock

As of September 30, 2019 and December 31, 2018, the Company's amended and restated certificate of incorporation authorized the Company to issue 10,000,000 shares of undesignated preferred stock. No shares of preferred stock were outstanding as of September 30, 2019 or December 31, 2018.

Common Stock

As of September 30, 2019 and December 31, 2018, the Company's amended and restated certificate of incorporation authorized the Company to issue 100,000,000 shares of $0.00001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to any preferential dividend rights of any series of preferred stock that may be outstanding. The Company did not declare any dividends through September 30, 2019.

9. 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, up to 1,000,000 shares of common stock were available for issuance pursuant to nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, and other stock awards. All shares of common stock that were eligible for issuance under the 2017 Inducement Plan after October 1, 2018, including any shares underlying any awards that expire or are otherwise terminated, reacquired to satisfy tax withholding obligations, settled in cash or repurchased by the Company in the future that would have been eligible for re-issuance under the 2017 Inducement Plan, were retired.

2015 Equity Incentive Plan

In September 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (the "2015 Plan"), and 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 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, 2019, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 1,648,429 shares. As of September 30, 2019, 2,460,900 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 856,603 and 948,761 were outstanding as of September 30, 2019 and December 31, 2018, 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:

	Nine Months Ended September 30,	
	2019	2018
Risk-free interest rate	2.27 %	2.65 %
Expected term (in years)	6.2	6.3
Expected volatility	101.70 %	96.56 %
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, 2019 through September 30, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	4,282,081	$ 20.53	7.91	$ 2,404
Granted	44,500	5.75		
Exercised	(66,376)	1.29		
Forfeited and cancelled	(686,811)	23.35		
Outstanding as of September 30, 2019	3,573,394	$ 20.16	6.54	$ 29
Options vested and expected to vest as of September 30, 2019	3,573,394	$ 20.16	6.54	$ 29
Options exercisable as of September 30, 2019	2,276,088 (1)	$ 18.25	5.74	$ 29

(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 options vest. This amount reflects the number of shares under options that were vested, as opposed to exercisable.

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2019 was $4.63 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, 2019 through September 30, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2018	626,407	$ 20.30
Granted	1,520,942	6.26
Vested	(150,271)	20.50
Forfeited and cancelled	(361,440)	11.41
Outstanding as of September 30, 2019	1,635,638	$ 9.19

Stock-Based Compensation

Stock-based compensation expense included in total costs and expenses on the condensed consolidated statement of operations included the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of revenue	$ 25	$ 194	$ 454	$ 560
Research and development	1,418	1,433	4,733	4,916
Sales and marketing	—	—	—	—
General and administrative	2,581	2,320	7,707	6,936
Total stock-based compensation expense	$ 4,024	$ 3,947	$ 12,894	$ 12,412

As of September 30, 2019, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $17,068 and $11,506, respectively, which is expected to be recognized over weighted average periods of 1.96 years and 2.90 years, respectively.

10. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	$ (55,319)	$ (32,740)	$ (142,760)	$ (94,187)
Denominator:				
Weighted average shares of common stock outstanding	41,364,387	30,982,192	41,296,377	30,938,026
Net loss per share, basic and diluted	$ (1.34)	$ (1.06)	$ (3.46)	$ (3.04)

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 nine months ended September 30, 2019 and 2018. All share amounts presented in the table below represent the total number outstanding as of September 30, 2019 and 2018.

	September 30,	
	2019	2018
Options to purchase common stock	3,573,394	4,323,353
Restricted stock unit awards	1,635,638	541,628
Total potential shares of common stock	5,209,032	4,864,981

11. Leases

The Company has operating leases for office space and laboratory facilities, and finance leases for its laboratory equipment. As a result of the Company's decision to actively seek partners for its commercial products (see Note 2), the Company terminated the finance leases for its fleet vehicles and recognized a loss on lease termination of $306 in the three months ended September 30, 2019. The components of lease expense were as follows:

	Nine Months Ended September 30, 2019
Operating lease expense	$ 555
Finance Leases:	
Amortization of right-to-use assets	$ 416
Interest expense	84
Total finance lease expenses	$ 500

During the three and nine months ended September 30, 2018 the Company recorded $204 and $682, respectively, of rent expense which was recognized on a straight-line basis over the term of the lease.

Operating Leases

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 February 2019, the Company entered into a sublease agreement with a third party for 21,056 square feet of office and laboratory space in St. Louis, Missouri with total future total rent payments of $3,538. The Company has also agreed to pay $1,472 of the total renovation and improvement costs incurred by the landlord, which is collateralized by a standby letter of credit held by the Company. The lease commenced in June 2019 and has a term that runs through June 2029.

Supplemental balance sheet information related to operating leases is as follows:

Operating Leases:		**September 30, 2019**
Gross cost	$	5,213
Accumulated amortization		(331)
Operating lease right-of-use assets	$	4,882
Other current liabilities	$	507
Other liabilities		3,686
Total operating lease liabilities	$	4,193

Finance Leases

Laboratory Equipment

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

Fleet Vehicles

The Company leased 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 began on the date the Company took delivery and continued for a period of four years. The Company returned all leased vehicles during the three months ended September 30, 2019.

Supplemental balance sheet information related to finance leases is as follows:

Finance Leases:	September 30, 2019
Property and equipment, gross	$ 435
Accumulated depreciation	(296)
Property and equipment, net	$ 139
Other current liabilities	$ 135
Other liabilities	159
Total finance lease liabilities	$ 294

Supplemental information related to operating and finance leases is as follows:

Supplemental Cash Flow Lease Information:	Nine Months Ended September 30, 2019
Operating cash flows from operating leases	$ 530
Operating cash flows from finance leases	86
Financing cash flows from finance leases	447
Leased assets obtained in exchange for new operating lease liabilities	$ 3,060
Weighted-Average Remaining Lease Term (in years):	
Operating leases	6.98
Finance leases	0.89
Weighted-Average Discount Rate:	
Operating leases	10.10 %
Finance leases	9.96 %

Future maturities of lease liabilities under operating and finance leases as of September 30, 2019 are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2019	$ 223	$ 36
2020	909	116
2021	934	—
2022	959	—
2023	877	—
Thereafter	2,024	—
Total undiscounted lease payments	5,926	152
Less: unrecognized interest	(1,733)	(8)
Total lease liability	$ 4,193	$ 144

The undiscounted lease payments presented in the table above are consistent with the future minimum lease payments disclosed in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2019 under the prior

lease guidance, with the exception of the undiscounted lease payments related to leased vehicles, which were returned during the three months ended September 30, 2019.

12. Related Party Transactions

Sublease

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 nine months ended September 30, 2019 and 2018 were $0 and $570, respectively.

Mr. Stephen Tullman, the former 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 certain of the Company's executive officers are and have been members of entities affiliated with NST, LLC.

The Company had no amounts payable to NST Consulting, LLC as of September 30, 2019 and December 31, 2018.

Asset Purchase Agreement with Allergan

In November 2018, the Company closed the acquisition of RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan Sales, LLC ("Allergan") pursuant to the terms of the Asset Purchase Agreement dated as of October 15, 2018 (as amended, the "Asset Purchase Agreement").

Pursuant to the Asset Purchase Agreement, the Company agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Certain current and former members of the Company's management team and board of directors are former holders of equity interests in Vicept Therapeutics, Inc. and Aspect Pharmaceuticals, LLC. In such capacities, these individuals may be entitled to receive a portion of the potential future payments payable by the Company.

For the nine months ended September 30, 2019, the Company incurred an expense of $576 and $0 related to royalties and/or milestones earned by Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc., respectively, under those agreements.

In October 2019, the Company sold the worldwide rights to RHOFADE to EPI Health, LLC ("EPI Health"), who agreed to assume the Company's obligation to pay the royalties and milestone payments under its existing agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. (see Note 19).

13. Agreements Related to Intellectual Property

Asset Purchase Agreement – Allergan Sales, LLC

In November 2018, the Company closed the acquisition of RHOFADE from Allergan pursuant to the Asset Purchase Agreement (see Note 12). The Company agreed to pay Allergan specified royalties, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to RHOFADE have expired or, if later, November 30, 2028. The Company incurred royalties earned by Allergan under the Asset Purchase Agreement of $ 440 and $0 during the three months ended September 30, 2019 and 2018, respectively, and $1,281 and $0 during the nine months ended

September 30, 2019 and 2018, respectively. The Company also agreed to pay Allergan a one-time payment of $5,000 upon the achievement of a specified development milestone related to the potential development of an additional dermatology product.

In October 2019, the Company sold the worldwide rights to RHOFADE to EPI Health, who agreed to assume the obligation to pay the royalties and milestone payments under the Asset Purchase Agreement (see Note 19).

License and Collaboration Agreement – Rigel Pharmaceuticals, Inc.

In August 2015, the Company entered into an exclusive, worldwide license and collaboration agreement with Rigel Pharmaceuticals, Inc. ("Rigel") for the development and commercialization of products containing two specified JAK inhibitors, which the Company refers to as ATI-501 and ATI-502. Under the agreement, the Company agreed to make aggregate payments of up to $80,000 upon the achievement of specified development milestones. During the three months ended September 30, 2019, the Company made a milestone payment of $4,000 to Rigel upon the achievement of a specified development milestone. With respect to any products the Company commercializes under the agreement, the Company will pay Rigel quarterly tiered royalties on its annual net sales of each product at a high single-digit percentage of annual net sales, subject to specified reductions, 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 countries under specified circumstances, ten years from the first commercial sale of such product.

In connection with the amendment of the agreement in October 2019, the Company agreed to pay Rigel an amendment fee of $1,500 in three installments of $500 in January 2020, April 2020 and July 2020. In addition, the parties modified certain other development milestones, and the Company agreed to increase the potential payments payable upon the achievement of such milestones from $10,000 to $10,500 in the aggregate.

License, Development and Commercialization Agreement – Cipher Pharmaceuticals Inc.

In April 2018, the Company entered into an exclusive license agreement with Cipher Pharmaceuticals Inc. ("Cipher") for the rights to obtain regulatory approval of and commercialize A-101 40% Topical Solution, which the Company marketed under the brand name ESKATA in the United States, in Canada for the treatment of seborrheic keratosis ("SK"). In September 2019, the Company and Cipher mutually terminated the exclusive license agreement.

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 ESKATA and A-101 45% Topical Solution. 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 a specified regulatory milestone in April 2017 and a milestone payment of $1,500 upon the achievement of a specified commercial milestone in May 2018. The payments were recorded as general and administrative expenses in the Company's condensed consolidated statement of operations.

Under the finder's services agreement, the Company is obligated to make an additional milestone payment of $3,000 upon the achievement of a specified commercial milestone. Under each of the assignment agreement and the finder's services agreement, the Company is also obligated to pay royalties on sales of ESKATA and any related products, at low single-digit percentages of net sales, subject to reduction in specified circumstances. During the nine months ended September 30, 2019 and 2018, the Company incurred an aggregate expense of $14 and $0, respectively, related to royalty payments under these agreements. Both agreements will terminate upon the expiration of the last pending, viable patent

claim of the patents acquired under the assignment agreement, but no sooner than 15 years from the effective date of the agreements.

14. Income Taxes

The Company did not record a federal or state income tax benefit for losses incurred during the nine months ended September 30, 2019 and 2018 due to the Company's conclusion that a valuation allowance was required for those periods.

15. Discontinued Operations

The components of loss from discontinued operations as reported in the Company's condensed consolidated statement of operations were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	$ 4,977	$ 510	$ 13,734	$ 2,043
Total revenue, net	4,977	510	13,734	2,043
Costs and expenses:				
Cost of revenue (excludes amortization)	1,118	126	4,396	278
Research and development	132	742	522	1,990
Sales and marketing	5,897	11,317	22,388	34,941
General and administrative	960	433	2,724	474
Intangible asset impairment	27,638	—	27,638	—
Amortization of definite-lived intangible	1,107	—	4,426	—
Total costs and expenses	36,852	12,618	62,094	37,683
Loss from discontinued operations	(31,875)	(12,108)	(48,360)	(35,640)
Other expense, net	(306)	—	(306)	—
Net loss from discontinued operations	$ (32,181)	$ (12,108)	$ (48,666)	$ (35,640)
Net loss from discontinued operations per share, basic and diluted	$ (0.78)	$ (0.39)	$ (1.18)	$ (1.15)
Weighted average common shares outstanding, basic and diluted	41,364,387	30,982,192	41,296,377	30,938,026

The following table presents the details of product sales, net included in discontinued operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
ESKATA	$ (32)	$ 510	$ 312	$ 2,043
RHOFADE	5,009	—	13,422	—
Total product sales, net	$ 4,977	$ 510	$ 13,734	$ 2,043

The following table presents information related to assets and liabilities reported as discontinued operations in the Company's condensed consolidated balance sheet:

	September 30, 2019	December 31, 2018
Accounts receivable, net	$ 17,191	$ 4,298
Inventory	189	791
Prepaid expenses and other current assets	—	1,073
Intangible asset held for sale	33,800	—
Discontinued operations - current assets	$ 51,180	$ 6,162
Property and equipment, net	$ —	$ 1,993
Intangible assets, net of accumulated amortization	—	65,678
Discontinued operations - non-current assets	$ —	$ 67,671
Accrued expenses	$ 14,501	$ 3,896
Current portion of lease liabilities	—	459
Discontinued operations - current liabilities	$ 14,501	$ 4,355
Other liabilities	$ —	$ 1,227
Discontinued operations - non- current liabilities	$ —	$ 1,227

The following table presents cash flow information related to discontinued operations:

	Nine Months Ended September 30, 2019	2018
Depreciation and amortization	$ 302	$ 160
Stock-based compensation expense	102	2,687
Intangible asset impairment charge	27,638	—
Loss on disposal of property and equipment	391	—
	$ 28,433	$ 2,847

The Company relied on Allergan to distribute RHOFADE on its behalf pursuant to the terms of a transition services agreement. Accounts receivable, net as of September 30, 2019 and December 31, 2018 included $17,191 and $3,838, respectively, related to amounts invoiced by Allergan for sales of RHOFADE.

As a result of the Company's decision to actively seek partners for its commercial products, the Company terminated the finance leases for its fleet vehicles and recognized a loss on lease termination of $306 in the three months ended September 30, 2019.

During the three months ended September 30, 2019, the Company also performed an interim impairment analysis of the RHOFADE intangible asset due its decision to discontinue commercial operations and actively seek a commercialization partner for RHOFADE. The Company classified the RHOFADE intangible asset as held for sale on its condensed consolidated balance sheet as of September 30, 2019. The Company's impairment analysis, which primarily utilized a third-party indication of fair value, resulted in a fair value for the RHOFADE intangible asset which was less

than its carrying value. As a result, the Company recorded an impairment charge of $27,638 to adjust the carrying value of the RHOFADE intangible asset to its net realizable value of $33,800, as of September 30, 2019 (see Note 19).

16. Restructuring Charges

On September 5, 2019, the Company announced the completion of a strategic review and its decision to refocus on its immuno-inflammatory development programs and to actively seek partners for its commercial products. As a result, on September 5, 2019, the Company terminated 63 employees ("terminated employees") and gave notice to an additional 23 employees ("noticed employees") who were asked to provide transition services through termination dates ranging between 4 to 6 months from the date notice was given. The terminated employees were entitled to receive cash severance payments as well as cash payments in lieu of sixty days' notice required by the Worker Adjustment and Retraining Notification Act (the "WARN Act"). The noticed employees are entitled to receive one-time cash severance payments which are not contingent upon providing additional services to the Company beyond September 5, 2019. In addition, certain noticed employees can earn retention bonuses if they continue to be employed by the Company through certain termination dates. The Company recorded a restructuring charge for the one-time severance and WARN Act payments, which was triggered immediately upon either terminating or giving notice to the impacted employees. The Company will expense the cost of retention bonuses for noticed employees over their respective service terms. During the three months ended September 30, 2019, the Company recognized expenses of $2,248 and $257 related to one-time cash payments for terminated employees and noticed employees, respectively. The Company committed to paying up to $388 for contingent retention bonuses, of which $75 was recognized in the three months ended September 30, 2019.

17. Segment Information

The Company has two reportable segments, therapeutics and contract research. The therapeutics segment is focused on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases. The Company marketed and sold RHOFADE during the nine months ended September 30, 2019. In October 2019, the Company sold the worldwide rights to RHOFADE (see Note 19). RHOFADE is a topical treatment for persistent facial erythema, or redness, associated with rosacea in adults. The Company marketed and sold ESKATA in the United States during the nine months ended September 30, 2019 and 2018 and discontinued sales and marketing of ESKATA in August 2019. ESKATA is a proprietary formulation of high-concentration hydrogen peroxide topical solution that the Company was marketing as an office-based prescription treatment for raised SKs. The Company is currently seeking a strategic partner to commercialize ESKATA worldwide.

The contract research segment earns revenue from the provision of laboratory services to clients through Confluence, the Company's wholly-owned subsidiary. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis. Corporate and other includes general and administrative expenses as well as eliminations of intercompany transactions. The Company does not report balance sheet information by segment since it is not reviewed by the chief operating decision maker, and all of the Company's tangible assets are held in the United States.

The Company's results of operations by segment for the three and nine months ended September 30, 2019 and 2018 are summarized in the tables below:

Three Months Ended September 30, 2019	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 2,943	$ (1,960)	$ 983
Cost of revenue (excludes amortization)	—	2,724	(1,898)	826
Research and development	16,245	—	(62)	16,183
Sales and marketing	96	16	—	112
General and administrative	—	956	5,770	6,726
Amortization of definite-lived intangible	—	—	—	—
Loss from operations	$ (16,341)	$ (753)	$ (5,770)	$ (22,864)
Loss from discontinued operations	$ (30,915)	$ —	$ (960)	$ (31,875)

Three Months Ended September 30, 2018	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 3,225	$ (2,107)	$ 1,118
Cost of revenue	—	2,823	(1,756)	1,067
Research and development	15,189	—	—	15,189
Sales and marketing	49	14	—	63
General and administrative	—	566	5,575	6,141
Loss from operations	$ (15,238)	$ (178)	$ (5,926)	$ (21,342)
Loss from discontinued operations	$ (11,675)	$ —	$ (433)	$ (12,108)

Nine Months Ended September 30, 2019	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 11,940	$ (8,808)	$ 3,132
Cost of revenue (excludes amortization)	—	11,584	(8,556)	3,028
Research and development	53,585	—	(251)	53,334
Sales and marketing	581	48	—	629
General and administrative	—	2,069	19,073	21,142
Goodwill impairment	18,504	—	—	18,504
Amortization of definite-lived intangible	—	—	—	—
Loss from operations	$ (72,670)	$ (1,761)	$ (19,074)	$ (93,505)
Loss from discontinued operations	$ (45,636)	$ —	$ (2,724)	$ (48,360)

Nine Months Ended September 30, 2018	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ 1,000	$ 8,779	$ (5,400)	$ 4,379
Cost of revenue	—	7,564	(4,501)	3,063
Research and development	41,482	—	—	41,482
Sales and marketing	55	34	—	89
General and administrative	—	1,557	18,924	20,481
Loss from operations	$ (40,537)	$ (376)	$ (19,823)	$ (60,736)
Loss from discontinued operations	$ (35,166)	$ —	$ (474)	$ (35,640)

Intersegment Revenue

Revenue for the contract research segment included $1,960 and $2,107 for services performed on behalf of the therapeutics segment for the three months ended September 30, 2019 and 2018, respectively, and $8,807 and $5,400 for the nine months ended September 30, 2019 and 2018, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

18. Legal Proceedings

Securities Class Actions

On July 30, 2019, plaintiff Linda Rosi ("Rosi") filed a putative class action complaint captioned*Rosi v. Aclaris Therapeutics, Inc., et al.*, in the U.S. District Court for the Southern District of New York against the Company and certain of its executive officers ("Defendants"). The complaint alleges that Defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired the Company's securities between May 8, 2018 and June 20, 2019.

On September 9, 2019, an additional plaintiff, Robert Fulcher ("Fulcher"), filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc., et al*., in the same court against the same Defendants.

On September 30, 2019, Rosi and Fulcher each filed separate motions to consolidate the cases and to be appointed "lead plaintiff" for the putative class. On October 15, 2019, Rosi filed a "notice of non-opposition" to Fulcher's motion to consolidate cases and to serve as lead plaintiff. The court has not yet appointed a lead plaintiff and no consolidated complaint has been filed.

Defendants dispute plaintiffs' claims and intend to defend the matter vigorously.

Patent Infringement

On October 8, 2019, the Company, together with Allergan, Inc., filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Taro Pharmaceuticals, Inc. ("Taro"), related to an Abbreviated New Drug Application ("ANDA") that Taro filed with the FDA to market a generic version of RHOFADE. The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. The Company received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents. Under the Asset Purchase Agreement (the "APA") with EPI Health, EPI Health agreed to file a motion to be substituted for the Company as a plaintiff party and has agreed to reimburse the Company for its reasonable fees and expenses so long as it remains a plaintiff party.

19. Subsequent Events

Asset Purchase Agreement with EPI Health

On October 10, 2019, the Company entered into an APA with EPI Health, pursuant to which the Company sold the worldwide rights to RHOFADE, which includes the assignment of certain licenses for related intellectual property assets (the "Disposition").

Pursuant to the APA, EPI Health has agreed to pay the Company total cash consideration of up to $55,000, consisting of (i) an upfront payment of $35,000 ($1,750 of which was placed in escrow) and (ii) potential sales milestone payments of up to $20,000 in the aggregate upon the achievement of specified levels of net sales (as defined in the APA) of products covered by the APA. In addition, EPI Health has agreed to pay the Company (i) a specified high single-digit royalty calculated as a percentage of net sales, on a product-by-product and country-by-country basis, until the date that

the patent rights related to a particular product, such as RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country, (ii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the Disposition in any territory outside of the United States, subject to specified exceptions and (iii) approximately $200 for certain inventory, subject to a specified post-closing inventory-related adjustment. In addition, EPI Health has agreed to assume the Company's obligation to pay specified royalties and milestone payments under its existing agreements with Allergan, Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

Repayment of the Term Loan Facility with Oxford

On October 10, 2019, the Company repaid in full the $30,000 borrowed under the Loan Agreement with Oxford (see Note 7). In addition, in accordance with the terms of the Loan Agreement, the Company paid (i) accrued and unpaid interest of approximately $70, (ii) a final payment fee of $1,725 and (iii) a prepayment fee of $600. Following this repayment, all of the Company's obligations under the Loan Agreement are deemed to be terminated, except as set forth in the agreement.

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, 2018, which are included in our Annual Report on Form 10-K filed with the SEC on March 18, 2019.

Overview

We are a physician-led biopharmaceutical company focused on immuno-inflammatory diseases. We currently have one commercial product and a diverse pipeline of drug candidates, including one late-stage investigational drug candidate. In September 2019, we announced the completion of a strategic review of our business, as a result of which we are refocusing our resources on our immuno-inflammatory development programs and seeking partners for our commercial products and certain development assets. In October 2019, we sold the worldwide rights to one of our commercial products, RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which includes the assignment of certain licenses for related intellectual property assets, as described further below under "— Recent Developments." Our other commercial product, ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, is a proprietary formulation of high concentration hydrogen peroxide which was approved by the U.S. Food and Drug Administration, or FDA, in December 2017 as an office-based prescription treatment for raised seborrheic keratosis, or SK, a common non-malignant

skin tumor. In August 2019, we voluntarily discontinued the commercialization of ESKATA in the United States and withdrew the marketing authorizations we had previously received for the product in all countries outside of the United States. We continue to maintain the New Drug Application, or NDA, for ESKATA in the United States. We are currently seeking a strategic partner to commercialize ESKATA worldwide.

We are developing another high-concentration formulation of hydrogen peroxide, A-101 45% Topical Solution, as a potential prescription treatment for common warts, also known as verruca vulgaris. On an annual basis, approximately 2.0 million people in the United States are diagnosed with common warts. In each of our two completed pivotal Phase 3 clinical trials, which we refer to as THWART-1 and THWART-2, subjects treated with A-101 45% Topical Solution achieved clinically meaningful and statistically significant outcomes for the primary and secondary efficacy endpoints. In addition, in February 2019, we commenced an open-label safety extension trial investigating A-101 45% Topical Solution as a potential treatment for common warts, for which we completed enrollment of 425 patients in May 2019. We expect this trial to be completed in the first half of 2020. We are seeking a partner to commercialize A-101 45% Topical Solution as a potential treatment for common warts.

In 2015, we in-licensed exclusive, worldwide rights from Rigel Pharmaceuticals, Inc., or Rigel, to certain inhibitors of the Janus kinase, or JAK, family of enzymes, which we refer to as ATI-501 and ATI-502, an oral and topical formulation, respectively, for specified dermatological conditions, including alopecia areata, or AA, and androgenetic alopecia, or AGA, also known as male or female pattern baldness. We are seeking a development and commercialization partner for ATI-501 and ATI-502 as potential treatments for alopecia. The following summarizes the status of our Phase 2 clinical trials of ATI-501 and ATI-502 as potential treatments for alopecia.

AA-201 Topical – This Phase 2 randomized, double-blinded, parallel-group, vehicle-controlled trial evaluated the safety, efficacy and dose response of two concentrations of ATI-502 on the regrowth of hair in 129 subjects with AA. In June 2019, we announced that ATI-502 did not achieve statistical superiority at the primary or secondary endpoints in this trial due to high rates of disease resolution in vehicle-treated patients.

AUAT-201 Oral – This Phase 2 randomized, double-blinded, parallel-group, placebo-controlled trial evaluated the safety, efficacy and dose response of three doses of ATI-501 on the regrowth of hair in 87 subjects with AA. In July 2019, we announced that ATI-501 achieved statistically significant improvement over placebo in several measures of hair growth, including the primary endpoint and certain secondary endpoints of this trial. ATI-501 was observed to be generally well-tolerated at all doses. There were no serious adverse events reported. All adverse events, or AEs, were mild or moderate in severity and rates of AEs were similar across all groups. No thromboembolic events were observed in the trial. The most common AEs across all groups were: nasopharyngitis, influenza, upper respiratory tract infection, urinary tract infection, acne, increased blood creatine phosphokinase, and sinusitis. Two subjects in each of the placebo and 400 mg groups and one subject in the 600 mg group had AEs leading to discontinuation of study drug, with no such AEs in the 800 mg group.

AGA-201 Topical – This ongoing Phase 2 open-label uncontrolled clinical trial is evaluating the safety and efficacy of ATI-502 on the regrowth of hair in 31 patients with AGA. We reported 6-month data in June 2019, and 12-month data are expected in the fourth quarter of 2019.

In 2016, in connection with our acquisition of Vixen Pharmaceuticals, Inc., or Vixen, we acquired additional intellectual property rights for the development and commercialization of certain JAK inhibitors for specified dermatological conditions.

In 2017, we acquired Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence. The acquisition of Confluence added small molecule drug discovery and preclinical development capabilities that allowed us to bring early-stage research and development activities in-house that we previously outsourced to third parties. We intend to leverage our proprietary drug discovery platform, called KINect, to identify potential drug candidates that we

may develop either independently or in collaboration with third parties. We also earn revenue from Confluence's provision of contract research services to third parties. We also acquired several preclinical drug candidates, including additional topical JAK inhibitors known as soft-JAK inhibitors, inhibitors of the mitogen-activated protein kinase-activated protein kinase 2, or MK2, signaling pathway and inhibitors of interleukin-2-inducible T cell kinase, or ITK.

We submitted an Investigational New Drug Application, or IND, in April 2019 for ATI-450, an investigational oral, novel, small molecule selective MK2 inhibitor compound, for the treatment of rheumatoid arthritis, which was allowed by the FDA in May 2019. MK2 is a key regulator of pro-inflammatory mediators including TNFα, IL-1β, IL-6, IL-8 and other essential pathogenic signals in chronic inflammatory and autoimmune diseases, as well as in cancer. As an oral drug candidate, ATI-450 is being developed as a potential alternative to injectable anti-TNF/anti-IL-1 biologics for treating immuno-inflammatory diseases.

We initiated a Phase 1 clinical trial for ATI-450 in approximately 60-80 subjects in August 2019, and data from this trial are expected by the end of the first quarter of 2020. If successfully completed, we expect to initiate a Phase 2 clinical trial for ATI-450 in subjects with rheumatoid arthritis in the first half of 2020. We are also considering developing ATI-450 for an additional inflammatory indication.

We expect to submit an IND or equivalent regulatory filing for ATI-1777, an investigational soft-JAK inhibitor compound, for the treatment of atopic dermatitis in mid-2020. Soft-JAK inhibitors are designed to be topically applied and active in the skin, but rapidly metabolized and inactivated when they enter the bloodstream, which may result in low systemic exposure. If the IND or regulatory filing is allowed, we expect to initiate a Phase 1/2 clinical trial in the second half of 2020. We are considering developing ATI-1777 as a potential treatment for moderate-to-severe atopic dermatitis.

We are considering developing our investigational ITK inhibitor compounds as potential treatments for psoriasis, inflammatory dermatoses, or inflammatory bowel disease.

Since our inception, we have incurred significant operating losses. Our net loss was $142.8 million for the nine months ended September 30, 2019 and $132.7 million for the year ended December 31, 2018. As of September 30, 2019, we had an accumulated deficit of $434.9 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical and clinical development. In addition, our drug candidates, even if they are approved by regulatory agencies for marketing, may not achieve commercial success. We may also not be successful in finding development and/or commercialization partners for our 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.

We have historically financed our operations primarily with sales of our convertible preferred stock, as well as net proceeds from our initial public offering, or IPO, in October 2015, and subsequent public offerings of, and a private placement of, our common stock. In the near term, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential partnerships 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 of one or more of our drug candidates.

Recent Developments

Divestiture of RHOFADE

On October 10, 2019, we entered into an Asset Purchase Agreement, or the APA, with EPI Health, LLC, or EPI Health, pursuant to which we sold the worldwide rights to RHOFADE, which includes the assignment of certain licenses for related intellectual property assets.

Pursuant to the APA, EPI Health has agreed to pay us total cash consideration of up to $55.0 million, consisting of (i) an upfront payment of $35.0 million ($1.75 million of which was placed in escrow) and (ii) potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales (as defined in the APA) of products covered by the APA. In addition, EPI Health has agreed to pay us (i) a specified high single-digit royalty calculated as a percentage of net sales, on a product-by-product and country-by-country basis, until the date that the patent rights related to a particular product, such as RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country, (ii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the disposition in any territory outside of the United States, subject to specified exceptions and (iii) $0.2 million for certain inventory, subject to a specified post-closing inventory-related adjustment. In addition, EPI Health has agreed to assume our obligation to pay specified royalties and milestone payments under our existing agreements with Allergan Sales, LLC, or Allergan, Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

Repayment of Term Loan Facility

On October 10, 2019, we repaid in full the $30 million borrowed under the Loan and Security Agreement, dated as of October 15, 2018, or the Loan Agreement, with Oxford Finance LLC, or Oxford. In addition, in accordance with the terms of the Loan Agreement, we paid (i) accrued and unpaid interest of $0.1 million, (ii) a final payment fee of $1.7 million and (iii) a prepayment fee of $0.6 million. Following this repayment, all of our obligations under the Loan Agreement are deemed to be terminated, except as set forth in the agreement.

Amendment to Rigel License and Collaboration Agreement

On October 15, 2019, we and Rigel entered into a First Amendment, or the First Amendment, to the License and Collaboration Agreement, originally dated as of August 27, 2015.

Pursuant to the First Amendment, we and Rigel agreed to eliminate certain of the development milestones and Rigel released us from any obligation to pay a milestone payment for such milestones. We also agreed to pay Rigel an amendment fee of $1.5 million to be paid in three installments of $500,000 in January 2020, April 2020 and July 2020. In addition, we modified certain other development milestones, and we agreed to increase the potential payments payable upon the achievement of such milestones from $10.0 million to $10.5 million in the aggregate. The First Amendment also provides that our obligation to use commercially reasonable efforts to develop, seek regulatory approval and commercialize at least one product would be deemed satisfied by us using commercially reasonable efforts to find a third party to use commercially reasonable efforts to develop, seek regulatory approval and commercialize at least one product.

Components of Our Results of Operations

Revenue

Product Sales, net

We sold RHOFADE in the United States during the nine months ended September 30, 2019. We relied on Allergan to distribute RHOFADE on our behalf pursuant to the terms of a transition services agreement. We sold RHOFADE to wholesalers in the United States, which, in turn, distributed it to pharmacies that ultimately filled patient prescriptions. We also entered into arrangements with third-party payors, including pharmacy benefit managers and government agencies, as well as group purchasing organizations, or GPOs, which provided for government mandated or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of RHOFADE. We never sold

RHOFADE outside of the United States. We sold the worldwide rights to RHOFADE to EPI Health in October 2019 (see "—Recent Developments").

We discontinued sales of ESKATA in the United States in August 2019. During the nine months ended September 30, 2019 and 2018, we sold ESKATA to one wholesaler, McKesson Specialty Care Distribution, or McKesson, which in turn resold ESKATA to health care providers. We also entered into agreements with two GPOs that provided for administrative fees and discounted pricing in the form of volume-based rebates and chargebacks. We never sold ESKATA outside of the United States.

Product sales, net has been reclassified to discontinued operations for all periods presented.

Contract Research

We earn revenue from the provision of laboratory services to clients through Confluence, our wholly-owned subsidiary. Contract research 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.

We have also received revenue from grants under the Small Business Innovation Research program of the National Institutes of Health, or NIH. During the nine months ended September 30, 2018, we had two active grants from NIH which were related to early-stage research. There are no remaining funds available to us under the grants.

Cost of Revenue

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

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

Research and Development Expenses

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

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing active pharmaceutical ingredients and preclinical and clinical trial materials;
- outsourced professional scientific development services;
- medical affairs expenses related to our drug candidates, including investigator-initiated studies;
- 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 to continue to incur research and development expenses in the near term as we continue the clinical development of A-101 45% Topical Solution as a potential treatment for common warts and ATI-450 as a potential treatment for rheumatoid arthritis and other inflammatory conditions, continue the development of our preclinical compounds, and continue to identify, research and develop additional 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 subjects;
- the number of subjects that ultimately participate in the trials;
- the number of doses subjects receive;
- the duration of subject follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the preparation of regulatory filings for marketing approval for our drug candidates, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. 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 primarily consist of market research activities related to A-101 45% Topical Solution and our JAK inhibitors.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance, investor relations and legal functions, including stock-based compensation, travel expenses and recruiting expenses. General and administrative expenses also include facility-related costs, patent filing and prosecution costs, professional fees for legal, auditing and tax services, insurance costs, as well as payments made under a terminated related party sublease agreement and milestone payments under our finder's services agreement. We anticipate that we will incur increased director and officer insurance premiums and legal expenses associated with defending securities class action lawsuits.

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 generally accepted accounting principles in the United States. 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. 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. We evaluate our estimates and judgments on an ongoing basis. Our 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 significant accounting policies and use of estimates as disclosed in the footnotes to our audited consolidated financial statements for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed with the SEC on March 18, 2019.

Revenue Recognition

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.

Product Sales, net

We recognize revenue from product sales at the point the customer obtains control, which generally occurs upon delivery, and also include estimates of variable consideration in the same period revenue is recognized. Components of variable consideration include trade discounts and allowances, product returns, government rebates, discounts and rebates, other incentives such as patient co-pay assistance, and other fee for service amounts. Variable consideration is recorded on the condensed consolidated balance sheet as either a reduction of accounts receivable, if payable to a customer, or as a current liability, if payable to a third party other than a customer. We consider all relevant information when estimating variable consideration such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of net revenue we can recognize is constrained by estimates of variable consideration which are included in the transaction price. Payment terms with customers do not exceed one year and, therefore, we do not account for a financing component in our arrangements. We expense incremental costs of obtaining a contract with a customer, including sales commissions, when incurred as the period of benefit is less than one year. Shipping and handling costs for product shipments to customers are recorded as sales and marketing expenses in the condensed consolidated statement of operations.

Trade Discounts and Allowances - We provided customers with trade discounts, rebates, allowances and other incentives. We record an estimate for these items as a reduction of revenue in the same period the revenue is recognized.

Government and Payor Rebates – We contracted with certain third-party payors, including pharmacy benefit managers and government agencies, for the payment of rebates with respect to utilization of our commercial products. We also entered into agreements with GPOs that provided for administrative fees and discounted pricing in the form of volume-based rebates. We are also subject to discount and rebate obligations under state Medicaid programs and Medicare. We record an estimate for these discounts and rebates as a reduction of revenue in the same period the revenue is recognized.

Other Incentives - Other incentives include our co-pay assistance program which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by third-party payors. We estimate and record an accrual for these incentives as a reduction of revenue in the period the revenue is recognized. Our estimated amounts for co-pay assistance are based upon the number of claims and the cost per claim that we expect to receive associated with product that has been sold to customers but remains in the distribution channel at the end of each reporting period.

Product Returns - Consistent with industry practice, we have a product returns policy which may provide customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the product to a patient. We record an estimate for the amount of product which may be returned as a reduction of revenue in the period the related revenue is recognized. Our estimates for product returns are based upon available industry data and our own sales information, including visibility into the inventory remaining in the distribution channel. There is no returns liability associated with sales of ESKATA as we have a no returns policy for ESKATA.

Contract Research

Revenue related to laboratory services 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 contract research revenue. We recognize contract research revenue in the amount to which we have the right to invoice.

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.

Inventory

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

Intangible Assets

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

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

During the three months ended September 30, 2019, we performed an interim impairment analysis of the RHOFADE intangible asset due to our decision to discontinue commercial operations and actively seek a commercialization partner for RHOFADE. We classified the RHOFADE intangible asset as held for sale on our condensed consolidated balance sheet as of September 30, 2019. Our impairment analysis, which primarily utilized a third-party indication of fair value, resulted in a fair value for the RHOFADE intangible asset which was less than its carrying value. As a result, we recorded an impairment charge of $27.6 million to adjust the carrying value of the RHOFADE intangible asset to its net realizable value, in the nine months ended September 30, 2019.

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which we perform during the fourth quarter, or when indicators of an impairment are present. We consider each of our operating segments, therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. We attributed the full amount of the goodwill in connection with the acquisition of Confluence, or $18.5 million, to our therapeutics segment. We perform an impairment test annually which is a qualitative assessment based upon current facts and circumstances related to operations of the therapeutics segment. If our qualitative assessment indicates an impairment may be present, we would perform the required quantitative analysis and an impairment charge would be recognized to the extent that the estimated fair value of the reporting unit is less than its carrying amount. However, any loss recognized would not exceed the total amount of goodwill allocated to that reporting unit.

During the nine months ended September 30, 2019, we performed an interim impairment analysis due to the decline in our stock price, which was considered a triggering event to evaluate goodwill for impairment. Our impairment analysis, using a market approach, noted that our stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, we recorded an impairment charge of $18.5 million, the full balance of goodwill, in the nine months ended September 30, 2019.

Leases

Leases represent a company’s right to use an underlying asset and a corresponding obligation to make payments to a lessor for the right to use those assets. We evaluate leases at their inception to determine if they are an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows are substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic

life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease.

We recognize assets and liabilities for leases at their inception based upon the present value of all payments due under the lease. We use an implicit interest rate to determine the present value of finance leases, and our incremental borrowing rate to determine the present value of operating leases. We determine incremental borrowing rates by referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. We recognize expense for operating and finance leases on a straight-line basis over the term of each lease, and interest expense related to finance leases is recognized over the lease term based on the effective interest method. We include estimates for any residual value guarantee obligations under our leases in lease liabilities recorded on our condensed consolidated balance sheet.

Right-of-use assets are included in other assets and property and equipment, net on our condensed consolidated balance sheet for operating and finance leases, respectively. Obligations for lease payments are included in current portion of lease liabilities and other liabilities on our condensed consolidated balance sheet for both operating and finance leases.

Contingent Consideration

We initially recorded the contingent consideration related to future potential payments based upon the achievement of specified development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in our condensed consolidated statement of operations.

During the nine months ended September 30, 2019, we updated our assumptions for contingent consideration related to the acquisition of Confluence as a result of the filing of an IND for ATI-450, which resulted in a charge of $0.7 million.

Recently Issued Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We are evaluating the impact of ASU 2018-18 on our consolidated financial statements.

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

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing

disclosure requirements. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. We are evaluating the impact of ASU 2018-13 on our consolidated financial statements.

In June 2018, the FASB, issued ASU 2018-07, Compensation-Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with non-employees except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 was effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year. We adopted this standard as of January 1, 2019, the impact of which on our consolidated financial statements was not significant.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, and ASU 2018-11, Targeted Improvements, both of which included a number of technical corrections and improvements, including additional options for transition. The new standard establishes a right-of-use model that requires a lessee to record a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods. The amendments in ASU 2016-02 must be applied to all leases existing at the date a company initially applies the standard.

We adopted the new standard on January 1, 2019, using the effective date as the date of initial application, and we used the modified retrospective approach. In addition, we elected the practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease identification and classification. We also elected the practical expedient to not separate lease and non-lease components, as well as the short-term lease exemption which allowed us to not capitalize leases with terms less than 12 months that do not contain a reasonably certain purchase option. Our consolidated financial statements have not been updated, and disclosures required by the new standard have not been provided, for periods before January 1, 2019.

The adoption of ASU 2016-02 resulted in recording additional assets and liabilities of $2.1 million and $2.3 million, respectively upon adoption on January 1, 2019. The adoption of ASU 2016-02 did not have a material impact on our consolidated statement of operations or cash flows.

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2018

	Three Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
Revenues:			
Product sales, net	$ —	$ —	$ —
Contract research	983	1,118	(135)
Other revenue	—	—	—
Total revenue, net	983	1,118	(135)
Costs and expenses:			
Cost of revenue	826	1,067	(241)
Research and development	16,183	15,189	994
Sales and marketing	112	63	49
General and administrative	6,726	6,141	585
Amortization of definite-lived intangible	—	—	—
Total costs and expenses	23,847	22,460	1,387
Loss from operations	(22,864)	(21,342)	(1,522)
Other income (expense), net	(274)	710	(984)
Loss from continuing operations	(23,138)	(20,632)	(2,506)
Loss from discontinued operations	(32,181)	(12,108)	(20,073)
Net loss	$ (55,319)	$ (32,740)	$ (22,579)

Revenue

Contract research revenue was $1.0 million and $1.1 million for the three months ended September 30, 2019 and 2018, respectively, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence. Revenue from product sales of ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Cost of Revenue

Cost of revenue was $0.8 million and $1.1 million for the three months ended September 30, 2019 and 2018, respectively, and related to providing laboratory services to our clients through Confluence. Cost of revenue for product sales related to ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
A-101 45% Topical Solution	$ 2,353	$ 2,697	$ (344)
JAK inhibitors	2,243	6,092	(3,849)
ATI-450	2,199	1,087	1,112
ESKATA	—	—	—
Personnel expenses	2,327	1,834	493
Restructuring expenses	304	—	304
Milestone payments	4,000	—	4,000
Other research expenses	1,339	2,046	(707)
Stock-based compensation	1,418	1,433	(15)
Total research and development expenses	$ 16,183	$ 15,189	$ 994

Expenses related to A-101 45% Topical Solution decreased primarily due to our two pivotal Phase 3 clinical trials, which were initiated during the third quarter of 2018 and were at or near completion during the three months ended September 30, 2019. We announced results from one of the Phase 3 clinical trials in September 2019 and from the other Phase 3 clinical trial in October 2019. Development expenses related to our JAK inhibitors decreased primarily as a result of several Phase 2 clinical trials of ATI-501 and ATI-502 which were at or near completion during the three months ended September 30, 2019. The increase in expenses for ATI-450 resulted primarily from preclinical development activities as well as the initiation of a Phase 1 clinical trial. Restructuring expenses primarily included the costs of termination benefits given to employees that were involuntarily terminated during the three months ended September 30, 2019. We incurred a one-time milestone payment of $4.0 million in the three months ended September 30, 2019 upon the achievement of a development milestone as specified in the license and collaboration agreement with Rigel. Other research expenses, which primarily included expenses for medical affairs activities and drug discovery research, decreased primarily as a result of lower medical affairs activities during the three months ended September 30, 2019. Research and development expenses related to ESKATA have been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Three Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
Direct marketing and professional fees	$ 112	$ 14	$ 98
Personnel expenses	—	—	—
Other sales and marketing expenses	—	49	(49)
Stock-based compensation	—	—	—
Total sales and marketing expenses	$ 112	$ 63	$ 49

Sales and marketing expenses primarily consisted of market research activities related to A-101 45% Topical Solution and our JAK inhibitors. Direct marketing and professional fees, personnel expenses, other sales and marketing expenses and stock-based compensation related to ESKATA and RHOFADE have been reclassified to discontinued

operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
Personnel expenses	$ 1,845	$ 1,570	$ 275
Restructuring expenses	552	—	552
Professional and legal fees	565	1,167	(602)
Facility and support services	735	565	170
Other general and administrative expenses	448	519	(71)
Stock-based compensation	2,581	2,320	261
Total general and administrative expenses	$ 6,726	$ 6,141	$ 585

Personnel and stock-based compensation expenses increased due to increased headcount. Restructuring expenses primarily included the costs of termination benefits given to employees that were involuntarily terminated during the three months ended September 30, 2019. Professional and legal fees included accounting, legal, investor relations and corporate communication costs, as well as legal fees related to patents. The decrease in professional and legal fees was primarily related to lower corporate communications costs as well as lower legal costs incurred related to patents. Facility and support services included general office expenses and information technology costs, which have increased due to our increased headcount.

Amortization of Definite-Lived Intangible

Amortization expense related to the intangible asset for RHOFADE intellectual property has been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Other Income (Expense), net

The $1.0 million decrease in other income (expense), net was primarily due to interest expense incurred on our debt with Oxford, which we borrowed in October 2018. We repaid the debt in full in October 2019 (see "—Recent Developments").

Loss from Discontinued Operations

On September 5, 2019, we announced the completion of a strategic review and our decision to refocus on our immuno-inflammatory development programs and to actively seek partners for our commercial products. The condensed consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to our commercial products as discontinued operations (see Note 15 to the consolidated financial statements included in this report for more information).

Comparison of Nine Months Ended September 30, 2019 and 2018

	Nine Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
Revenues:			
Product sales, net	$ —	$ —	$ —
Contract research	3,132	3,379	(247)
Other revenue	—	1,000	(1,000)
Total revenue, net	3,132	4,379	(1,247)
Costs and expenses:			
Cost of revenue	3,028	3,063	(35)
Research and development	53,334	41,482	11,852
Sales and marketing	629	89	540
General and administrative	21,142	20,481	661
Goodwill impairment	18,504	—	18,504
Amortization of definite-lived intangible	—	—	—
Total costs and expenses	96,637	65,115	31,522
Loss from operations	(93,505)	(60,736)	(32,769)
Other income (expense), net	(589)	2,189	(2,778)
Loss from continuing operations	(94,094)	(58,547)	(35,547)
Loss from discontinued operations	(48,666)	(35,640)	(13,026)
Net loss	$ (142,760)	$ (94,187)	$ (48,573)

Revenue

Contract research revenue was $3.1 million and $3.4 million for the nine months ended September 30, 2019 and 2018, respectively, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence. Other revenue consisted of an upfront payment of $1.0 million we received upon signing of a license agreement with Cipher in April 2018. Revenue from product sales of ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Cost of Revenue

Cost of revenue was $3.0 million and $3.1 million for the nine months ended September 30, 2019 and 2018, respectively, and related to providing laboratory services to our clients through Confluence. Cost of revenue for product sales related to ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Research and Development Expenses

The following table summarizes our research and development expenses:

	Nine Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
A-101 45% Topical Solution	$ 12,216	$ 4,223	$ 7,993
JAK inhibitors	13,306	17,806	(4,500)
ATI-450	5,617	2,522	3,095
ESKATA	—	—	—
Personnel expenses	7,586	6,179	1,407
Restructuring expenses	304	—	304
Milestone payments	4,000	—	4,000
Change in contingent consideration	734	866	(132)
Other research expenses	4,838	4,970	(132)
Stock-based compensation	4,733	4,916	(183)
Total research and development expenses	$ 53,334	$ 41,482	$ 11,852

Expenses related to A-101 45% Topical Solution increased primarily due to our ongoing Phase 3 clinical trials, which we initiated during the third quarter of 2018. Development expenses related to our JAK inhibitors decreased primarily as a result of several Phase 2 clinical trials of ATI-501 and ATI-502 which were at or near completion during the nine months ended September 30, 2019. The increase in expenses for ATI-450 resulted primarily from preclinical development activities as well as the initiation of a Phase 1 clinical trial. Personnel expenses increased due to increased headcount. Restructuring expenses primarily include the costs of termination benefits given to employees that were involuntarily terminated during the three months ended September 30, 2019. We incurred a one-time milestone payment of $4.0 million in the nine months ended September 30, 2019 upon the achievement of a development milestone as specified in the license and collaboration agreement with Rigel. The change in contingent consideration during the nine months ended September 30, 2019 was the result of updates to our assumptions as a result of the filing of an IND for ATI-450. The change in contingent consideration during the nine months ended September 30, 2018 was the result of updates to our assumptions related to drug discovery research on our soft-JAK inhibitors, which progressed more quickly than we had originally planned. Other research expenses, which primarily included expenses for medical affairs activities as well as drug discovery, were consistent period over period. The decrease in stock-based compensation was primarily driven by the timing of the issuance of the equity awards during the twelve months preceding September 30, 2019, as well as the relatively lower fair value of those awards. Research and development expenses related to ESKATA have been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Nine Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
Direct marketing and professional fees	$ 621	$ 41	$ 580
Personnel expenses	—	—	—
Other sales and marketing expenses	8	48	(40)
Stock-based compensation	—	—	—
Total sales and marketing expenses	$ 629	$ 89	$ 540

Sales and marketing expenses primarily consisted of market research activities related to A-101 45% Topical Solution and our JAK inhibitors. Direct marketing and professional fees, personnel expenses, other sales and marketing expenses and stock-based compensation related to ESKATA and RHOFADE have been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Nine Months Ended September 30,		
	2019	2018	Change
	(In thousands)		
Personnel expenses	$ 6,435	$ 5,124	$ 1,311
Restructuring expenses	552	—	552
Professional and legal fees	2,980	3,811	(831)
Facility and support services	2,091	1,774	317
Milestone payments	—	1,500	(1,500)
Other general and administrative expenses	1,377	1,336	41
Stock-based compensation	7,707	6,936	771
Total general and administrative expenses	$ 21,142	$ 20,481	$ 661

Personnel and stock-based compensation expenses increased due to increased headcount. Restructuring expenses primarily include the costs of termination benefits given to employees that were involuntarily terminated during the nine months ended September 30, 2019. Professional and legal fees included accounting, legal, investor relations and corporate communication costs, as well as legal fees related to patents. The decrease in professional and legal fees was primarily related to lower corporate communications costs as well as lower legal costs incurred related to patents. Facility and support services included general office expenses and information technology costs, which have risen due to our increased headcount. We incurred a one-time milestone payment of $1.5 million in the nine months ended September 30, 2018 upon the achievement of a milestone as specified in the finder's services agreement with KPT Consulting, LLC.

Goodwill Impairment

During the nine months ended September 30, 2019, we performed an interim impairment analysis due to the decline in our stock price. Our impairment analysis noted that our stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, we recorded an impairment charge of $18.5 million writing off the full balance of goodwill.

Amortization of Definite-Lived Intangible

Amortization expense related to the intangible asset for RHOFADE intellectual property has been reclassified to discontinued operations for all periods presented (see Note 15 to the consolidated financial statements included in this report for more information).

Other Income (Expense), net

The $2.8 million decrease in other income (expense), net was primarily due to interest expense incurred on our debt with Oxford, which we borrowed in October 2018. We repaid the debt in full in October 2019 (see "—Recent Developments").

Loss from Discontinued Operations

On September 5, 2019, we announced the completion of a strategic review and our decisions to refocus on our immuno-inflammatory development programs and to actively seek partners for our commercial products. The condensed consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to our commercial products as discontinued operations (see Note 15 to the consolidated financial statements included in this report for more information).

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 over the last several years primarily through sales of our equity securities in public offerings and a private placement transaction. In October 2018, we entered into the Loan Agreement with Oxford, which we repaid in full in October 2019.

As of September 30, 2019, we had cash, cash equivalents and marketable securities of $91.4 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 sublease obligations, capital lease obligations and contingent obligations under acquisition and intellectual property licensing agreements, which are summarized below under "Contractual Obligations and Commitments."

Loan and Security Agreement with Oxford

In October 2018, we entered into the Loan Agreement with Oxford. The agreement provided for up to $65.0 million in term loans. Of the $65.0 million, we borrowed $30.0 million in October 2018. In October 2019, we repaid in full the $30.0 million that was outstanding under the Loan Agreement. The Loan Agreement provided for interest only payments through the payment date immediately prior to November 1, 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 1, 2021 and continuing through the maturity date of October 1, 2023. The Loan Agreement provided for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately preceded the month in which the interest was to accrue plus 6.25%. The Loan Agreement also provided for a final payment equal to 5.75% of the original principal amount of the term loans drawn.

We had the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of (i) 3% of the original principal amount of the aggregate term loans drawn for any prepayment prior to the first anniversary of the applicable funding date, (ii) 2% of the original principal amount of the aggregate term loans drawn for any prepayment between the first and second anniversaries of the applicable funding date or (iii) 1% of the original principal amount of the aggregate term loans drawn for any prepayment after the second anniversary of the applicable funding date but before October 1, 2023.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
	(In thousands)	
Net cash used in operating activities	$ (76,055)	$ (73,563)
Net cash provided by investing activities	49,241	79,873
Net cash provided by (used in) financing activities	(307)	78
Net increase (decrease) in cash and cash equivalents	$ (27,121)	$ 6,388

Operating Activities

During the nine months ended September 30, 2019, operating activities used $76.1 million of cash primarily resulting from our net loss of $142.8 million, partially offset by non-cash adjustments of $66.0 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2019 consisted of a $9.9 million increase in accounts payable and accrued expenses and a $4.4 million decrease in prepaid expenses and other current assets, which were partially offset by a $13.0 million increase in accounts receivable. The increase in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of September 30, 2019, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of September 30, 2019 primarily included sales discounts and allowances related to sales of RHOFADE, as well as expenses related to our Phase 3 clinical trials for A-101 45% Topical Solution, our Phase 2 clinical trials for ATI-501 and ATI-502 and preclinical development and Phase 1 clinical trial activities for ATI-450. The decrease in prepaid expenses and other current assets was due to research and development activities primarily related to preclinical development activities for ATI-450 and ATI-502 which concluded during the nine months ended September 30, 2019 and reduced sales and marketing activities related to our decision to no longer use a sales force to promote RHOFADE in September 2019. In addition, because the annual renewal of our corporate insurance policies occurred in October 2019, the balance of prepaid insurance was minimal as of September 30, 2019. The increase in accounts receivable was primarily the result of sales of RHOFADE during the nine months ended September 2019. Non-cash expenses of $66.0 million were composed of an intangible asset impairment charge of $27.6 million, a goodwill impairment charge of $18.5 million, stock-based compensation expense of $13.0 million, a charge of $0.7 million related to the change in contingent consideration and depreciation and amortization expense of $6.1 million.

During the nine months ended September 30, 2018, operating activities used $73.6 million of cash primarily resulting from our net loss of $94.2 million, partially offset by changes in our operating assets and liabilities of $3.7 million, and non-cash adjustments of $16.9 million. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2018 consisted of an $8.8 million increase in accounts payable and accrued expenses, which was partially offset by a $3.5 million increase in prepaid expenses and other current assets, a $0.6 million increase in accounts receivable and a $1.0 million increase in inventory. The increase in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of September 30, 2018, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of September 30, 2018 primarily included sales and marketing expenses related to the commercial launch of ESKATA in May 2018, as well as expenses related to our Phase 3 clinical trials for A-101 45% Topical Solution, and our Phase 2 clinical trials for ATI-501 and ATI-502. The increase in prepaid expenses and other current assets was primarily due to sales and marketing expenses related to our direct-to-consumer advertising campaign for ESKATA which began in October 2018, partially offset by a $2.0 million Prescription Drug User Fee Act, or PDUFA, fee paid to the FDA in conjunction with the filing of the NDA for ESKATA, for which we received a refund during the nine months ended September 30, 2018. The increases in accounts receivable and inventory were the result of the commercial launch of ESKATA. Non-cash expenses of $16.9 million were primarily composed of stock-based compensation expense.

Investing Activities

During the nine months ended September 30, 2019, investing activities provided $49.2 million of cash, consisting of proceeds from sales and maturities of marketable securities of $171.9 million, partially offset by purchases of marketable securities of $121.3 million, and purchases of equipment of $1.3 million.

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

Financing Activities

During the nine months ended September 30, 2019, financing activities used $0.3 million of cash primarily related to finance lease payments.

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

Funding Requirements

We anticipate we will incur net losses in the near term as we continue the clinical development of A-101 45% Topical Solution as a potential treatment for common warts and ATI-450 as a potential treatment for rheumatoid arthritis and other inflammatory conditions, continue the development of our preclinical compounds, and continue to identify, research and develop additional drug candidates. We may not be able to generate revenue from these programs if, among other things, our clinical trials are not successful, the FDA does not approve our drug candidates currently in clinical trials when we expect, or at all, or we are not able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

Our primary uses of capital are, and we expect will continue in the near term to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. In addition, we are investing in a new research facility and equipment for our drug discovery operations. Our future funding requirements will be heavily determined by the resources needed to support 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, in particular after we cease to be an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, which we expect to occur on December 31, 2020.

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 consolidated financial statements that appear in Item 1 of this Quarterly Report on Form 10-Q based on our current operating assumptions. 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 of ATI-450, to develop our preclinical compounds, and to support our discovery efforts. 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 or generate revenue from transactions with third-party partners for the development and/or commercialization of our drug candidates, we may need to substantially curtail our planned operations.

We may raise additional capital through the sale of equity or 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 and development of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our funding requirements in the near term will depend on many factors, including:

- the number and development requirements of the drug candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our drug candidates;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the extent to which we in-license or acquire additional drug candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and earn revenue from such arrangements; and
- the revenue earned from our commercial products as a result of licenses to, or partnerships with, third parties.

Contractual Obligations and Commitments

We occupy space for our headquarters in Wayne, Pennsylvania under a sublease agreement which has a term through October 2023. We occupy office and laboratory space in St. Louis, Missouri under an operating lease agreement which has a term through June 2029.

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

Under various agreements, we may 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 other 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 with KPT Consulting, LLC, we have agreed to make a remaining payment of $3.0 million upon the achievement of a specified commercial milestone. In addition, we have agreed to pay royalties on sales of ESKATA or other related products at a low single-digit percentage of net sales, as defined in the agreement.

Under a license agreement with Rigel, we have agreed to make remaining aggregate payments of up to $76.0 million upon the achievement of specified development milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.5 million to Rigel upon the achievement of a second set of development milestones. In addition, in connection with the amendment of the agreement in October 2019, we agreed to pay Rigel an amendment fee of $1.5 million in three installments of $500,000 in January 2020, April 2020 and July 2020. 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 an annual payment of $0.1 million through March 2022, which amounts are creditable against any specified future payments that may be paid under the agreement. With respect to any covered products that we commercialize under the agreement, 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 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 agreement, we will be obligated to pay Columbia a portion of any consideration we receive from such sublicenses in specified circumstances.

Under a merger agreement with Confluence, we are obligated to make remaining aggregate payments of up to $75.0 million upon the achievement of specified 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 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 JOBS Act 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.

In connection with the Loan Agreement with Oxford, we were subject to risks relating to changes in market interest rates. We repaid the debt under the Loan Agreement in full in October 2019.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019, 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 internal controls over financial reporting related to RHOFADE, which was acquired in November 2018. 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. Net revenues from sales of RHOFADE were $4.4 million and $12.8 million during the three and nine months ended September 30, 2019, respectively.

(b) *Changes in Internal Control Over Financial Reporting*

There have not been any changes in our internal control over financial reporting during our fiscal quarter ended September 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As a result of the divestiture of RHOFADE in October 2019, management discontinued analyzing and evaluating our internal control over financial reporting with respect to RHOFADE.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Securities Class Actions

On July 30, 2019, plaintiff Linda Rosi ("Rosi") filed a putative class action complaint captioned*Rosi v. Aclaris Therapeutics, Inc., et al.*, in the U.S. District Court for the Southern District of New York against us and certain of our executive officers ("Defendants"). The complaint alleges that Defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired our securities between May 8, 2018 and June 20, 2019.

On September 9, 2019, an additional plaintiff, Robert Fulcher ("Fulcher"), filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc., et al*., in the same court against the same Defendants.

On September 30, 2019, Rosi and Fulcher each filed separate motions to consolidate the cases and to be appointed "lead plaintiff" for the putative class. On October 15, 2019, Rosi filed a "notice of non-opposition" to Fulcher's motion to consolidate cases and to serve as lead plaintiff. The court has not yet appointed a lead plaintiff and no consolidated complaint has been filed.

Defendants dispute plaintiffs' claims and intend to defend the matter vigorously.

Patent Infringement

On October 8, 2019, we, together with Allergan, Inc., filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Taro Pharmaceuticals, Inc. ("Taro"), related to an Abbreviated New Drug Application ("ANDA") that Taro filed with the FDA to market a generic version of RHOFADE. The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. We received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents. Under the APA with EPI Health, EPI Health agreed to file a motion to be substituted for us as a plaintiff party and has agreed to reimburse us for our reasonable fees and expenses so long as we remain a plaintiff party.

In addition, from time to time, we are subject to litigation and claims arising in the ordinary course of business but, except as stated above, 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 numerous risks. You should carefully consider the following risks and all other information contained in this Quarterly Report, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

Risks Related to Our Business, Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We have a limited operating history. Since inception, we have incurred significant net losses. We incurred net losses of $132.7 million and $142.8 million for the year ended December 31, 2018 and the nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $434.9 million. We have financed our operations over the last several years primarily from public offerings and a private placement of our common stock, as well as debt financing that has since been repaid in full. We have one commercial product, ESKATA, that we are no longer distributing, marketing or selling, one late-stage investigational drug candidate and other preclinical and clinical drug candidates that we are developing.

We have devoted substantially all of our financial resources and efforts to the development of our drug candidates, including preclinical studies and clinical trials, and from 2018 to October 2019, to the commercialization of our products. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to continue to incur significant expenses and operating losses in the near term as we:

- continue the clinical development of A-101 45% Topical Solution as a potential treatment for common warts and pursue a partner to commercialize A-101 45% Topical Solution;
- continue the clinical development of ATI-450, our MK2 inhibitor, as a potential treatment for rheumatoid arthritis and potentially an additional inflammatory indication;
- continue to develop our preclinical drug candidates, including ATI-1777, a soft-JAK inhibitor, and our ITK inhibitors;
- seek to discover and develop additional drug candidates;
- identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates;
- maintain, expand and protect our intellectual property portfolio; and
- incur legal, accounting, investor relations and other administrative expenses in operating as a public company.

To become and remain profitable, we must succeed in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates and identifying and consummating transactions with third-party partners for the further development and/or commercialization of our drug candidates, as well as discovering and developing additional drug candidates. We are in the early stages of most of these activities. We may never succeed in

these activities and, even if we do, may never earn revenue from our drug candidates that is significant enough to achieve profitability.

For any of our drug candidates, our revenue will be dependent, in part, upon our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize those drug candidates. Further, we will be dependent on our potential third-party partners' ability to obtain marketing approval and successfully commercialize the product, upon the size of the markets in the territories where marketing approval is obtained, the accepted price for the product, and the ability to obtain coverage and reimbursement, if any. If we fail to identify and enter into partnerships with third parties to further develop, obtain marketing approval for and/or commercialize our drug candidates, any partnerships we enter into do not result in the successful development, marketing approval for and commercialization of our drug candidates, the number of addressable patients is not as significant as estimated by our potential third-party partners, the indication approved by regulatory authorities is narrower than expected, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not earn significant revenue from our potential third-party partners for such drug candidates, even if approved.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials, the development of any of our drug candidates or the identification and consummation of transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations.

Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical and clinical development. In addition, we may not be able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and our drug candidates, if approved, may not achieve commercial success. 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 of September 30, 2019, we had cash, cash equivalents and marketable securities of $91.4 million. We believe that our existing cash, cash equivalents and marketable securities as of the date of this Quarterly Report will enable us to fund our operating expenses and capital expenditure requirements for a period greater than 12 months from the date of this report based on our current operating assumptions. These assumptions may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional products or drug candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the drug candidates that we may pursue;

- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our drug candidates;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the extent to which we in-license or acquire additional drug candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and earn revenue from such arrangements; and
- the revenue earned from our commercial products as a result of licenses to, or partnerships with, third parties.

We expect that we will require additional capital to complete the clinical development of ATI-450, to develop our preclinical compounds and to support our discovery efforts. 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 could be forced to curtail our planned operations.

Our business is dependent on the successful development of our drug candidate, ATI-450.

Our pipeline includes ATI-450, our investigational oral, novel, selective MK2 inhibitor compound, which we are developing for rheumatoid arthritis and potentially for an additional inflammatory indication. We submitted an IND in April 2019 for ATI-450 for the treatment of rheumatoid arthritis, which was allowed by the FDA in May 2019, and initiated a Phase 1 clinical trial in approximately 60-80 subjects in August 2019. The success of our business will significantly depend on our successful development of and/or our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize ATI-450.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies, intellectual property, potential future revenue streams or drug candidates.

Until such time, if ever, as we can earn substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and partnership agreements. To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through partnerships, strategic alliances or marketing, distribution or licensing arrangements with third-party partners, we may be required to relinquish valuable rights to our technologies, intellectual property, potential future revenue streams, or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development efforts or grant rights to third parties to develop technologies, intellectual property, or drug candidates that we would otherwise prefer to develop ourselves.

We have a limited operating history and recently changed our strategic focus to focus on the development of our immuno-inflammatory portfolio, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations over the last several years have been largely focused on raising capital, undertaking preclinical studies and conducting clinical trials, and acquiring new drug candidates and related intellectual property. In 2018 and

2019, we were also focused on the commercialization of two commercial products. In September 2019, we announced the completion of a strategic review of our business, as a result of which we are refocusing our resources on our immuno-inflammatory development programs and actively seeking commercialization partners for our commercial products and certain development assets. We have had limited time to demonstrate our ability to successfully develop, manufacture and identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a longer history of developing and partnering drugs. We may also encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in obtaining marketing approval for our drug candidates and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development or commercialization of our drug candidates by a potential third-party partner could be delayed.

Risks Related to the Development and Potential Commercialization of Our Drug Candidates

If we are unable to successfully develop our drug candidates and identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, or experience significant delays in doing so, our business will be harmed.

We have invested significant efforts and financial resources in the development of our drug candidates and the identification of potential drug candidates. Our ability to earn substantial revenue from our drug candidates will depend heavily on our ability to successfully develop and identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and commercialize these drug candidates. The success of any drug candidates that we develop, including A-101 45% Topical Solution and ATI-450, will depend on several factors, including:

- successful completion of preclinical studies and our clinical trials;
- successful development of manufacturing processes for any of our drug candidates that receive marketing approval;
- receipt of timely approvals from applicable regulatory authorities;
- the identification and consummation of transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates;
- the commercial launch of our drug candidates by a third-party partner, if approved;
- our third-party partners' ability to achieve acceptance of our drug candidates, if approved, by patients, the medical community and third-party payors, and willingness of patients to pay out of pocket for our drug candidates when third-party payor coverage and reimbursement is limited or unavailable;

- our third-party partners' ability to achieve success in educating physicians and patients about the benefits, administration and use of our drug candidates, if approved;
- the prevalence and severity of adverse events experienced with our drug candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments for the proposed indications of our drug candidates;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our drug candidates and otherwise protecting the intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs;
- our third-party partners' ability to compete effectively with other treatment procedures; and
- our third-party partners' ability to maintain a continued acceptable safety, tolerability and efficacy profile of our drug candidates following marketing approval.

Whether marketing approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates' success in clinical trials will not guarantee marketing approval. If, following submission, the NDA for any drug candidate is not accepted for substantive review, or even if it is accepted for substantive review, the FDA or other comparable foreign regulatory authorities may require additional studies or clinical trials, additional data, or additional manufacturing steps, or require other conditions before they will reconsider or approve the application. If the FDA or other comparable foreign regulatory authorities require additional studies, clinical trials or data, this could increase costs and cause delays in the marketing approval process, which may require the expenditure of additional resources. These delays would also impact our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. In addition, the FDA or other comparable foreign regulatory authorities may not consider sufficient any additional required studies, clinical trials, data or information that we perform and complete or generate, or we may decide to abandon the program.

It is possible that our drug candidates currently in development will never obtain marketing approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, which would harm our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of and identification and consummation of transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

The risk of failure for our drug candidates is high. It is impossible to predict when or if any of our drug candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining regulatory approval for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans for use in the target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome.

A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our drug candidates, our costs will increase, our drug candidate development process will be slowed, the commercial prospects of our drug candidates will be harmed, and our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates will be delayed. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our drug candidates. If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may not be able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and our potential third-party partners may:

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which our third-party partners may have the exclusive right to commercialize our drug candidates or allow competitors to bring drugs to market before our third-party partners do, which would impact our ability to successfully identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population. Trials may be subject to delays as a result of subject enrollment taking longer than anticipated or subject withdrawal. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the drug candidate in the trial;
- the availability of drugs approved to treat the skin disease in the trial;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of subjects for clinical trials would result in significant delays and could require us or them to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Any delays in completing clinical trials would delay or prevent our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

Our clinical trials may fail to demonstrate the safety and efficacy of our drug candidates, or serious adverse or unacceptable side effects may be identified during the development of our drug candidates, which could prevent or delay our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, increase our costs or necessitate the abandonment or limitation of the development of some of our drug candidates.

Before our potential third-party partners obtain marketing approvals for the commercial sale of our drug candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our

drug candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the drug candidate studied for the target indication.

If our drug candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for our drug candidates. Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the drug candidate.

Additionally, if we or others identify undesirable side effects caused by our drugs, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval to market such product;
- regulatory authorities may require additional warnings on the labels;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients;
- our reputation and physician or patient acceptance of our drug candidates, if approved, may suffer; and
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates would be harmed.

Any of these events could prevent us from identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize the particular drug candidate and could significantly harm our business, results of operations and prospects.

Changes in methods of drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and may also require additional testing, FDA notification or FDA approval. Any of these changes could cause our drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

We may not be successful in our efforts to increase our pipeline of drug candidates, including by in-licensing or acquiring additional drug candidates.

A key element of our strategy is to build and expand our pipeline of drug candidates. To build our pipeline, we may seek to in-license or acquire additional drug candidates. We may not be able to identify or develop drug candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential drug candidates that we identify, in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and drug candidates that we identify for specific indications. As such, we are currently primarily focused on the development of A-101 45% Topical Solution as a potential treatment for common warts and ATI-450 as a potential treatment for rheumatoid arthritis and an additional immuno-inflammatory condition. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future development programs and drug candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through partnerships, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

For any of our drug candidates that receive marketing approval, our third-party partners may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

For any of our drug candidates that receive marketing approval, our third-party partners may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our third-party partners fail to obtain an adequate level of acceptance for our drug candidates, we may not earn significant revenue and we may not become profitable. The degree of market acceptance of any drug candidate, if approved, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our third-party partners' ability to offer the products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- the ability of our potential third-party partners to retain a sales force;
- the strength of our potential third-party partners' marketing and distribution support;
- the availability of third-party payor coverage and adequate reimbursement or the willingness of patients to pay for these products;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

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

The development and commercialization of new drugs is highly competitive. We will face competition with respect to any drug candidates that we may seek to develop or through our potential third-party partners, commercialize, in the future, from many different sources, including major pharmaceutical, biotechnology and specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions.

With respect to A-101 45% Topical Solution as a potential treatment for common warts, we are aware of one company that received a CE Mark approval for an over-the-counter treatment for the non-surgical removal of warts, and four companies developing drug candidates for the treatment of common warts. In addition, there are over-the-counter drugs for the treatment of common warts and other drugs have been used off-label as treatments for common warts.

With respect to ATI-450 as a potential treatment for rheumatoid arthritis, we are aware of a number of companies conducting late-stage clinical trials for rheumatoid arthritis. In addition, there are numerous commercial products for the treatment of rheumatoid arthritis.

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

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

The success of A-101 45% Topical Solution as a potential treatment for common warts or our other drug candidates, if approved, will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these products.

We believe the success of A-101 45% Topical Solution as a potential treatment for common warts or our other drug candidates, if approved, will depend on obtaining and maintaining coverage and adequate reimbursement as a prescription treatment or in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for our prescription drug products.

Third-party payors determine which prescription drug products they will cover and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including: the third-party payor's determination that a product is safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals or current clinical practice guidelines; and whether there are competitive products, either branded or generic, and the pricing of those products. Many private third-party payors, such as managed care plans, manage access to drug products' coverage partly to control costs for their plans, and may use drug formularies and medical policies to limit their exposure. Obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and our potential third-party partners may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our products with third-party payors at levels that are profitable to us, or at all.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. Accordingly, these updates could impact the demand for A-101 45% Topical Solution as a potential treatment for common warts or our other drug candidates, if approved. Our drug candidates, if approved, may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients or sufficient to allow our potential third-party partners to sell our drug candidates, if approved, on a competitive and profitable basis. Our results of operations could be adversely affected by the Affordable Care Act and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that our potential third-party partners could receive for any of our drug candidates, if approved, and could adversely affect our profitability. We cannot predict how pending and future health care legislation

will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our drug candidates could harm our business.

Foreign governments also have their own health care reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to our drug candidates, if approved, under any foreign reimbursement system. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take up to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of our drug candidate to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our drug candidates, if approved, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any of our commercial products or drug candidates that we may develop and are commercialized by our potential third-party partners.

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and an even greater risk relating to any of our commercial products that we have sold. If we cannot successfully defend ourselves against claims that our commercial products or drug candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in

- decreased demand for our commercial product or any drug candidates that we may develop and are commercialized by our potential third-party partners;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- our inability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may need to increase our insurance coverage and we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct clinical trials for our drug candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We engage CROs to conduct clinical trials of our drug candidates. We expect to continue to rely on third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third

parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. Consequently, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase substantially and our ability to earn revenue from those partnerships could be delayed significantly.

Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process for our potential third-party partners.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our drug candidates, if approved, producing additional losses and depriving us of potential revenue.

We contract with third parties for the manufacture and supply of our drug candidates for preclinical and clinical testing. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture and supply of our drug candidates for preclinical and clinical testing. For example, we have entered into an exclusive, ten-year, automatically renewable supply agreement with PeroxyChem, a manufacturer of hydrogen peroxide, to provide the active pharmaceutical ingredient that is used in A-101 45% Topical Solution for the potential treatment of common warts. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates at an acceptable cost and/or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development efforts.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after the NDA or comparable marketing application is submitted to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as

those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, and identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize, our drug candidates.

We may be unable to establish any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs by our third-party suppliers for the active pharmaceutical ingredients for our drug candidates; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drug products.

Our drug candidates may compete with other products and drug candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval of our drug candidates.

If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement. We do not currently have arrangements in place for redundant supply or a second source for the active pharmaceutical ingredients and/or drug product for our drug candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates on a timely and competitive basis.

We intend to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. If those arrangements are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We intend to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. For example, we intend to seek a partner to commercialize A-101 45% Topical Solution as a potential treatment for common warts and a partner to further develop and commercialize ATI-501 and ATI-502 as potential treatments for alopecia. Our likely partners for any such arrangements include large and

mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of our drug candidates. Our ability to earn revenue from these arrangements will depend on our partners' abilities to successfully perform the functions assigned to them in these arrangements.

Partnerships involving our drug candidates would pose the following risks to us:

- partners have significant discretion in determining the efforts and resources that they will apply to these arrangements;
- partners may not perform their obligations as expected;
- partners may not pursue development, marketing approval or commercialization of any drug candidates that achieve marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our drug candidates if the partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- drug candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own products or drug candidates, which may cause our partners to cease to devote resources to the development and/or commercialization of our drug candidates, if approved;
- a partner with marketing and distribution rights to one or more of our drug candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such drug candidates;
- disagreements with partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of drug candidates, might lead to additional responsibilities for us with respect to drug candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- partners may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development and/or commercialization of the applicable drug candidates.

Partnership agreements may not lead to development, marketing approval or commercialization of drug candidates in the most efficient manner or at all. If a present or future partner of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish partnerships, we may have to alter our development and commercialization plans.

Our drug development programs for our drug candidates will require substantial additional capital. For some of our drug candidates, we intend to partner with pharmaceutical and biotechnology companies for the further development and/or commercialization of those drug candidates.

We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a partnership will depend, among other things, upon our assessment of the partner's resources and expertise, the terms and conditions of the proposed arrangement and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The partner may also consider alternative drug candidates or technologies for similar indications that may be available to partner on and whether such a partnership could be more attractive than the one with us for our drug candidate. Partnerships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

We may not be able to negotiate partnerships on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such drug candidate, or reduce or delay its development program or one or more of our other development programs, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate revenue.

We may not have access to all information regarding our products and drug candidates that are subject to partnership agreements. Consequently, our ability to inform our stockholders about the status of our products and drug candidates that are subject to these agreements, and our ability to make business and operational decisions, may be limited.

We may not have access to all information regarding our products and drug candidates that are or may become subject to agreements with partners, including potentially material information about clinical trial design, execution and timing, safety and efficacy, clinical trial results, regulatory affairs, manufacturing, marketing, sales and other areas known by our partners. In addition, we may have confidentiality obligations under our agreements with such partners. Therefore, our ability to keep our stockholders informed about the status of products or drug candidates will be limited by the degree to which our partners keep us informed and by the degree to which our partners allow us to disclose information to the public or provide such information to the public themselves. If our partners do not inform us timely about the status of our products or drug candidates that are the subject of the partnership, we may make operational and investment decisions that we would not have made had we been fully informed, which may have an adverse impact on our business, prospects, financial condition and results of operations.

We are dependent upon EPI Health for the commercialization of RHOFADE, and if we successfully identify and consummate transactions with third-party partners to develop and/or commercialize ESKATA and our drug candidates, we will be dependent on the success of such third-party partners.

In October 2019, EPI Health acquired worldwide rights to RHOFADE from us pursuant to an Asset Purchase Agreement, which included the assignment of certain licenses for related intellectual property assets Pursuant to the Asset Purchase Agreement, among other payment obligations, EPI Health has agreed to pay us potential sales milestone

payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales, a specified high single-digit royalty calculated as a percentage of net sales, and 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in any territory outside of the United States, subject to specified exceptions. We also intend to seek a partner to commercialize ESKATA and if approved, A-101 45% Topical Solution as a potential treatment for common warts, and intend to seek partners to further develop and/or commercialize ATI-501 and ATI-502 as potential treatments for alopecia and our other drug candidates. We cannot control the timing or quantity of resources that our existing or future potential third-party partners will dedicate to developing and/or commercializing these products and drug candidates. Our partners may not perform their obligations according to our expectations or standards of quality. Our partners could terminate our existing agreements for a number of reasons, including that they may have other, higher priority products in development or because our partnered programs may no longer be a priority for them. If any of our partnership agreements were to be terminated or if any of our partners do not perform as expected, we could lose the opportunity to earn any revenues from the arrangements with such third-party partners, incur unforeseen costs, and suffer damage to the reputation of the product and as a company generally.

Our sublease could terminate if the master lease is terminated for any reason, thus terminating our rights to our corporate headquarters.

We sublease space for our corporate headquarters. While the term of the sublease extends until October 2023, if for any reason the master lease is terminated or expires prior to October 2023, our sublease will also automatically terminate. In such an event, we would need to obtain a new direct lease with the master landlord or negotiate and enter into a new lease for office space at a different location, which we may not be able to do on commercially reasonable terms, if at all.

Risks Related to Our Intellectual Property

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

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

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

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

uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

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

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the ability to stop others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Our issued U.S. patents, with claims directed to treatment of SK and acrochordons with high-concentration hydrogen peroxide of at least 23%, including ESKATA and A-101 45% Topical Solution, are scheduled to expire in 2022, and our issued U.S. patents with claims directed to high-concentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution, and methods of use and applicators for the same are scheduled to expire in 2035. Certain issued U.S. patents relating to our JAK inhibitors, ATI-501 and ATI-502, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S., European and Japanese patents that we exclusively license from Columbia University with claims directed to the use of third-party JAK inhibitors for the treatment of hair loss disorders, including alopecia areata and androgenetic alopecia, and inducing hair growth, expire in 2031. We currently do not have any patents issued directed to our lead soft-JAK inhibitor, ATI-1777, but any claims that may issue would expire in 2038. Our issued U.S. patent covering our lead inhibitor of the MK2 signaling pathway, ATI-450, expires in 2034 and other issued patents covering different MK2 signaling pathway inhibitors expire in 2031 and 2032. Our issued patents covering our novel inhibitors of ITK expire between 2035 and 2038. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us or our potential third-party partners with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our issued patents or other intellectual property. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar administrative proceedings outside the United States, in parallel with litigation or, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products and drug candidates. Such a loss of patent protection would harm our business.

In such a proceeding, a court or administrative board may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any such proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties. For instance, we are aware of third parties that have marketed high-concentration hydrogen peroxide solutions over the internet for the treatment of warts. These parties do not appear to have regulatory authority, and we have not authorized them in any way to market these products. However, to date we have refrained from seeking to enforce our intellectual property rights against these third parties due to the transient nature of their activities.

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

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

With respect to ATI-501 and ATI-502, if we do not elect to exercise our first right to do so, Rigel may enforce the licensed patents relating to ATI-501 and ATI-502 against any infringing third party in the field of dermatology. In addition, Rigel has the first right, but not the obligation, to enforce the licensed patents relating to ATI-501 and ATI-502 against any infringing party outside of the field of dermatology. With respect to the licensed patents from Columbia University, Columbia University has the first right to initiate, control and defend any proceedings related to the validity, enforceability or infringement of the licensed patent rights and in doing so, has no obligation to assert more than one licensed patent in one jurisdiction against a third party. With respect to the licensed patents from Columbia University, if Columbia University does not elect to exercise its first right to do so, we may enforce the licensed patent rights relating to an infringement of the licensed patent rights against any infringing third party.

If we breach our license agreement with Rigel, it could compromise our ability to identify and consummate transactions with potential third-party partners to further develop, obtain marketing approval for and commercialize our JAK inhibitors, ATI-501 and ATI-502.

We entered into an exclusive license agreement with Rigel, which grants us the rights to certain patent rights and other intellectual property owned by them relating to the JAK inhibitors ATI-501 and ATI-502 in the field of dermatology. If we materially breach or fail to perform any provision under this license agreement, including failure to make payments to Rigel when due or failure to use commercially reasonable efforts to find a third party to develop and commercialize a JAK inhibitor, Rigel has the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed Rigel's patent rights and other intellectual property would end, which would negatively impact our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

If we breach our agreement with the Selling Stockholders of Vixen, it could compromise our ability to identify and consummate transactions with potential third-party partners to further develop, obtain marketing approval for and commercialize our JAK inhibitors, ATI-501 and ATI-502.

In March 2016, we entered into a stock purchase agreement with the stockholders of Vixen, pursuant to which we purchased all of the stock of Vixen and assumed its license agreement with Columbia University. If we fail to use commercially reasonable efforts to develop and commercialize a JAK inhibitor for alopecia, the license agreement with Columbia University will be transferred to the Selling Stockholders of Vixen following any adverse resolution of any dispute relating thereto. Upon the effective date of such transfer, our right to practice the licensed Columbia University patent rights and know-how would end, which would negatively impact our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

If we breach our agreement with Columbia University, it could compromise our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

In March 2016, as part of the Vixen acquisition, we assumed a license agreement with Columbia University, which grants us the right under certain patent rights and know-how owned by Columbia University relating to the use of JAK inhibitors to treat hair-loss disorders. If we materially breach or fail to perform any provision under this license agreement, including failure to make payments to Columbia University when due and failure to use commercially reasonable efforts to develop and commercialize a licensed product, Columbia University has the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed Columbia University patent rights and know-how would end, which would negatively impact our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

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

Filing, prosecuting and defending patents on our drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. For example, the use of A-101 45% Topical Solution for the treatment of warts is currently covered by issued patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. Two U.S. patents are issued, and patent applications are pending in the United States, the European Union and other foreign countries directed to high-concentration hydrogen peroxide formulations, including A-101 45% Topical Solution and methods of use.

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

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our invention in such countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our drug candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates. For example, we exclusively license intellectual property from Rigel in the field of dermatology related to our JAK inhibitors, ATI-501 and ATI-502. We also exclusively license intellectual property from Columbia University related to the use of JAK inhibitors for the treatment of hair loss disorders. It may be necessary for our potential third-party partners to use the patented or proprietary technology of third parties to commercialize our drug candidates. If our potential third-party partners are not able to obtain a license from these third parties on commercially reasonable terms, our business could be harmed, possibly materially.

Our third-party licensors may develop JAK inhibitors, including those related to our drug candidates, outside of the field of dermatology.

We exclusively license intellectual property from Rigel in order to develop, use, manufacture, sell and commercialize ATI-501 and ATI-502 in the field of dermatology. Rigel has retained the rights under such intellectual property to develop, use, manufacture, sell and commercialize ATI-501 and ATI-502 outside of the field of dermatology. If Rigel were to commercialize such JAK inhibitors outside the field of dermatology, such a product could possibly be used off-label for a dermatology indication, which could negatively impact our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, which in turn would impact our ability to earn revenue from the arrangements with such third-party partners. Rigel also retained the intellectual property rights to develop, use, manufacture, sell and commercialize other structurally similar JAK inhibitors. If Rigel commercializes a structurally similar JAK inhibitor, such a product could directly compete with our drug candidates, if approved.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our success depends upon our ability to identify and consummate transactions with potential third-party partners to develop, obtain marketing approval for and/or commercialize our drug candidates and earn revenue from those partnerships and for our proprietary technologies to be used without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Consequently, we could be forced, including by court order, to cease developing the infringing technology or drug candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent our third-party partners from commercializing our drug candidates, if approved, or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing drug candidate or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that we, our employees or our licensors have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees were previously employed at other biotechnology or pharmaceutical companies. Although we and our licensors try to ensure that our employees and our licensors' employees do not use the proprietary information or know-how of others in their work for us, we or our licensors may be subject to claims that these employees, our licensors or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Some of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking and maintaining patents for our drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

The validity, scope and enforceability of any of our patents that cover any of our commercial products or any of our drug candidates can be challenged by competitors.

The likelihood that a third party will challenge the patents covering a commercial product is increased because it is a marketed product. The challenge may come in the form of a patent office proceeding, such as an *inter partes* review, challenging the validity of the patents or a district court proceeding, such as a paragraph IV litigation arising out of the filing of an abbreviated new drug application, or ANDA.

If a third party files an ANDA or 505(b)(2) application for a generic of a commercial product, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange

Book-listed patents for the applicable approved drug, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our commercial products.

On October 8, 2019, we, together with Allergan, Inc., filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Taro Pharmaceuticals, Inc., or Taro, related to an ANDA that Taro filed with the FDA to market a generic version of RHOFADE. The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. We received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents. Under the APA with EPI Health, EPI Health agreed to file a motion to be substituted for us as a plaintiff party and has agreed to reimburse us for our reasonable fees and expenses so long as we remain a plaintiff party. If EPI Health is not able to successfully defend the RHOFADE intellectual property and a generic version of RHOFADE is approved, our ability to earn revenue under the APA with EPI Health would be negatively impacted.

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

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

Our success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, drug candidates and our target indications. Our issued U.S. patent with claims directed to treatment of SK with ESKATA is scheduled to expire in 2022 and our issued U.S. formulation and applicator patents with claims directed to high-concentration hydrogen peroxide formulations and applicators containing the same, including ESKATA and A-101 45% Topical Solution, and methods of use is scheduled to expire in 2035. Certain issued U.S. patents relating to our JAK inhibitors, ATI-501 and ATI-502, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S., European, Japanese and South Korean patents licensed from Columbia University relating to the use of certain third-party JAK inhibitors for the treatment of hair loss disorders, including alopecia areata and androgenetic alopecia, and inducing hair growth, expire in 2031. We currently do not have any patents issued directed to our lead soft-JAK inhibitor, ATI-1777, but any claims that may issue would expire in 2038. Our issued U.S. patent covering ATI-450, our lead inhibitor of the MK2 signaling pathway, expires in 2034 and other issued patents covering different MK2 signaling pathway inhibitors expire in 2031 and 2032. Our issued patents covering our novel inhibitors of ITK expire between 2035 and 2038. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting our drug candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, for a drug candidate. The Hatch-Waxman Act permits a patent extension term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the total patent term including the period of extension cannot exceed 14 years from the product's approval date. Furthermore, this extension is limited to only one patent per regulatory review period that covers the approved product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

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

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our products, services or technologies from our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, our products, services or technologies may need to be rebranded, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to ESKATA and A-101 45% Topical Solution but that are not covered by the claims of the patents that we own;
- others may be able to make a JAK inhibitor that is similar to the JAK inhibitors we intend to partner that is not covered by the patents that we exclusively license and have the right to enforce;

- we, our licensors or any third-party partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we, our licensors or any third-party partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in major commercial markets; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to Regulatory Approval of Our Drug Candidates and Other Legal Compliance Matters

If our potential third-party partners are not able to obtain, or if there are delays in obtaining, required regulatory approvals, our drug candidates will not be able to be commercialized, and our ability to earn revenue from arrangements with such third-party partners will be materially impaired.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Commission and EU Member State Competent Authorities and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a drug candidate will prevent our potential third-party partners from commercializing the drug candidate. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our potential third-party partners from obtaining marketing approval or prevent or limit commercial use. If any of our drug candidates receive marketing approval, the accompanying label may limit the approved use of our product in this way, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a drug candidate. Any marketing approval our potential third-party partners ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If our potential third-party partners experience delays in obtaining approval or if they fail to obtain approval of our drug candidates, the commercial prospects for our drug candidates may be harmed and our ability to earn revenue from arrangements with such third-party partners will be materially impaired.

Failure to obtain marketing approval in international jurisdictions would prevent our drug candidates from being marketed abroad.

In order to market and sell our drugs in the European Union and any other jurisdictions, our potential third-party partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. Our potential third-party partners may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our potential third-party partners' ability to obtain approval elsewhere. Our potential third-party partners may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drug candidates in any market.

A variety of risks associated with marketing our drug candidates by our potential third-party partners internationally could harm our business.

If our drug candidates are marketed internationally by our potential third-party partners, if approved, our potential third-party partners would be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign reimbursement, pricing and insurance regimes;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- logistical challenges resulting from distributing our drug candidates to foreign countries; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may compromise our ability to earn revenue from arrangements with potential third-party partners for our drug candidates.

Any drug candidate for which our potential third-party partners obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and our potential third-party partners may be subject to penalties if they fail to comply with regulatory requirements or if they experience unanticipated problems with our drug candidates, when and if any of them are approved.

Any drug candidate for which our potential third-party partners obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug candidate, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug candidate may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the drug by our potential third-party partners.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if our potential third-party partners do not market our drugs for their approved indications, they may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- recall or withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications;
- clinical holds;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our drugs;
- drug seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with the European Union's requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal

information can also lead to significant penalties and sanctions. These and other risks associated with the failure by our potential third-party partners to comply with regulatory requirements may compromise our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Our potential third-party partners' relationships with third-party payors, health care professionals and customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other health care laws and regulations, and any failure to comply with such laws and regulations could have a material adverse effect on our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Health care providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any of our drug candidates for which marketing approval is obtained. Our potential third-party partners' arrangements with third-party payors, health care professionals and customers may expose them to broadly applicable fraud and abuse and other health care laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which they sell, market and distribute any drug candidates for which marketing approval is obtained. In addition, we and our potential third-party partners may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we or they conduct business. The applicable federal, state and foreign health care laws and regulations that may affect our or our potential third-party partners' ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state health care programs such as Medicare and Medicaid. Further, several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the Anti-Kickback Statute has been violated. The intent standard was further amended by the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act (that can be enforced through civil whistleblower or qui tam actions), and the civil monetary penalties law, which impose criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on covered health care providers, health plans, and health care clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the Affordable Care Act (commonly known as the Physician Payments Sunshine Act) and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics or medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or other "transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals, as well as applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members. All such reported information is publicly available; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to health care providers; state, local and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures; state laws that require drug manufacturers to report pricing information regarding certain drugs; and/or that require registration of certain employees engaged in marketing activities in the location; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our or our potential third-party partners' business arrangements with third parties will comply with applicable health care laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our or our potential third-party partners' business practices, including relationships with physicians and other health care providers, some of whom may recommend, purchase and/or prescribe our drug candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. By way of example, some of our consulting arrangements with physicians may not meet all of the criteria of the personal services safe harbor under the federal Anti-Kickback Statute. Accordingly, they may not qualify for safe harbor protection from government prosecution. A business arrangement that does not substantially comply with a safe harbor, however, is not necessarily illegal under the Anti-Kickback Statute, but may be subject to additional scrutiny by the government.

If our or our potential third-party partners' operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us or them, we or our potential third-party partners may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government health care programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we or they become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our or their operations, which could have a material adverse effect on our ability to earn revenue from arrangements with such third-party partners for our drug candidates. If any physician or other health care provider or entity with whom we or our potential third-party partners expect to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government health care programs, which could also materially affect our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Recently enacted and future legislation may increase the difficulty and cost for our potential third-party partners to obtain marketing approval of our drug candidates and commercialize our drug candidates, if approved, and affect the prices our potential third-party partners may obtain.

In the United States, and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our

drug candidates, restrict or regulate post-approval activities and affect our potential third-party partners' ability to profitably sell any of our drug candidates for which our potential third-party partners obtain marketing approval, and consequently affect our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The Affordable Care Act, which was signed into law in 2010, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for the health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to commercial products are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government health care programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment there have been judicial and Congressional challenges to, as well efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the

implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a new final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS, has stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act. We continue to evaluate the impact of the Affordable Care Act and efforts to repeal or replace the Affordable Care Act on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year that became effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was signed into law in January 2013, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any similar new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our ability to earn revenue from arrangements with our potential third-party partners for our drug candidates.

We expect that the Affordable Care Act, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that our potential third-party partners receive for any approved drug candidate. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other health care reforms may prevent our potential third-party partners from being able to generate revenue, attain profitability, or commercialize our drug candidates, if approved, which in turn may impact our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. In addition, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump Administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump Administration released a "Blueprint", or plan, to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal health care programs, incentivize manufacturers to lower the list price of their drugs, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have both

stated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on obtaining marketing approvals for our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject our potential third-party partners to more stringent drug labeling and post-marketing testing and other requirements. These risks may compromise our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, our potential third-party partners may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available procedures. If reimbursement of our drug candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our potential third-party partners may not able to generate revenue, which in turn may adversely affect our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our development or manufacturing efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

The inherent dangers in production and transportation of hydrogen peroxide could cause disruptions and could expose us to potentially significant losses, costs or liabilities.

Our operations are subject to significant hazards and risks inherent in the use and transport of hydrogen peroxide, the active ingredient in A-101 45% Topical Solution. Hydrogen peroxide can decompose in the presence of organic materials and is categorized as an oxidizer and is corrosive. Hydrogen peroxide should be stored in cool, dry, well-ventilated areas and away from any flammable or combustible substances. The hazards and risks associated with producing and transporting hydrogen peroxide include fires, explosions, third-party interference (including terrorism) and mechanical failure of equipment at our facilities or those of our supplier of hydrogen peroxide. The occurrence of any of these events could result in production and distribution difficulties and disruptions, personal injury or wrongful death claims and other damage to properties.

We are subject to governmental economic sanctions and export and import controls that could impair our potential third-party partners' ability to compete in international markets or subject us or our potential third-party partners to liability if we or they are not in compliance with applicable laws.

As a U.S. company, we are subject to U.S. import and export controls and economic sanctions laws and regulations, and we are required to import and export our drug candidates, technology and services in compliance with those laws and regulations, including the U.S. Export Administration Regulations, the International Traffic in Arms Regulations, and economic embargo and trade sanction programs administered by the Treasury Department's Office of Foreign Assets Control.

U.S. economic sanctions and export control laws and regulations prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. While we are currently taking precautions to prevent doing any business, directly or indirectly, with countries, governments and persons targeted by U.S. sanctions and to ensure that our drug candidates, are not exported or used by countries, governments and persons targeted by U.S. sanctions, such measures may be circumvented.

Furthermore, if we or our third-party partners export our drug candidates, the exports may require authorizations, including a license, a license exception or other appropriate government authorization. Complying with export control and sanctions regulations may be time-consuming and may result in the delay or loss of sales opportunities. Failure to comply with export control and sanctions regulations may expose us or our potential third-party partners to government investigations and penalties.

If we are found to be in violation of U.S. sanctions or import or export control laws, it could result in civil and criminal, monetary and non-monetary penalties, including possible incarceration for those individuals responsible for the violations, the loss of export or import privileges and reputational harm.

We and our potential third-party partners are subject to anti-corruption and anti-money laundering laws with respect to our and their operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We and our potential third-party partners are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and possibly other anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We or our potential third-party partners may engage third-party intermediaries in connection with the development or commercialization of our drug candidates and to obtain necessary permits, licenses and other regulatory approvals. We, our potential third-party partners or the third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned

or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

Risks Related to Employee Matters and Managing Our Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, development, clinical, financial, legal and business development expertise of Dr. Neal Walker, our Chief Executive Officer, Dr. David Gordon, our Chief Medical Officer, Frank Ruffo, our Chief Financial Officer, and Kamil Ali-Jackson, our Chief Legal Officer, as well as the other members of our scientific and clinical teams. Although we have entered into employment agreements with certain of our executive officers, each of them may currently terminate their employment with us or resign at any time. We do not maintain "key person" insurance for any of our key executives other than for Dr. Walker.

Recruiting and retaining qualified scientific, manufacturing and clinical personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our employees, independent contractors, consultants, third-party partners, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, third-party partners, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state health care laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements by our potential third-party partners in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions

and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we are subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

We may not realize the anticipated benefits of our acquisition of Confluence.

In August 2017, we acquired Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence, including several preclinical drug candidates and Confluence's contract research services business. Acquisitions are inherently risky, and we may not realize the anticipated benefits of the acquisition of Confluence. Specifically, we are subject to the risks that:

- we receive inadequate or unfavorable data from preclinical studies or clinical trials evaluating the acquired preclinical drug candidates;
- we fail to manage the complexities resulting from the larger combined company with distant business locations; and
- we fail to maintain relationships with customers, suppliers and employees.

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

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained.

Although our common stock is listed on The Nasdaq Global Select Market, we cannot assure you that an active trading market for our shares will be sustained. If an active market for our common stock is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all.

The trading price of the shares of our common stock has been and is likely to continue to be volatile.

Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of any clinical trials we may conduct, or changes in the development status of our drug candidates;
- any delay in our regulatory filings for any of our drug candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;

- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure of any of our drug candidates to receive marketing approval;
- unanticipated serious safety concerns related to the use of any drug candidate or previously sold commercial product;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the structure of health care payment systems;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In the past, stockholders have initiated class action lawsuits against pharmaceutical companies following periods of volatility in the market prices of these companies' stock. For example, two purported class action complaints were filed against us and certain of our executive officers alleging violations of certain federal securities laws. We and the other defendants dispute the plaintiffs' claims and intend to defend these matters vigorously. These cases, and additional litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If we fail to maintain compliance with the listing requirements of The Nasdaq Global Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $5 million and stockholders' equity of at least $10 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) of at least $15 million and a total market value of listed securities of at least $50.0 million.

We may fail to satisfy one or more Nasdaq Global Market requirements for continued listing of our common stock in the future. There can be no assurance that we will be successful in maintaining the listing of our common stock on the Nasdaq Global Market, or, if transferred, on the Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us or our business, our market and our competitors. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plan or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 100,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our equity incentive plan or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Sales of a substantial number of shares of our common stock into the market could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements are available for sale in the public market subject to vesting arrangements and exercise of options, and the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

Additionally, certain holders of shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by some or all of our stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of

control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors is elected each year;
- stockholders are not entitled to remove directors other than by a 662/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own a substantial portion of our common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. The interests of this group of stockholders may not coincide with our interests or the interests of other stockholders.

We are an "emerging growth company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this report;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We currently expect that we will remain an emerging growth company until December 31, 2020.

We also qualify as a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act, and so long as we remain a smaller reporting company, we benefit from some of the same scaled disclosure requirements.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting, and perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2018, we had federal and state net operating loss carryforwards of $199.5 million and $212.4 million, respectively, which will begin to expire in 2032. As of December 31, 2018, we also had federal research and development tax credit carryforwards of $4.9 million which begin to expire in 2032, and state research and development tax credit carryforwards of $0.1 million which begin to expire in 2022. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have completed an analysis under Section 382 for net operating loss carryforwards generated from July 13, 2012 through December 31, 2016. Although we have experienced Section 382 ownership changes since 2012, we have concluded that we should have sufficient ability to utilize net

operating loss carryforwards accumulated during the periods tested. We have not yet determined if a Section 382 ownership change has occurred during the year ended December 31, 2017, or for Confluence prior to the acquisition. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

The 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law which significantly revised the Internal Revenue Code of 1986, as amended. The federal income tax legislation, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the changes to the federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the changes in the federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future and our stock may not appreciate in value.

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

We will incur significant costs and increased demands upon management as a result of being a public company.

As a public company listed in the United States, we incur, and will continue to incur, particularly after we cease to be an "emerging growth company," significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more

difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:(i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

None.

Item 6. Exhibits

Exhibit No.	Document
2.1+#	Asset Purchase Agreement, by and between the Registrant and EPI Health, LLC, dated as of October 10, 2019 (incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581) filed with the SEC on October 11, 2019).
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^	First Amendment to License and Collaboration Agreement, by and between the Registrant and Rigel Pharmaceuticals, Inc. dated as of October 15, 2019 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581) filed with the SEC on October 17, 2019).
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.

+ Pursuant to Item 601(a)(5) of Regulation S-K promulgated by the SEC, certain exhibits and schedules to this agreement have been omitted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, any or all of such omitted exhibits or schedules.

Pursuant to Item 601(b)(2)(ii) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of the exhibit.

^ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ACLARIS THERAPEUTICS, INC.

Date: November 7, 2019

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

Date: November 7, 2019

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

Exhibit 31.1

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 September 30, 2019 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: November 7, 2019

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

Exhibit 31.2

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 September 30, 2019 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: November 7, 2019

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

Exhibit 32.1

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 September 30, 2019, 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 7th day of November, 2019.

/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.
